# Import Alert 66-40

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💆 TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=IMPORT ALERT 66-40&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/CMS\_IA/IMPORTALERT\_189.HTML)

EMAIL (MAILTO:?SUBJECT=IMPORT ALERT 66-40&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/CMS\_IA/IMPORTALERT\_189.HTML)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public). Import Alert # 66-40 Published Date: 04/12/2018 Type: DWPE

# **Import Alert Name:**

"Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs"

# **Reason for Alert:**

\*\*\* Foreign inspections of pharmaceutical manufacturers are being performed. Detention without physical examination may be appropriate when an FDA inspection has revealed that a firm is not operating in conformity with current good manufacturing practices (GMP's).

Detention without physical examination may also be appropriate when FDA receives information concerning inspections conducted by foreign or other government authorities under a Memorandum of Understanding or other agreement that FDA concludes reveals conditions or practices warranting detention of either particular products or all products manufactured by a firm.

DWPE of such firms remains in effect until such time as FDA is satisfied that the appearance of a violation has been removed, either by reinspection or submission of appropriate documentation to the responsible FDA Center. \*\*\*

# Guidance:

\*\*\* Districts may detain, without physical sampling and analysis, the indicated drug products from the foreign processors noted in the Red List of this import alert.

Foreign processors listed on the Red List of this import alert who would like to request removal from that list should provide information to FDA to adequately demonstrate that the manufacturer has resolved the conditions that gave rise to the appearance of the violation, so that the agency will have confidence that future entries will be in compliance. This may include a letter detailing its corrective actions, accompanied by documentation. For guidance on removal from detention without physical examination, refer to FDA-s Regulatory Procedures Manual, Chapter 9, "Detention Without Physical Examination (DWPE)." Information supporting removal should be sent to CDER's Office of Compliance, (HFD-300). \*\*\*

# **Product Description:**

Various drugs (See attachment)

# Charge:

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods and controls used in its manufacture and control of pharmaceutical products do not appear to conform to current good manufacturing practices within the meaning of Section 501(a)(2) (B)."

## OASIS Charge Code: DRUG GMPS

#### List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

| AUSTRALIA   |                             |
|---|-----------------------------|
| Delta Laboratories Pty Ltd  | Date Published : 09/28/2017 |
| 8 Warringah CL , Somersby, New South Wales AUSTRALIA<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 09/28/2017  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)   | Date Published: 09/28/2017  |
| Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs   | Date Published: 09/28/2017  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 61 Human and Animal Drugs<br>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 09/28/2017  |
| 62 Human and Animal Drugs<br>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 09/28/2017  |
| 63 Human and Animal Drugs   | Date Published: 09/28/2017  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs   | Date Published: 09/28/2017  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs   | Date Published: 09/28/2017  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices     | Date Published: 09/28/2017  |
| Jalco Cosmetics Pty Ltd.  | Date Published : 03/08/2018 |
| 45 King Rd , Hornsby, New South Wales AUSTRALIA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products   |                             |
| 60 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 03/08/2018  |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 03/08/2018  |
| 62 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 03/08/2018  |
| 63 Human and Animal Drugs   | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products<br>64 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products   |                             |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 03/08/2018  |
| Radpharm Scientific   | Date Published : 09/10/2009 |
| 57 Oatley Court , Belconnen, AUSTRALIA<br>66 V I P 99 Miscellaneous Patent Medicines, Etc., Human - Investigational, Small Volume Parenteral <100ml<br>Notes: Nexavir | Date Published: 09/10/2009  |

#### AUSTRIA

| Schrofner Cosmetics Gmbh  | Date Published : 10/20/2017 |
|---|-----------------------------|
| Robinigstrase 26a , Salzburg, Salzburg AUSTRIA<br>55 Pharm Necess & Ctnr For Drug/Bio               | Date Published: 10/20/2017  |
| Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices                                     | Date Published: 10/20/2017  |
| 60 Human and Animal Drugs<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices        | Date Published. 10/20/2017  |
| 61 Human and Animal Drugs<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices        | Date Published: 10/20/2017  |
| 62 Human and Animal Drugs   | Date Published: 10/20/2017  |
| Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs        | Date Published: 10/20/2017  |
| Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs        | Date Published: 10/20/2017  |
| Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices                                     |                             |
| <i>65</i> Human and Animal Drugs<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 10/20/2017  |
| 66 Human and Animal Drugs<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices        | Date Published: 10/20/2017  |
|   |                             |

#### BELGIUM

#### Laboratoria Qualiphar NV Date Published : 01/18/2011 Rijksweg 9, Bornem, Antwerp BELGIUM 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/18/2011 Notes: All drug products 60 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 61 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 62 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 63 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 64 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 65 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 66 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products

#### BRAZIL

| Lima & Pergher Ind. Com. Rep Ltda  | Date Published : 07/15/2016 |
|--|-----------------------------|
| Av Airton Borges Da Silva 740 , Minas Gerais, BRAZIL<br>55 Pharm Necess & Ctnr For Drug/Bio                    | Date Published: 07/15/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                              |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 07/15/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs | Date Published: 07/15/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                              |                             |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 07/15/2016  |
| Notes. All Drugs and Drug Froducts, Froblem(s). (GMF) Good Manuacturing Fractices                              |                             |

| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
|---|-----------------------------|
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| Lima & Pergher Industria e Comercio S/A   | Date Published : 07/15/2016 |
| Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 07/15/2016  |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 60 Human and Animal Drugs   | Date Published: 07/15/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 07/15/2016  |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/15/2016  |
| 65 Human and Animal Drugs   | Date Published: 07/15/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 07/15/2016  |
|   |                             |

# CANADA

#### Aleeda Inc Date Published : 05/29/2012 7115 Tomken Rd , Mississauga, ON CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/29/2012 60 - - - -- Human and Animal Drugs Date Published: 05/29/2012 61 - - - -- Human and Animal Drugs Date Published: 05/29/2012 62 - - - - Human and Animal Drugs Date Published: 05/29/2012 63 - - - -- Human and Animal Drugs Date Published: 05/29/2012 64 - - - -- Human and Animal Drugs Date Published: 05/29/2012 65 - - - - Human and Animal Drugs Date Published: 05/29/2012 66 - - - -- Human and Animal Drugs Date Published: 05/29/2012 Attix Pharmaceuticals Inc. Date Published : 02/18/2015 184 Front St Unit 801, Toronto, Ontario CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 60 - - - -- Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 63 - - - -- Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

| <i>64</i> Human and Animal Drugs   | Date Published: 02/18/2015   |
|--|------------------------------|
| Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs                          | Date Published: 02/18/2015   |
| Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs                          | Date Published: 02/18/2015   |
| Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices   | Date 1 ubilished. 02/10/2013 |
| Aztex Enterprises Ltd.   | Date Published : 10/19/2017  |
| 5155 Fairview Street , Burlington, Ontario CANADA<br>53 Cosmetics  | Date Published: 10/19/2017   |
| Desc: All Drug and Drug Products   |                              |
| Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.<br>55 Pharm Necess & Ctnr For Drug/Bio | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  |                              |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products   | Date Published: 10/19/2017   |
| 60 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  |                              |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 10/19/2017   |
| 62 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  | Data Dublishadi 10/10/2017   |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/19/2017   |
| 64 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs   | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  | Date Fublished. 10/19/2017   |
| 66 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  |                              |
| Aztex Enterprises Ltd.   | Date Published : 10/19/2017  |
| 5155 Fairview Street , Burlington, Ontario CANADA<br>53 Cosmetics  | Date Published: 10/19/2017   |
| Desc: All Drug and Drug Products   | Date Fublished. 10/13/2017   |
| Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.  |                              |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products   | Date Published: 10/19/2017   |
| 60 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  |                              |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 10/19/2017   |
| 62 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products<br>63 Human and Animal Drugs   | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  | Date 1 ublished. 10/19/2017  |
| 64 Human and Animal Drugs  | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs   | Date Published: 10/19/2017   |
| Notes: All Drug and Drug Products  |                              |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/19/2017   |
| Notes. All Drug and Drug Floducts  |                              |
| Baxter Healthcare  | Date Published : 04/10/2014  |
| Unknown Street , Mississauga, ON CANADA<br>55 R 55 Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent)                           | Date Published: 04/10/2014   |
| Desc: 0.9% Sodium Chloride Injection USP   |                              |
| 65 <i>R 12</i> Potassic Saline (Injection) (Replenisher)   | Date Published: 04/10/2014   |

CMI Cosmetic Manufacturers Inc.

90 Moyal Court, Concord, On CANADA

Date Published : 09/28/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: (GMP) Good Manufacturing Practices 60 - - - -- Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: (GMP) Good Manufacturing Practices

#### Cellex-C International Inc.

9 New St, Toronto, Ontario CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products

#### **Deserving Health International Corp**

13160 Vanier PI Unit 110, Richmond, British Columbia CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Gemini Packaging Ltd.

Date Published: 09/28/2015

#### Date Published : 06/02/2017

Date Published: 06/02/2017

#### Date Published : 11/02/2017

Date Published: 11/02/2017

#### Date Published : 12/10/2015

| 12071 Jacobson Way , Richmond, British Columbia CANADA<br>55 Pharm Necess & Ctnr For Drug/Bio                            | Date Published: 12/10/2015  |
|--|-----------------------------|
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 12/10/2015  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 12/10/2015  |
| 60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices           | Date Published. 12/10/2015  |
| 61 Human and Animal Drugs  | Date Published: 12/10/2015  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                                       |                             |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices           | Date Published: 12/10/2015  |
| 63 Human and Animal Drugs  | Date Published: 12/10/2015  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                                       |                             |
| 64 Human and Animal Drugs  | Date Published: 12/10/2015  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs           | Date Published: 12/10/2015  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 66 Human and Animal Drugs  | Date Published: 12/10/2015  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| HOMEOCAN LABORATORIES  | Date Published : 05/03/2017 |
| 3025 De l'Assomption Blvd , Montreal, Quebec CANADA  |                             |
| 53 Cosmetics<br>Desc: All Drugs and Drug Products  | Date Published: 05/03/2017  |
| Notes: Problem(s); (GMP) Good Manufacturing Practices  |                             |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s); (GMP) Good Manufacturing Practices  |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 05/03/2017  |
| 56 Antibiotics (Human/Animal)  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                                       |                             |
| 60 Human and Animal Drugs  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs           | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                                       |                             |
| 62 Human and Animal Drugs  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs           | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 64 Human and Animal Drugs  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Data Rublishadi 05/02/2017  |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices           | Date Published: 05/03/2017  |
| 66 Human and Animal Drugs  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| Homeocan Inc   | Date Published : 05/03/2017 |
| 3025 Del Assomption , Lasalle, QC CANADA   |                             |
| 53 Cosmetics   | Date Published: 05/03/2017  |
| Desc: All Drugs and Drug Products<br>Notes: Problem(s); (GMP) Good Manufacturing Practices                               |                             |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)  | Date Published: 05/03/2017  |
| Desc: All Drugs and Drug Products  |                             |
| Notes: Problem(s); (GMP) Good Manufacturing Practices<br>55 Pharm Necess & Ctnr For Drug/Bio                             | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Data Duklishadi 05/02/2017  |
| 60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices           | Date Published: 05/03/2017  |
| 61 Human and Animal Drugs  | Date Published: 05/03/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
|  |                             |

62 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Homeolab USA Inc. 3025 De l'Assomption Blvd , Montreal, Quebec CANADA 53 - - - - Cosmetics Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 54 - - - -- Vit/Min/Prot/Unconv Diet(Human/Animal) Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 60 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 62 - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices International Laboratories (Canada) Ltd. 63 Skyline Cres NE, Calgary, Alberta CANADA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug Products 61 - - - - Human and Animal Drugs Notes: All Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug Products 66 - - - - Human and Animal Drugs Notes: All Drug Products

#### Pax-All Manufacturing Inc

5000 Howard Business Parkway, Windsor, On CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug Products 60 - - - - Human and Animal Drugs Notes: All Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017

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Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017 Date Published: 05/03/2017

Date Published: 05/03/2017

#### Date Published : 03/14/2014

Date Published: 03/14/2014

#### Date Published : 02/23/2012

Date Published: 02/23/2012 Date Published: 02/23/2012 Date Published: 02/23/2012 Notes: All Drug Products Date Published: 02/23/2012 62 - - - - Human and Animal Drugs Notes: All Drug Products 63 - - - - Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products 64 - - - -- Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products 66 - - - -- Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products Date Published : 11/30/2017 **Ross Healthcare Inc.** 6-1520 Cliveden Ave , Delta, British Columbia CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/30/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 11/30/2017 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products 65 - - - -- Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Date Published: 11/30/2017 Notes: All Drug and Drug Products

#### CHINA

| Attix Pharmaceuticals (Xiamen)  | Date Published : 05/13/2016 |
|---|-----------------------------|
| Xiangyue Road , NO. 7 Xinganlu , Shamen, Fujian CHINA<br><i>54</i> Vit/Min/Prot/Unconv Diet(Human/Animal) | Date Published: 05/13/2016  |
| Desc: All Drugs and Drug Products   |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products                                 | Date Published: 05/13/2016  |
| 56 Antibiotics (Human/Animal)   | Date Published: 05/13/2016  |
| Notes: All Drugs and Drug Products<br>60 Human and Animal Drugs   | Date Published: 05/13/2016  |
| Notes: All Drugs and Drug Products  |                             |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products                                    | Date Published: 05/13/2016  |
| 62 Human and Animal Drugs   | Date Published: 05/13/2016  |
| Notes: All Drugs and Drug Products<br>63 Human and Animal Drugs   | Date Published: 05/13/2016  |
| Notes: All Drugs and Drug Products  | Date Published: 05/13/2016  |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products                                    | Date Published: 05/13/2016  |
| 65 Human and Animal Drugs   | Date Published: 05/13/2016  |
| Notes: All Drugs and Drug Products<br>66 Human and Animal Drugs   | Date Published: 05/13/2016  |
| Notes: All Drugs and Drug Products  |                             |
| Ausmetics Daily Chemicals (Guangzhou) Co., Ltd.   | Date Published : 12/20/2016 |

| Economic And Technical , NO. 1 Jinxiulu; Huangpu , Guangzhou, Guangdong CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio                | Date Published: 12/20/2016  |
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| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)                  | Date Published: 12/20/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs                      | Date Published: 12/20/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                             |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      | Date Published: 12/20/2016  |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      | Date Published: 12/20/2016  |
| 53 Human and Animal Drugs   | Date Published: 12/20/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>54 Human and Animal Drugs                      | Date Published: 12/20/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>55 Human and Animal Drugs                      | Date Published: 12/20/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      | Date Published: 12/20/2016  |
| Baoying County Fukang Medical Appliance Co., Ltd.   | Date Published : 09/20/2016 |
| rade of , Su Zhongbeilu; Baoyingxian , Yangzhou, Jiangsu CHINA<br>5 Pharm Necess & Ctnr For Drug/Bio                                | Date Published: 09/20/2016  |
| lotes: All Drug and Drug Products<br>6 Antibiotics (Human/Animal)   | Date Published: 09/20/2016  |
| lotes: All Drug and Drug Products<br>0 Human and Animal Drugs   |                             |
| lotes: All Drug and Drug Products   | Date Published: 09/20/2016  |
| <i>1</i> Human and Animal Drugs<br>otes: All Drug and Drug Products   | Date Published: 09/20/2016  |
| 2 Human and Animal Drugs<br>lotes: All Drug and Drug Products   | Date Published: 09/20/2016  |
| 3 Human and Animal Drugs  | Date Published: 09/20/2016  |
| otes: All Drug and Drug Products<br>4 Human and Animal Drugs  | Date Published: 09/20/2016  |
| otes: All Drug and Drug Products<br>5 Human and Animal Drugs  | Date Published: 09/20/2016  |
| lotes: All Drug and Drug Products   |                             |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 09/20/2016  |
| Beijing Rimeng Biological Technology Co. Ltd.   | Date Published : 01/24/2018 |
| lo. 6a Tielunan , Daxing , Beijing, Beijing CHINA<br>i3 Cosmetics   | Date Published: 01/24/2018  |
| lesc: All Drug and Drug Products<br>lotes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. |                             |
| 5 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 01/24/2018  |
| otes: All Drug and Drug Products<br>6 Antibiotics (Human/Animal)  | Date Published: 01/24/2018  |
| lotes: All Drug and Drug Products<br>0 Human and Animal Drugs   | Date Published: 01/24/2018  |
| lotes: All Drug and Drug Products<br>1 Human and Animal Drugs   | Date Published: 01/24/2018  |
| lotes: All Drug and Drug Products   |                             |
| 2 Human and Animal Drugs<br>lotes: All Drug and Drug Products   | Date Published: 01/24/2018  |
| 3 Human and Animal Drugs<br>lotes: All Drug and Drug Products   | Date Published: 01/24/2018  |
| 4 Human and Animal Drugs  | Date Published: 01/24/2018  |
| Notes: All Drug and Drug Products<br>55 Human and Animal Drugs  | Date Published: 01/24/2018  |
| Notes: All Drug and Drug Products   |                             |

| 66 Human and Animal Drugs   | Date Published: 01/24/2018   |
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| Notes: All Drug and Drug Products   |  |
| Beijing Shunxin Meihua Bio-technical Co., Ltd.  | Date Published : 07/22/2014  |
| No 7 Fuqiandongjie , Shunyi District , Shunyiqu, Beijingshi CHINA   | Data Rublishad: 07/22/2014   |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All drug products; Firm refused FDA inspection  | Date Published: 07/22/2014   |
| 56 Antibiotics (Human/Animal)   | Date Published: 07/22/2014   |
| Notes: All drug products; Firm refused FDA inspection   |  |
| <i>60</i> Human and Animal Drugs<br>Notes: All drug products; Firm refused FDA inspection   | Date Published: 07/22/2014   |
| 61 Human and Animal Drugs   | Date Published: 07/22/2014   |
| Notes: All drug products; Firm refused FDA inspection   |  |
| 62 Human and Animal Drugs<br>Notes: All drug products; Firm refused FDA inspection  | Date Published: 07/22/2014   |
| 63 Human and Animal Drugs   | Date Published: 07/22/2014   |
| Notes: All drug products; Firm refused FDA inspection   |  |
| <i>64</i> Human and Animal Drugs<br>Notes: All drug products; Firm refused FDA inspection   | Date Published: 07/22/2014   |
| 65 Human and Animal Drugs   | Date Published: 07/22/2014   |
| Notes: All drug products; Firm refused FDA inspection   |  |
| 66 Human and Animal Drugs   | Date Published: 07/22/2014   |
| Notes: All drug products; Firm refused FDA inspection   |  |
| Beijing Taiyang Pharmaceutical Industry Co Ltd  | Date Published : 04/29/2016  |
| No 1 Shuangqiao Xili , Chaoyang , Beijing, Beijing CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 04/29/2016   |
| Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices   |  |
| 56 Antibiotics (Human/Animal)   | Date Published: 04/29/2016   |
| Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices   |  |
| 60 Human and Animal Drugs   | Data Publishad: 01/20/2016   |
| 60 Human and Animal Drugs<br>Notes: All drugs and drug products:Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 04/29/2016   |
| Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 04/29/2016<br>Date Published: 04/29/2016   |
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| <ul> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> </ul>  | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016   |
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| <ul> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> </ul>   | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016   |
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| <ul> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> </ul>  | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2017   |
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| <ul> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> </ul>   | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017   |
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| <ul> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>67 Human and Animal Drugs</li> <li>Notes: All drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>68 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>69 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Dr</li></ul>  | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017   |
| Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017                               |
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| Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices<br><b>Bicooya Cosmetics Limited</b><br>NO 17 Yanhu Lu , Yiwu , Jinhua, Zhejiang CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017                               |
| <ul> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Dr</li></ul>  | Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2016<br>Date Published: 04/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017<br>Date Published: 06/29/2017 |

| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |
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| 66 Human and Animal Drugs  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |

#### **Bluetech Chemicals Limited**

Rm 703, No. 25, Lane 175, Shanghai, CN-31 CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Notes: All drug products 60 - - - -- Human and Animal Drugs Notes: All drug products 61 - - - -- Human and Animal Drugs Notes: All drug products 62 - - - - Human and Animal Drugs Notes: All drug products 63 - - - - Human and Animal Drugs Notes: All drug products 64 - - - - Human and Animal Drugs Notes: All drug products 65 - - - - Human and Animal Drugs Notes: All drug products 66 - - - -- Human and Animal Drugs Notes: All drug products

#### Boai NKY Pharmaceuticals Ltd.

No. 9 Zhongshan Road , Boai County , Jiaozuo, Henan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Notes: All drug products 60 - - - -- Human and Animal Drugs Notes: All drug products 61 - - - - Human and Animal Drugs Notes: All drug products 62 - - - - Human and Animal Drugs Notes: All drug products 63 - - - - Human and Animal Drugs Notes: All drug products 64 - - - - Human and Animal Drugs Notes: All drug products 65 - - - - Human and Animal Drugs Notes: All drug products 66 - - - -- Human and Animal Drugs Notes: All drug products

# Boai Xinda Food Co., Ltd.

The North Of Dong Wang He, Xiaojing , Boai, Henansheng CHINA 55 - - - -- Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Notes: All drug products 60 - - -- Human and Animal Drugs Notes: All drug products 61 - - - -- Human and Animal Drugs Notes: All drug products 62 - - - -- Human and Animal Drugs Notes: All drug products 63 - - - -- Human and Animal Drugs Notes: All drug products 63 - - - -- Human and Animal Drugs Notes: All drug products 64 - - - -- Human and Animal Drugs Notes: All drug products 64 - - - -- Human and Animal Drugs Notes: All drug products Date Published: 06/29/2017

#### Date Published : 09/17/2010

Date Published: 09/17/2010 Date Published: 09/17/2010

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Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010

| 65 Human and Animal Drugs |
|---------------------------|
| Notes: All drug products  |
| 66 Human and Animal Drugs |
| Notes: All drug products  |

#### **CR Zizhu Pharmaceutical Co Ltd**

No. 27, Chaoyang North Rd , Chaoyang District , Beijing, Haidian CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drugs and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drugs and Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products 61 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products 64 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products

### Changshu Huagang Pharmaceuticals Co., Ltd

Yuxiang Village, Shanghu Town, , Changshu City, Jiangsu Province CHINA 50 - - - -- Color Additiv Food/Drug/Cosmetic Desc: All drug and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug and drug products 56 - - - - Antibiotics (Human/Animal) Desc: All drug and drug products 60 - - - -- Human and Animal Drugs Notes: All drug and drug products 61 - - - -- Human and Animal Drugs Notes: All drug and drug products 62 - - - -- Human and Animal Drugs Notes: All drug and drug products 63 - - - - Human and Animal Drugs Notes: All drug and drug products 64 - - - -- Human and Animal Drugs Notes: All drug and drug products 65 - - - - Human and Animal Drugs Notes: All drug and drug products 66 - - - -- Human and Animal Drugs Notes: All drug and drug products **Changzhou Anyuan Import & Export** 

# Fuchen Garden Suite , 1-403; Xinbei District , Changzhou, Jiangsu CHINA

55 - - -- Pharm Necess & Ctnr For Drug/Bio
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
56 - - - -- Antibiotics (Human/Animal)
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
60 - - - -- Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
61 - - - -- Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
61 - - - -- Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
62 - - -- Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
62 - - -- Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
63 - - -- Human and Animal Drugs

Date Published: 09/17/2010

Date Published: 09/17/2010

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Date Published: 03/08/2017

Date Published: 03/08/2017 Date Published: 03/08/2017

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Date Published: 08/11/2017 Date Published: 08/11/2017 Date Published: 08/11/2017 Date Published: 08/11/2017 Date Published: 08/11/2017

| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs   | Date Published: 08/11/2017  |
|--|-----------------------------|
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Fublished. 00/11/2017  |
| 65 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs   | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| Changzhou Jintan Qianyao Pharmaceutical Raw Materials  | Date Published : 05/04/2017 |
| No. 678 Zhuangcheng , Chengzhou , Jintan, Jiangsu CHINA  |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)   | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products  | Date i ublished. 05/04/2017 |
| 60 Human and Animal Drugs  | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products  |                             |
| 61 Human and Animal Drugs  | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs   | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products  |                             |
| 63 Human and Animal Drugs  | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products  |                             |
| 64 Human and Animal Drugs  | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs   | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products  |                             |
| 66 Human and Animal Drugs  | Date Published: 05/04/2017  |
| Notes: All Drug and Drug Products  |                             |
| Changzhou SPL Company, Ltd.  | Date Published : 09/10/2009 |
| West Rd., Hutang Township, Wujin City, Changzhou City, Jiangsusheng CHINA  |                             |
| <i>55 R 75</i> Crude Heparin (Pharmaceutic Necessity)<br>Notes: All heparin products 3/10/2008   | Date Published: 09/10/2009  |
| 55 R 99 Pharmaceutic Necessities, N.E.C.   | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  |                             |
| 57 D 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)  | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  | Data Dublishadi 00/10/2000  |
| 61 L 08 Heparin Sodium (Anti-Coagulant)<br>Notes: All heparin products 3/10/2008   | Date Published: 09/10/2009  |
| 61 L 22 Anti-Coagulant Heparin Sol   | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  |                             |
| 61 L 30 Heparin Calcium (Anti-Coagulant)   | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008<br>74 L IS Heparin Coating Chemicals,  | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  | Date Fublished: 03/10/2003  |
| 80 N ZW Heparin Vascular access flush  | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  |                             |
| <i>81 J BR</i> Test, Heparin Neutralization<br>Notes: All heparin products 3/10/2008   | Date Published: 09/10/2009  |
| <i>81 J OX</i> Analyzer, Heparin, Automated  | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  |                             |
| <i>81 K FF</i> Assay, Heparin  | Date Published: 09/10/2009  |
| Notes: All heparin products 3/10/2008  | Data Dublishadi 00/10/2000  |
| <i>88 / AZ</i> Heparin<br>Notes: All heparin products 3/10/2008  | Date Published: 09/10/2009  |
|  | Data Dublishad ( 00/02/2014 |
| China Resources Sanjiu Medical and Pharmaceutical Co., Ltd.<br>No. 1 Guanqing Rd , Guanlan Hi-Tech Park, Longhua District , Shenzhen , Guangdong CHINA | Date Published : 09/03/2014 |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 09/03/2014  |
| Notes: (GMP) Good Manufacturing Practices  |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 09/03/2014  |
| Notes: (GMP) Good Manufacturing Practices  |                             |
|  |                             |

| 60 Human and Animal Drugs   | Date Published: 09 | 9/03/2014 |
|---|--------------------|-----------|
| Notes: (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 09 | 9/03/2014 |
| Notes: (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 09 | 9/03/2014 |
| Notes: (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 09 | 9/03/2014 |
| Notes: (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs  | Date Published: 09 | 9/03/2014 |
| Notes: (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: (GMP) Good Manufacturing Practices   | Date Published: 09 | 9/03/2014 |
| 66 Human and Animal Drugs<br>Notes: (GMP) Good Manufacturing Practices  | Date Published: 09 | 9/03/2014 |
| Chongqing Imperial Bio Chem Co  | Date Published : 0 | 9/10/2009 |
| 5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbeiqu, Zhongqingshi CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All APIs 3/16/2009                                      | Date Published: 09 | 9/10/2009 |
| 56 Antibiotics (Human/Animal)<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| 60 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| 61 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| 62 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| 63 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| <i>64</i> Human and Animal Drugs<br>Notes: All APIs 3/16/2009   | Date Published: 09 | 9/10/2009 |
| 65 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| 66 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09 | 9/10/2009 |
| Chongqing Lummy Pharmaceutical Co. Ltd.   | Date Published : 0 | 4/19/2016 |
| Economic And Technological, NO. 2 the 4th Branch Rd, Huaa??Nan Road, Chongqing, Changshou District CHI 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 04 | 4/19/2016 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)  | Date Published: 04 | 4/19/2016 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs  | Date Published: 04 | 4/19/2016 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 04 | 4/19/2016 |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 04 | 4/19/2016 |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 04 | 4/19/2016 |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 04 | 4/19/2016 |
| 65 Human and Animal Drugs   | Date Published: 04 | 4/19/2016 |

Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices

# **Chongqing Paiquiang Agribyproduct Co., Ltd** 158 Gonglongpo , Yudong , Chongqing, CHINA

55 - - - -- Pharm Necess & Ctnr For Drug/Bio Notes: All APIs 3/16/2009 56 - - - -- Antibiotics (Human/Animal)

65 - - - - Human and Animal Drugs

Date Published : 09/10/2009

Date Published: 04/19/2016

Date Published: 09/10/2009

| Notes: All APIs 3/16/2009<br>60 Human and Animal Drugs  | Date Published: 09/10/2009  |
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| Notes: All APIs 3/16/2009   | Date Tublished. 03/10/2009  |
| 61 Human and Animal Drugs   | Date Published: 09/10/2009  |
| Notes: All APIs 3/16/2009   |                             |
| 62 Human and Animal Drugs   | Date Published: 09/10/2009  |
| Notes: All APIs 3/16/2009   |                             |
| 3 Human and Animal Drugs<br>lotes: All APIs 3/16/2009   | Date Published: 09/10/2009  |
| 4 Human and Animal Drugs  | Date Published: 09/10/2009  |
| otes: All APIs 3/16/2009  |                             |
| 5 Human and Animal Drugs  | Date Published: 09/10/2009  |
| otes: All APIs 3/16/2009  |                             |
| 66 Human and Animal Drugs<br>Notes: All APIs 3/16/2009  | Date Published: 09/10/2009  |
| ixi Zhixin Bird Clean-Care Product Co., Ltd.  | Date Published : 11/22/2016 |
| O. 137 Balilu , Cixi , Ningbo, Zhejiang CHINA   |                             |
| 5 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 11/22/2016  |
| otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>6 Antibiotics (Human/Animal)          | Date Published: 11/22/2016  |
| otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 0 Human and Animal Drugs  | Date Published: 11/22/2016  |
| otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| / Human and Animal Drugs<br>otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices              | Date Published: 11/22/2016  |
| 2 Human and Animal Drugs  | Date Published: 11/22/2016  |
| otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 3 Human and Animal Drugs  | Date Published: 11/22/2016  |
| otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Data Dublishady 11/22/2016  |
| Human and Animal Drugs<br>otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                | Date Published: 11/22/2016  |
| Human and Animal Drugs  | Date Published: 11/22/2016  |
| otes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices   |                             |
| δ Human and Animal Drugs  | Date Published: 11/22/2016  |
| tes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                             |
| <b>ercy Personal Care Products Co., Ltd</b><br>n'Wen Industrial , Lane 299 Cangsong Road; Zone Pan County , Jinhua, CHINA | Date Published : 05/10/2012 |
| 5 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 05/10/2012  |
| otes: All Drug Products   |                             |
| δ Antibiotics (Human/Animal)  | Date Published: 05/10/2012  |
| otes: All Drug Products<br>) Human and Animal Drugs   | Date Published: 05/10/2012  |
| otes: All Drug Products   | Date Fublished. 03/10/2012  |
| 1 Human and Animal Drugs  | Date Published: 05/10/2012  |
| otes: All Drug Products   |                             |
| 2 Human and Animal Drugs  | Date Published: 05/10/2012  |
| otes: All Drug Products<br>3 Human and Animal Drugs   | Date Published: 05/10/2012  |
| otes: All Drug Products   |                             |
| 4 Human and Animal Drugs  | Date Published: 05/10/2012  |
| otes: All Drug Products   |                             |
| 5 Human and Animal Drugs  | Date Published: 05/10/2012  |
| otes: All Drug Products<br>6 Human and Animal Drugs   | Date Published: 05/10/2012  |
| lotes: All Drug Products  |                             |
| oshan Flying Medical Products Co., Ltd.   | Date Published : 05/23/2017 |
| o. 49 Xiangshan 2th Road , Fengtain Industrial District , Foshan, Guangdong CHINA   |                             |
| 53 Cosmetics  | Date Published: 05/23/2017  |

Date Published: 05/23/2017

Desc: All Drug and Drug Products

53 - - - - Cosmetics

| Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza  | lkonium chloride antiseptic   |
|--|---|
| towelettes) are subject to DWPE under this notice.<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. iso  |   |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  |   |
| 56 Antibiotics (Human/Animal)  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. iso  | propyl alcohol pads or  |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  |   |
| <i>60</i> Human and Animal Drugs   | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isop   | propyl alcohol pads or  |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  |   |
| 61 Human and Animal Drugs  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isophannel (series and a strength of the product | propyl alconol pads or  |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.<br>62 Human and Animal Drugs   | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. iso  |   |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  | stopyt alconol page of  |
| 63 Human and Animal Drugs  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isop   | propyl alcohol pads or  |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  |   |
| 64 Human and Animal Drugs  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isop   | propyl alcohol pads or  |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  | Data Dublish at 05/00/0047  |
| 65 Human and Animal Drugs  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isop benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.   | bropyr alconor paus or  |
| 66 Human and Animal Drugs  | Date Published: 05/23/2017  |
| Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. iso  |   |
| benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  |   |
| 68 Animal Devices and Diagnostic Products  |   |
| 00 Animai Devices and Diagnostic Froducts  | Date Published: 05/23/2017  |
| Desc: All Drug and Drug Products   |   |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza  |   |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.  | lkonium chloride antiseptic   |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 L RR Kit, First Aid  |   |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 L - RR Kit, First Aid<br>Desc: All Drug and Drug Products  | Ikonium chloride antiseptic<br>Date Published: 05/23/2017   |
| <ul> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza towelettes) are subject to DWPE under this notice.</li> <li><i>79 L - RR</i> Kit, First Aid</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza</li> </ul>   | Ikonium chloride antiseptic<br>Date Published: 05/23/2017   |
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| <ul> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza towelettes) are subject to DWPE under this notice.</li> <li><i>79 L - RR</i> Kit, First Aid</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza</li> </ul>   | Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic  |
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| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 L - RR Kit, First Aid<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 N - AB Gauze/Sponge, Nonresorbable For External Use<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 O - AO First aid kit without drug<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 O - HO First aid kit without drug<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>80 L - KB Pad, Alcohol<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 66; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br><b>Foshan Jinxiong Technology Co., Ltd.</b><br>Shang'an, Danzhao Town , Lijia Development Zone, , Foshan, CHINA<br>53 J Personal Cleanliness Desc: All Drug and Drug Products Notes: For Industry code 53]; only products found to be drug products are subject to DWPE under this listing. $55 Pharm Necess & Ctm For Drug/BioNotes: All Drug and Drug Products56 Antibiotics (Human/Animal)$   | Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 02/14/2018<br>Date Published: 02/14/2018   |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 L - <i>RR</i> Kit, First Aid<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 N - AB Gauze/Sponge, Nonresorbable For External Use<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 O - HO First aid kit without drug<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>80 L - <i>KB</i> Pad, Alcohol<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>80 L - <i>KB</i> Pad, Alcohol<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br><b>Foshan Jinxiong Technology Co., Ltd.</b><br>Shang'an, Danzhao Town , Lijia Development Zone, , Foshan, CHINA<br>53 J Personal Cleanliness<br>Desc: All Drug and Drug Products<br>Notes: For industry code 53J; only products found to be drug products are subject to DWPE under this listing.<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products   | Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 02/14/2018<br>Date Published: 02/14/2018<br>Date Published: 02/14/2018<br>Date Published: 02/14/2018 |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 L - RR Kit, First Aid<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 N - AB Gauze/Sponge, Nonresorbable For External Use<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 O - AO First aid kit without drug<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>79 O - HO First aid kit without drug<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br>80 L - KB Pad, Alcohol<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 53; 66; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benza<br>towelettes) are subject to DWPE under this notice.<br><b>Foshan Jinxiong Technology Co., Ltd.</b><br>Shang'an, Danzhao Town , Lijia Development Zone, , Foshan, CHINA<br>53 J Personal Cleanliness Desc: All Drug and Drug Products Notes: For Industry code 53]; only products found to be drug products are subject to DWPE under this listing. $55 Pharm Necess & Ctm For Drug/BioNotes: All Drug and Drug Products56 Antibiotics (Human/Animal)$   | Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 05/23/2017<br>Ikonium chloride antiseptic<br>Date Published: 02/14/2018<br>Date Published: 02/14/2018<br>Date Published: 02/14/2018                               |

61 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products

#### FriendsUnion(Tianjin) enterprises Itd.

Suites 1808-9 Guohua Building, 857 Dagu-, Nan Road, Hexi, Tianjin, China, tianjin, CN-12 CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Notes: All drug products 60 - - - - Human and Animal Drugs Notes: All drug products 61 - - - -- Human and Animal Drugs Notes: All drug products 62 - - - - Human and Animal Drugs Notes: All drug products 63 - - - Human and Animal Drugs Notes: All drug products 64 - - - -- Human and Animal Drugs Notes: All drug products 65 - - - - Human and Animal Drugs Notes: All drug products 66 - - - -- Human and Animal Drugs Notes: All drug products

# Guangdong Pharmaceutical Factory #1

91 Fangcun Dadao , Guangzhou, CHINA
61 G - - -- A-Bacterial Pt. II (Not Antibiotic)
Notes: Active Pharmaceutical Ingredients 12/12/1997
61 H - - -- A-Bacterial Pt. III (Not Antibiotic)
Notes: Active Pharmaceutical Ingredients 12/12/1997

#### Guangdong Zhanjiang Jimin Pharmaceutical Co., Ltd.

NO. 59 Renmin South Road, Zhangjiang, Guangdong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 62 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices

Date Published: 02/14/2018 Date Published: 02/14/2018 Date Published: 02/14/2018 Date Published: 02/14/2018

Date Published: 02/14/2018

Date Published: 02/14/2018

#### Date Published : 09/17/2010

Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010 Date Published: 09/17/2010

#### Date Published : 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

#### Date Published : 08/21/2017

Date Published: 08/21/2017

| Guangzhou Baiyunshan Pharmaceutical Co., Ltd.  | Date Published : 10/25/2017 |
|--|-----------------------------|
| No. 52 Xiaogang Damalu , Baiyun , Guangzhou, CHINA   |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 60 Human and Animal Drugs  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 61 Human and Animal Drugs  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 62 Human and Animal Drugs  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 63 Human and Animal Drugs  | Date Published: 10/25/2017  |
|  | Date Fublished. 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 64 Human and Animal Drugs  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 65 Human and Animal Drugs  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| 66 Human and Animal Drugs  | Date Published: 10/25/2017  |
| Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                        |                             |
| Guangzhou Haishi Biological Technology Co., Ltd.   | Date Published : 03/14/2016 |
| 1/F,2/F, Bldg.1, no.3, Songyuan Rd , New Industrial Zone, No.11 She, Xiamao , Guangdong, Guangzhou CHINA |                             |

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products

#### Hangzhou Facecare Cosmetics Co., Ltd.

Dev. Area, Hangzhou Economic; 755 Nongken Road, Hangzhou, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 03/14/2016

Date Published : 09/14/2017

Date Published: 09/14/2017

| Hebei Yuxing Bio-Engineering Co Ltd  | Date Published : 07/08/2016           |
|--|---------------------------------------|
| Xicheng District , Ningjin County , Ningjin, Hebei CHINA   |                                       |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)  | Date Published: 07/08/2016            |
| Desc: All Drugs and Drug Products  |                                       |
| Notes: Problem(s); (GMP) Good Manufacturing Practices;For Product code 54, only drugs and drug product | ucts are subject to this Import Alert |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      |                                       |
| 56 Antibiotics (Human/Animal)  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                                       |
| 60 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      |                                       |
| 61 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      |                                       |
| 62 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      |                                       |
| 63 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                                       |
| 64 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                                       |
| 65 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                                       |
| 66 Human and Animal Drugs  | Date Published: 07/08/2016            |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                                       |
| Hency Libus Dharmassutias Co. 1 to   | Date Published : 03/29/2018           |
| Henan Lihua Pharmaceutical Co., Ltd.<br>Middle Of Huanghe Street , Anyang, Henan CHINA                 | Date Published : 03/29/2018           |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 03/29/2018            |
| Notes: All Drug and Drug Products  | Date Fublished. 03/29/2010            |
| 56 Antibiotics (Human/Animal)  | Date Published: 03/29/2018            |
| Notes: All Drug and Drug Products  | Date 1 ublished. 03/29/2010           |
| 60 Human and Animal Drugs  | Date Published: 03/29/2018            |
| Notes: All Drug and Drug Products  | Date 1 ubilanea. 00/23/2010           |
| 61 Human and Animal Drugs  | Date Published: 03/29/2018            |
| Notes: All Drug and Drug Products  |                                       |
| 62 Human and Animal Drugs  | Date Published: 03/29/2018            |
|  | Date i abilitica. 00/20/2010          |

Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs

# Hubei Danao Pharmaceutical Co., Ltd.

Fandan Road, Danjiangkou, Shiyan, Hubei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - -- Human and Animal Drugs

Date Published : 11/01/2017 Date Published: 11/01/2017

Date Published: 03/29/2018

Date Published: 03/29/2018

Date Published: 03/29/2018

Date Published: 03/29/2018

Date Published: 11/01/2017

| Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 11/01/2017  |
|--|---|
| Hubei Goto Healthcare Co., Ltd.  | Date Published : 01/10/2018   |
| Servo Ind. Park 5th FI , 1 Qilin Road , Xiangfan, Hubei CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products;   |   |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug<br>Products;   | Date Published: 01/10/2018  |
| 60 Human and Animal Drugs<br>Notes: All Drug and Drug  | Date Published: 01/10/2018  |
| Products;<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug   | Date Published: 01/10/2018  |
| Products;<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug   | Date Published: 01/10/2018  |
| Products;<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug   | Date Published: 01/10/2018  |
| Products;<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug   | Date Published: 01/10/2018  |
| Products;<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug   | Date Published: 01/10/2018  |
| Products;  | Data Dublishadi 01/10/2018  |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug  | Date Published: 01/10/2018  |
|  | Date Published. 01/10/2016  |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.   | Date Published : 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio  |   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)  | Date Published : 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published : 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br><b>Hunan Norchem Pharmaceutical Co. Ltd.</b><br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br><i>55 Pharm</i> Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br><i>56 Antibiotics</i> (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br><i>60 Human and Animal Drugs</i><br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs  | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br>Hunan Norchem Pharmaceutical Co. Ltd.<br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br><b>Hunan Norchem Pharmaceutical Co. Ltd.</b><br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published : 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017<br>Date Published: 10/18/2017   |
| Notes: All Drug and Drug<br>Products;<br><b>Hunan Norchem Pharmaceutical Co. Ltd.</b><br>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs   | Date Published : 10/18/2017<br>Date Published: 10/18/2017   |
| <ul> <li>Notes: All Drug and Drug<br/>Products;</li> <li>Hunan Norchem Pharmaceutical Co. Ltd.</li> <li>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br/>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>56 Antibiotics (Human/Animal)</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>60 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>61 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>62 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>62 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>63 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>64 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (</li></ul>   | Date Published : 10/18/2017<br>Date Published: 10/18/2017                               |
| <ul> <li>Notes: All Drug and Drug<br/>Products;</li> <li>Hunan Norchem Pharmaceutical Co. Ltd.</li> <li>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br/>55 Pharm Necess &amp; Ctnr For Drug/Bio<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>60 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>61 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>62 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>62 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>63 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>64 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs<br/>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs<br/>Notes: Add Drugs A Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs<br/>Notes</li></ul> | Date Published : 10/18/2017<br>Date Published: 10/18/2017 |
| <ul> <li>Notes: All Drug and Drug<br/>Products;</li> <li>Hunan Norchem Pharmaceutical Co. Ltd.</li> <li>No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA<br/>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>56 Antibiotics (Human/Animal)</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>60 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>61 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>61 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>62 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>63 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>64 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>66 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br/>65 Human and Animal Drugs</li> <li>Notes: Add Drugs and Drug Products;Problem(s): (GMP) Good Manufactur</li></ul>   | Date Published : 10/18/2017<br>Date Published: 10/18/2017                               |

| Notes: All Drugs; (GMP) Good Manufacturing Practices   |                                |
|--|--------------------------------|
| 61 Human and Animal Drugs  | Date Published: 08/05/2016     |
| Notes: All Drugs; (GMP) Good Manufacturing Practices   |                                |
| 62 Human and Animal Drugs  | Date Published: 08/05/2016     |
| Notes: All Drugs; (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs                                | Date Published: 08/05/2016     |
| Notes: All Drugs; (GMP) Good Manufacturing Practices   |                                |
| 64 Human and Animal Drugs  | Date Published: 08/05/2016     |
| Notes: All Drugs; (GMP) Good Manufacturing Practices   |                                |
| 65 Human and Animal Drugs<br>Notes: All Drugs; (GMP) Good Manufacturing Practices                                | Date Published: 08/05/2016     |
| 66 Human and Animal Drugs  | Date Published: 08/05/2016     |
| Notes: All Drugs; (GMP) Good Manufacturing Practices   |                                |
| Jiangmen Nowadays Daily Goods Co., Ltd.  | Date Published : 06/07/2017    |
| Boyukou Liangde Chong , Jiangmen, Guangdong CHINA  |                                |
| 53 Cosmetics   | Date Published: 06/07/2017     |
| Desc: All Drug and Drug Products   | are subject to DMDE under this |
| Notes: For Industry Codes 53; 80; & 95; only drug and drug products (i.e. OTC hand sanitizers and wipes) notice. | are subject to DWPE under this |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products  |                                |
| 56 Antibiotics (Human/Animal)  | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs   | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products  |                                |
| 61 Human and Animal Drugs  | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs   | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products  | Date Fublished. 00/07/2017     |
| 63 Human and Animal Drugs  | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products  |                                |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 06/07/2017     |
| 65 Human and Animal Drugs  | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products  |                                |
| 66 Human and Animal Drugs  | Date Published: 06/07/2017     |
| Notes: All Drug and Drug Products<br>80 General Hospital/Personal Use  | Date Published: 06/07/2017     |
| Desc: All Drug and Drug Products   |                                |
| Notes: For Industry Codes 53; 80; & 95; only drug and drug products (i.e. OTC hand sanitizers and wipes)         | are subject to DWPE under this |
| notice.<br>95 Light Emitting Non-Device Products   | Date Published: 06/07/2017     |
| Desc: All Drug and Drug Products   | Date Fublished. 00/07/2017     |
| Notes: For Industry Codes 53; 80; & 95; only drug and drug products (i.e. OTC hand sanitizers and wipes)         | are subject to DWPE under this |
| notice.  |                                |
| Jiangsu YongAn Pharmaceutical Co., Ltd   | Date Published : 11/27/2017    |
| Chuzhou Industrial Park , No. 8 Jing 15th Road , Huaian, Jiangsu CHINA   |                                |
| <i>55</i> Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products                                  | Date Published: 11/27/2017     |
| 56 Antibiotics (Human/Animal)  | Date Published: 11/27/2017     |
| Notes: All Drug and Drug Products  |                                |
| 60 Human and Animal Drugs  | Date Published: 11/27/2017     |
| Notes: All Drug and Drug Products<br>61 Human and Animal Drugs   | Date Published: 11/27/2017     |
| Notes: All Drug and Drug Products  |                                |
| 62 Human and Animal Drugs  | Date Published: 11/27/2017     |
| Notes: All Drug and Drug Products<br>63 Human and Animal Drugs   | Date Published: 11/27/2017     |
| Notes: All Drug and Drug Products  | Date i ublished. 11/21/2011    |
| 64 Human and Animal Drugs  | Date Published: 11/27/2017     |
|  |                                |

| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products                                   | Date Published: 11/27/2017<br>Date Published: 11/27/2017 |
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| Jilin Shulan Synthetic Pharmaceutical Co. Ltd.  | Date Published : 03/01/2018                              |
| No. 2066 Peoples Main Road , Shulan , Jilin, Jilin CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Natasi All Drugs and Drug Braduate/Drablem(a); (CMB) Coad Manufacturing Bractices                    | Date Published: 03/01/2018                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 03/01/2018                               |
| 60 Human and Animal Drugs   | Date Published: 03/01/2018                               |
| tes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>Human and Animal Drugs<br>tes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices            | Date Published: 03/01/2018                               |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 03/01/2018                               |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 03/01/2018                               |
| 64 Human and Animal Drugs   | Date Published: 03/01/2018                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs  | Date Published: 03/01/2018                               |
| otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>6 Human and Animal Drugs<br>otes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices        | Date Published: 03/01/2018                               |
| Jinan Jinda Pharmaceutical Chemistry Co., Ltd.  | Date Published : 11/25/2015                              |
| No. 6121 Longquan Road , Zhangqui City (Jinan), Shandong CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 11/25/2015                               |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs  | Date Published: 11/25/2015                               |
| Notes: All Drug and Drug Products<br>61 Human and Animal Drugs  | Date Published: 11/25/2015                               |
| Notes: All Drug and Drug Products   | Date Published: 11/25/2015                               |
| 62 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 11/25/2015                               |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 11/25/2015                               |
| 64 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 11/25/2015                               |
| 65 Human and Animal Drugs   | Date Published: 11/25/2015                               |
| Notes: All Drug and Drug Products<br>66 Human and Animal Drugs  | Date Published: 11/25/2015                               |
| Notes: All Drug and Drug Products   |  |
| <b>Kunshan Chemicals &amp; Pharmaceutical Factory</b><br>No 242 Kun Tai Road , Kunshan City , Jiangsu, CHINA  | Date Published : 09/10/2009                              |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 09/10/2009                               |
| Notes: 8/30/2007<br>56 Antibiotics (Human/Animal)   | Date Published: 09/10/2009                               |
| Notes: 8/30/2007<br>60 Human and Animal Drugs   | Date Published: 09/10/2009                               |
| Notes: 8/30/2007<br>61 Human and Animal Drugs   | Date Published: 09/10/2009                               |
| Notes: 8/30/2007  |  |

- Date Published: 09/10/2009
- Date Published: 09/10/2009
- Date Published: 09/10/2009

Notes: 8/30/2007

Notes: 8/30/2007

62 - - - -- Human and Animal Drugs

63 - - - - Human and Animal Drugs

| 65 Human and Animal Drugs   | Date Published:                    | 09/10/2009 |
|---|------------------------------------|------------|
| Notes: 8/30/2007<br>66 Human and Animal Drugs<br>Notes: 8/30/2007   | Date Published:                    | 09/10/2009 |
| Lijiang Yinghua Biochemical and Pharmaceutical Co., Ltd.  | Date Published :                   | 02/08/2018 |
| Industrial Park , Nankou; Gucheng , Lijiang, Yunnan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published:                    | 02/08/2018 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices   |                                    |            |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices                                      | Date Published:                    | 02/08/2018 |
| 60 Human and Animal Drugs   | Date Published:                    | 02/08/2018 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published:                    | 02/08/2018 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices   | Date Fublicitiou                   | 02/00/2010 |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices  | Date Published:                    | 02/08/2018 |
| 63 Human and Animal Drugs   | Date Published:                    | 02/08/2018 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs  | Data Dubliahadu                    | 00/00/0010 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices   | Date Published:                    | JZ/U0/ZU10 |
| 65 Human and Animal Drugs   | Date Published:                    | 02/08/2018 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published:                    | 02/08/2018 |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices   |                                    |            |
| Lumis Global Pharmaceuticals Co. Ltd.   | Date Published :                   | 02/15/2017 |
| Huishang Mansion Unit 305 , 2 Wudayuan Rd Donghu Ntdz , Wuhan, Hubei CHINA  | Data Dublishadu                    | 00/45/0047 |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)<br>Notes: All Drug and Drug Products;For Industry Code 54, only drug and drug products are subject to DWPE unde | Date Published: (<br>r this notice | JZ/15/2017 |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)  | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products   |                                    |            |
| 60 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published:                    | 02/15/2017 |
| 61 Human and Animal Drugs   | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs  | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products   | Date i ublished.                   | 52/10/2011 |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published:                    | 02/15/2017 |
| 64 Human and Animal Drugs   | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs  | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products   | Date Fublished.                    | 52/15/2017 |
| 66 Human and Animal Drugs   | Date Published:                    | 02/15/2017 |
| Notes: All Drug and Drug Products   |                                    |            |
| <b>Ming Fai Industrial (Shenzhen) Co LTD</b><br>Bainikeng, Pinghu , Ming Fai Industrial Estate , Shenzhen, Guangdong CHINA                                | Date Published :                   | 12/21/2017 |
| 53 J Personal Cleanliness   | Date Published:                    | 12/21/2017 |
| Desc: All Drug and Drug Products<br>Notes: For industry code 53J; only products found to be drug products are subject to DWPE under this listing.         |                                    |            |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published:                    | 12/21/2017 |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)  | Date Published:                    | 10/01/0017 |
| Notes: All Drug and Drug Products   | Date Fublished.                    | 12/21/2017 |
| 60 Human and Animal Drugs   | Date Published:                    | 12/21/2017 |
| Notes: All Drug and Drug Products<br>61 Human and Animal Drugs  | Date Published:                    | 12/21/2017 |
| Notes: All Drug and Drug Products   |                                    |            |
|   |                                    |            |

| 62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products   |
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| <ul> <li>Nanjing Maohai Biotech Co.</li> <li>8 Developing Zone, Yaxi Town, Gaochun County, Nanjing Jiangsu Province, CHINA</li> <li>55 R - 75 Crude Heparin (Pharmaceutic Necessity)</li> <li>Desc: Crude Heparin (Pharmaceutical Necessity)</li> <li>61 L - 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-Coagulant)</li> </ul>  |
| Nantong Strip Medical Supply Co LtdBuilding A , 182 Yuelong South Rd , Nantong, Jiangsu CHINA50 Color Additiv Food/Drug/CosmeticNotes: All Drug Products53 CosmeticsNotes: All Drug Products55 Pharm Necess & Ctnr For Drug/BioNotes: All Drug Products60 Human and Animal DrugsNotes: All Drug Products61 Human and Animal DrugsNotes: All Drug Products62 Human and Animal DrugsNotes: All Drug Products63 Human and Animal DrugsNotes: All Drug Products64 Human and Animal DrugsNotes: All Drug Products65 Human and Animal DrugsNotes: All Drug Products65 Human and Animal DrugsNotes: All Drug Products65 Human and Animal DrugsNotes: All Drug Products66 Human and Animal DrugsNotes: All Drug Products67 Human and Animal DrugsNotes: All Drug Products67 Human and Animal DrugsNotes: All Drug Products67 Human and Animal DrugsNotes: All Drug Products60 Human and Animal DrugsNotes: All Drug Products61 Human and Animal DrugsNotes: All Drug Products62 General Hospital/Person |
| Ningbo Smart Pharmaceutical Co., Ltd.<br>Sec. C1, Ningbo Eco. & , Tech. Dev. Zone, Beilun District , Ningbo, Zhejiang CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug Products<br>62 - Human and Animal Drugs   |

Date Published: 12/21/2017 Date Published: 12/21/2017 Date Published: 12/21/2017 Date Published: 12/21/2017 Date Published: 12/21/2017

# Date Published : 10/18/2011

Date Published: 10/18/2011

Date Published: 10/18/2011

#### Date Published : 03/27/2013

Date Published: 03/27/2013

#### Date Published : 04/08/2011

Date Published: 04/08/2011

62 - - - -- Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - -- Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - -- Human and Animal Drugs

Notes: All Drug Products

| Ningbo Unichem Household Products Co Ltd.  | Date Published : 03/05/2013 |
|--|-----------------------------|
| No. 27 Luotuo Jiedao Jiushu Fangnanlu , Zhenhai , Ningbo, Zhejiang CHINA           |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 03/05/2013  |
| 56 Antibiotics (Human/Animal)  | Date Published: 03/05/2013  |
| <i>60</i> Human and Animal Drugs   | Date Published: 03/05/2013  |
| 61 Human and Animal Drugs  | Date Published: 03/05/2013  |
| 62 Human and Animal Drugs  | Date Published: 03/05/2013  |
| 63 Human and Animal Drugs  | Date Published: 03/05/2013  |
| 64 Human and Animal Drugs  | Date Published: 03/05/2013  |
| 65 Human and Animal Drugs  | Date Published: 03/05/2013  |
| 66 Human and Animal Drugs  | Date Published: 03/05/2013  |
| Ningbo Zhixin Bird Clean-Care Product Co. Ltd.                                     | Date Published : 11/22/2016 |
| 137 Bali Road , Zhangqi Town , Zhejang, CHINA                                      |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| <i>60</i> Human and Animal Drugs   | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 61 Human and Animal Drugs  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 62 Human and Animal Drugs  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 63 Human and Animal Drugs  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 64 Human and Animal Drugs  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 65 Human and Animal Drugs  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
| 66 Human and Animal Drugs  | Date Published: 11/22/2016  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                             |
|  |                             |

#### Northeast Pharmaceutical Group Co., Ltd.

37 Zhonggongbeijie, Tiexi, Chenyang, Liaoning CHINA

45 - - - - Food Additives (Human Use)

Notes: All Pharmaceutical Products; \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products.; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE Date Published: 08/28/2010

46 - - - -- Food Additives (Human Use)

Notes: All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE Date Published: 08/28/2010

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)

Notes: \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: 10/30/2007;All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products;NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### 56 - - - - Antibiotics (Human/Animal)

Notes: 10/30/2007 All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

Date Published : 09/10/2009

Date Published: 08/28/2010

Date Published: 09/10/2009

Date Published: 09/10/2009

## 60 - - - -- Human and Animal Drugs

Notes: 10/30/2007 All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: PRODUCT CODE 60S[[[]26 FOR PRODUCT SUCRALFATE IS EXEMPT FROM THIS ALERT. NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### 61 - - -- Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### 62 - - - -- Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### 63 - - -- Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products;NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### 64 - - - -- Human and Animal Drugs

Notes: 10/30/2007: All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### 65 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products:NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

66 - - - -- Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### Nox Bellcow Cosmetics Co. Ltd.

| No. 50 Dongfu North Road , Nantou Town , Zhongshan City, Guangdong CHINA                                 |                            |
|--|----------------------------|
| 53 L F - 01 Cleansing (Cold Creams, Cleansing Lotions, Liquids, Pads) (Skin Care Preparations), Pads     | Date Published: 12/27/2017 |
| Desc: Clear Defense Moisturizing Hand Sanitizing Wipes with Ethyl Alcohol                                |                            |
| Notes: (GMP) Good Manufacturing Practices; Note; For Product Codes 53LF01 and 53LY01; only drug and drug | g products are subject to  |
| DWPE under this notice   |                            |
| 53 L Y - 99 Other Skin Care Preparations, N.E.C., Not Elsewhere Classified (NEC)                         | Date Published: 12/27/2017 |
| Desc: Clear Defense Moisturizing Hand Sanitizing Wipes with Ethyl Alcohol                                |                            |
| Notes: (GMP) Good Manufacturing Practices; Note; For Product Codes 53LF01 and 53LY01; only drug and drug | g products are subject to  |
| DWPE under this notice   |                            |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
| 56 Antibiotics (Human/Animal)  | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
| 60 Human and Animal Drugs  | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
| <i>61</i> Human and Animal Drugs   | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
| 62 Human and Animal Drugs  | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
| 63 Human and Animal Drugs  | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
| <i>64</i> Human and Animal Drugs   | Date Published: 12/27/2017 |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                                   |                            |
|  |                            |

### Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

# Date Published: 09/10/2009

# Date Published: 09/10/2009

Date Published: 09/10/2009

# Date Published : 12/27/2017

| 65 Human and Animal Drugs   | Date Published: 12/27/2017  |
|---|-----------------------------|
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices | Date Published: 12/27/2017  |
| <b>Qinhuangdao Zizhu Pharmaceutical, Co.</b><br>No 10, Longhai Road , Economic & Technological Development Zon , Qinhuangdao, Hebei CHINA                                     | Date Published : 03/08/2017 |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 03/08/2017  |
| Notes: All Drugs and Drug Products<br>56 Antibiotics (Human/Animal)   | Date Published: 03/08/2017  |
| Notes: All Drugs and Drug Products<br>60 Human and Animal Drugs   | Date Published: 03/08/2017  |
| Notes: All Drugs and Drug Products  | Date i ubished. 03/00/2017  |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products  | Date Published: 03/08/2017  |
| 62 Human and Animal Drugs   | Date Published: 03/08/2017  |
| Notes: All Drugs and Drug Products<br>63 Human and Animal Drugs   | Date Published: 03/08/2017  |
| Notes: All Drugs and Drug Products  |                             |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products  | Date Published: 03/08/2017  |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products   | Date Published: 03/08/2017  |
| 66 Human and Animal Drugs   | Date Published: 03/08/2017  |
| Notes: All Drugs and Drug Products  |                             |
| Shandong Vianor Biotech Co., Ltd.   | Date Published : 08/22/2017 |
| Innovation Park Unit D , Technology Ave , Linyi, Shandong CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)  | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices   |                             |
| 60 Human and Animal Drugs<br>Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices  | Date Published: 08/22/2017  |
| 61 Human and Animal Drugs   | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices   |                             |
| 64 Human and Animal Drugs<br>Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices  | Date Published: 08/22/2017  |
| 65 Human and Animal Drugs   | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 08/22/2017  |
| Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices   |                             |
| Shanghai Biochemial And Pharmaceutical Co Ltd   | Date Published : 09/10/2009 |
| Room A403, No. 494 Zhongxing Road , Shanghai, CHINA<br><i>55 R</i> 75 Crude Heparin (Pharmaceutic Necessity)  | Date Published: 09/10/2009  |
| Notes: All heparin products 1/21/2009   | Data Dublishadi 00/40/2000  |
| 55 R 99 Pharmaceutic Necessities, N.E.C.<br>Notes: All heparin products 1/21/2009   | Date Published: 09/10/2009  |
| <i>57 D 38</i> Whole Blood (Human) Heparin (Blood and Blood Derivatives)<br>Notes: All heparin products 1/21/2009   | Date Published: 09/10/2009  |
| 61 L 08 Heparin Sodium (Anti-Coagulant)   | Date Published: 09/10/2009  |
| Notes: All heparin products 1/21/2009<br>61 L 22 Anti-Coagulant Heparin Sol   | Date Published: 09/10/2009  |
| Notes: All heparin products 1/21/2009   |                             |
| <i>61 L 30</i> Heparin Calcium (Anti-Coagulant)<br>Notes: All heparin products 1/21/2009  | Date Published: 09/10/2009  |
| 74 L IS Heparin Coating Chemicals,  | Date Published: 09/10/2009  |
|   |                             |

| Notes: All heparin products 1/21/2009<br><i>80 N ZW</i> Heparin Vascular access flush | Date Published: 09/10/2009                               |
|---|--|
| Notes: All heparin products 1/21/2009   | Date Fublished: 05/10/2003                               |
| <i>81 J BR</i> Test, Heparin Neutralization   | Date Published: 09/10/2009                               |
| Notes: All heparin products 1/21/2009   |  |
| 81 J OX Analyzer, Heparin, Automated  | Date Published: 09/10/2009                               |
| Notes: All heparin products 1/21/2009   |  |
| 81 K FF Assay, Heparin  | Date Published: 09/10/2009                               |
| Notes: All heparin products 1/21/2009<br>88 / AZ Heparin                              | Date Published: 09/10/2009                               |
| Notes: All heparin products 1/21/2009   | Date Fublished. 03/10/2003                               |
|   |  |
| Shanghai Huhui Daily Use Chemical Products Co., Ltd.                                  | Date Published : 04/03/2013                              |
| Pudong District , NO 8 Ludalu , Shanghai, Shanghai CHINA                              |  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 04/03/2013                               |
| 60 Human and Animal Drugs<br>61 Human and Animal Drugs                                | Date Published: 04/03/2013<br>Date Published: 04/03/2013 |
| 62 Human and Animal Drugs   | Date Published: 04/03/2013<br>Date Published: 04/03/2013 |
| 63 Human and Animal Drugs   | Date Published: 04/03/2013                               |
| 64 Human and Animal Drugs   | Date Published: 04/03/2013                               |
| 65 Human and Animal Drugs   | Date Published: 04/03/2013                               |
| 66 Human and Animal Drugs   | Date Published: 04/03/2013                               |
|   |  |
| Shanghai Life-Beauty Cosmetics Co., Ltd.  | Date Published : 03/28/2014                              |
| NO 2000 Fengxianglu , Baoshan , Shanghai, Shanghai CHINA                              |  |
| 53 E 06 Shampoos (Hair Preparations, Non-coloring)                                    | Date Published: 03/28/2014                               |
| Desc: Dandruff Shampoo  |  |
| Notes: (GMP) Good Manufacturing Practices   | Data Dublishad 02/20/2014                                |
| 53 F 04 Hair Shampoos (Coloring) (Hair Coloring Preparations)                         | Date Published: 03/28/2014                               |
| Desc: Dandruff Shampoo<br>Notes: (GMP) Good Manufacturing Practices                   |  |
| 53 J 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C.              | Date Published: 03/28/2014                               |
| Desc: Hand Sanitizers   |  |
| Notes: (GMP) Good Manufacturing Practices   |  |
| 53 J Personal Cleanliness   | Date Published: 03/28/2014                               |
| Desc: Antiperspirants   |  |
| Notes: (GMP) Good Manufacturing Practices   |  |
| 53 L 03 Face,Body,and Hand (excluding Shaving Preparations) (Skin Care Preparations)  | Date Published: 03/28/2014                               |
| Desc: Hand Sanitizers   |  |
| Notes: (GMP) Good Manufacturing Practices   |  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   | Data Dubliahadi 02/20/2014                               |
| 60 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices      | Date Published: 03/28/2014                               |
| 61 Human and Animal Drugs   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   | Date 1 ublished. 03/20/2014                              |
| 62 Human and Animal Drugs   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   |  |
| 63 Human and Animal Drugs   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   |  |
| 64 Human and Animal Drugs   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   |  |
| 65 Human and Animal Drugs   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   |  |
| 66 Human and Animal Drugs   | Date Published: 03/28/2014                               |
| Notes: All Drugs;(GMP) Good Manufacturing Practices                                   |  |
| Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.                                 | Date Published : 09/10/2009                              |
| 1317 Jianchuanlu , Minhang District , Shanghai, Shanghai CHINA                        |  |
|   |  |

 1317 Jianchuanlu , Minhang District , Shanghai, Shanghai CHINA

 55 - - - Pharm Necess & Ctnr For Drug/Bio

 Date Published: 09/10/2009

 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products only.

| 56 Antibiotics (Human/Animal)<br>Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject | Date Published: 09/10/2009<br>to DWPE for heparin products |
|--|--|
| only.<br>60 Human and Animal Drugs   | Date Published: 09/10/2009                                 |
| Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject only.                            | t to DWPE for heparin products                             |
| 61 Human and Animal Drugs  | Date Published: 09/10/2009                                 |
| Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject                                  | to DWPE for heparin products                               |
| only.<br>62 Human and Animal Drugs   | Date Published: 09/10/2009                                 |
| Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject                                  |  |
| only.  |  |
| 63 Human and Animal Drugs  | Date Published: 09/10/2009                                 |
| Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject only.                            | to DWPE for neparin products                               |
| 64 Human and Animal Drugs  | Date Published: 09/10/2009                                 |
| Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject                                  | t to DWPE for heparin products                             |
| only.<br>65 Human and Animal Drugs   | Date Published: 09/10/2009                                 |
| Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject                                  |  |
| only.  |  |
| 66 Human and Animal Drugs<br>Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject     | Date Published: 09/10/2009                                 |
| only.  |  |
| Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.  | Date Published : 09/10/2009                                |
| 387 Shangqiulu , Shanghai, Shanghai CHINA  | Date Fublished . 03/10/2003                                |
| 55 R 75 Crude Heparin (Pharmaceutic Necessity)   | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009<br>55 R 99 Pharmaceutic Necessities, N.E.C.  | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009  |  |
| 57 D 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)  | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009<br><i>61 L 08</i> Heparin Sodium (Anti-Coagulant)  | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009  |  |
| <i>61 L 22</i> Anti-Coagulant Heparin Sol<br>Notes: All Heparin Products 1/21/2009   | Date Published: 09/10/2009                                 |
| 61 L 30 Heparin Calcium (Anti-Coagulant)   | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009  |  |
| 74 <i>L IS</i> Heparin Coating Chemicals,<br>Notes: All Heparin Products 1/21/2009   | Date Published: 09/10/2009                                 |
| 80 N ZW Heparin Vascular access flush  | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009<br><i>81 J BR</i> Test, Heparin Neutralization   | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009  | Date Fublished. 03/10/2003                                 |
| <i>81 J OX</i> Analyzer, Heparin, Automated<br>Notes: All Heparin Products 1/21/2009   | Date Published: 09/10/2009                                 |
| 81 K FF Assay, Heparin   | Date Published: 09/10/2009                                 |
| Notes: All Heparin Products 1/21/2009  |  |
| <i>88 I AZ</i> Heparin<br>Notes: All Heparin Products 1/21/2009  | Date Published: 09/10/2009                                 |
|  |  |
| Shanghai Weierya Daily Chemicals Factory<br>No. 1072 Dongsheng Lu , Shanghai, Shanghai CHINA   | Date Published : 09/14/2017                                |
| 53 J 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C.   | Date Published: 09/14/2017                                 |
| Desc: Hand Sanitizer   |  |
| Notes: Problem(s); (GMP) Good Manufacturing Practices<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 09/14/2017                                 |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices   |  |
| 56 Antibiotics (Human/Animal)  | Date Published: 09/14/2017                                 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs                                 | Date Published: 09/14/2017                                 |
|  |  |
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| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                       | 4/0047  |
|--|-----------------------|---------|
| <i>61</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                  | Date Published: 09/2  | 4/2017  |
| 62 Human and Animal Drugs  | Date Published: 09/2  | 4/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs                         | Date Published: 09/2  | 14/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs                         | Date Published: 09/2  | 14/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                       |         |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                         | Date Published: 09/*  | 4/2017  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                         | Date Published: 09/2  | 4/2017  |
|  |                       |         |
|  | Date Published : 11/  | 02/2017 |
| Chunzai Garden Wuya Hong , Cao Town , Shanwei, Guangdong CHINA   | Data Dublish a du 44/ | 00047   |
| <i>53 I 01</i> Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products)<br>Desc: Dentifrices | Date Published: 11/0  | )2/2017 |
| Notes: (GMP) Good Manufacturing Practices; For Product Code 531[[[01; only drug and drug products are subjec                           | to DWPE under this    | notice  |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 11/0  |         |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)                     | Date Published: 11/0  | )2/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs                         | Date Published: 11/0  | 12/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                       |         |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                  | Date Published: 11/0  | )2/2017 |
| 62 Human and Animal Drugs  | Date Published: 11/0  | )2/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs                         | Date Published: 11/0  | )2/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Data Dubliabadi 11/0  | 00/0047 |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                         | Date Published: 11/0  | )2/2017 |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                         | Date Published: 11/0  | )2/2017 |
| 66 Human and Animal Drugs  | Date Published: 11/0  | )2/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                       |         |
| Shenzhen Senton Science & Technology Co.,Ltd.<br>Longdong Community 294 , Longnanlu; Longgang , Shenzhen, Guangdong CHINA              | Date Published : 11/  | 21/2017 |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 11/2  | 21/2017 |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)   | Date Published: 11/2  | 21/2017 |
| Notes: All Drug and Drug Products  |                       |         |
| <i>60</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 11/2  | 21/2017 |
| 61 Human and Animal Drugs  | Date Published: 11/2  | 21/2017 |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs   | Date Published: 11/2  | 21/2017 |
| Notes: All Drug and Drug Products<br>63 Human and Animal Drugs   | Date Published: 11/2  | 21/2017 |
| Notes: All Drug and Drug Products  | Date i ublished. 11/2 | 1/2017  |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 11/2  | 21/2017 |
| 65 Human and Animal Drugs  | Date Published: 11/2  | 21/2017 |
| Notes: All Drug and Drug Products  |                       | 04/0047 |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 11/2  | 21/2017 |
|  |                       |         |
| · · · · <b>,</b> · · · · · · · · · · · · · · · · · · ·   | Date Published : 03/  | 22/2018 |
| No. 680 Hongpai Road , Dongxing , Neijiang, Sichuan CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio                                       | Date Published: 03/2  | 22/2018 |
|  |                       |         |

Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products

#### Sichuan Pharmaceutical Co., Ltd.

189 Huayuanlu, Pengzhou, Chengdou, Sichuan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Notes: All drug products 60 - - - -- Human and Animal Drugs Notes: All drug products 61 - - - -- Human and Animal Drugs Notes: All drug products 62 - - - - Human and Animal Drugs Notes: All drug products 63 - - - - Human and Animal Drugs Notes: All drug products 64 - - - - Human and Animal Drugs Notes: All drug products 65 - - - - Human and Animal Drugs Notes: All drug products 66 - - - -- Human and Animal Drugs Notes: All drug products

#### Suzhou No. 4 Pharmaceutical Factory

171 Baiyanglu , Suzhou, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio 56 - - - - Antibiotics (Human/Animal) 60 - - - Human and Animal Drugs 61 - - - Human and Animal Drugs 62 - - - Human and Animal Drugs 63 - - - Human and Animal Drugs 64 - - - Human and Animal Drugs 65 - - - Human and Animal Drugs 66 - - - - Human and Animal Drugs

#### Suzhou Pharmaceutical Technology Co.,Ltd

Tongjing Commercial Plaza Room 920 # 3 , Jiefang Rd , Suzhou, Jiangsu CHINA 55 - - - -- Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - -- Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - -- Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - -- Human and Animal Drugs Date Published: 03/22/2018

#### Date Published : 05/08/2012

Date Published: 05/08/2012

#### Date Published : 07/10/2014

Date Published: 07/10/2014 Date Published: 07/10/2014 Date Published: 07/10/2014 Date Published: 07/10/2014 Date Published: 07/10/2014 Date Published: 07/10/2014 Date Published: 07/10/2014 Date Published: 07/10/2014

#### Date Published : 10/17/2016

Date Published: 10/17/2016

| Notes: All Drug and Drug Products   |  |
|---|--|
| 63 Human and Animal Drugs   | Date Published: 10/17/2016                               |
| Notes: All Drug and Drug Products<br>64 Human and Animal Drugs                      | Date Published: 10/17/2016                               |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs                      | Date Published: 10/17/2016                               |
| Notes: All Drug and Drug Products   |  |
| 66 Human and Animal Drugs   | Date Published: 10/17/2016                               |
| Notes: All Drug and Drug Products   |  |
| Taizhou Kanglin Health Protection Products Co., Ltd.                                | Date Published : 01/15/2013                              |
| The West of Qiliqiao , Economic Development Zone , Taizhou, Jiangsu Province CHINA  |  |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)   | Date Published: 01/15/2013                               |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 01/15/2013<br>Date Published: 01/15/2013 |
| 56 Antibiotics (Human/Animal)<br>60 Human and Animal Drugs                          | Date Published: 01/15/2013                               |
| 61 Human and Animal Drugs   | Date Published: 01/15/2013                               |
| 62 Human and Animal Drugs   | Date Published: 01/15/2013                               |
| 63 Human and Animal Drugs   | Date Published: 01/15/2013                               |
| 64 Human and Animal Drugs   | Date Published: 01/15/2013                               |
| 65 Human and Animal Drugs   | Date Published: 01/15/2013                               |
| 66 Human and Animal Drugs<br><i>80 L KB</i> Pad, Alcohol                            | Date Published: 01/15/2013<br>Date Published: 01/15/2013 |
| ou L KB Pau, Alcohol  | Date Published. 01/15/2013                               |
| Tianjin Boai NKY International Ltd.   | Date Published : 09/17/2010                              |
| Suites 1808-9 Guohua Building , Dagu-Nan Road, Hexi District , Tianjin, CN-12 CHINA |  |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All drug products                     | Date Published: 09/17/2010                               |
| 56 Antibiotics (Human/Animal)   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 60 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| <i>61</i> Human and Animal Drugs<br>Notes: All drug products                        | Date Published: 09/17/2010                               |
| 62 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 63 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  | Date Published: 09/17/2010                               |
| <i>64</i> Human and Animal Drugs<br>Notes: All drug products                        | Date Published: 09/17/2010                               |
| 65 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 66 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| Tianjin Boai Pharmaceutical Co. Ltd   | Date Published : 09/17/2010                              |
| NO. 4 Ronghua Road , Xiqing , Tianjin, Tianjin CHINA                                |  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 09/17/2010                               |
| Notes: All drug products<br>56 Antibiotics (Human/Animal)                           | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 60 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 61 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  | Data Dubliahadi 00/17/2010                               |
| <i>62</i> Human and Animal Drugs<br>Notes: All drug products                        | Date Published: 09/17/2010                               |
| 63 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 64 Human and Animal Drugs   | Date Published: 09/17/2010                               |
| Notes: All drug products  |  |
| 65 Human and Animal Drugs   | Date Published: 09/17/2010                               |
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Notes: All drug products 66 - - - -- Human and Animal Drugs Notes: All drug products

#### Tianjin Boai Pharmaceutical Ltd. co.

6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin, CN-12 CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Notes: All drug products 60 - - - -- Human and Animal Drugs Notes: All drug products 61 - - - -- Human and Animal Drugs Notes: All drug products 62 - - - - Human and Animal Drugs Notes: All drug products 63 - - - - Human and Animal Drugs Notes: All drug products 64 - - - -- Human and Animal Drugs Notes: All drug products 65 - - - - Human and Animal Drugs Notes: All drug products 66 - - - -- Human and Animal Drugs

### Notes: All drug products

#### Tianjin Zhongan Pharmaceutical Co., Ltd.

Xiqing, 188 Fukang Road, Tianjin, Tianjin CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: Problem: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: Problem: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices 62 - - - -- Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: Problem: (GMP) Good Manufacturing Practices

#### Wuhan Chinese Moxibustion Technology Dev. Co., Ltd.

Wuhan Pharmaceutical Industry Park , East Lake High-Tech , Wuhan, Hubei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All Drug and Drug Products
56 - - - - Antibiotics (Human/Animal)
Notes: All Drug and Drug Products
60 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
61 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
62 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
63 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
63 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
63 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
64 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products
64 - - - - Human and Animal Drugs
Notes: All Drug and Drug Products

Date Published: 09/17/2010

#### Date Published : 09/17/2010

Date Published: 09/17/2010

#### Date Published : 02/11/2016

Date Published: 02/11/2016 Date Published: 02/11/2016 Date Published: 02/11/2016 Date Published: 02/11/2016 Date Published: 02/11/2016 Date Published: 02/11/2016 Date Published: 02/11/2016 Date Published: 02/11/2016

#### Date Published : 10/19/2017

Date Published: 10/19/2017

| 65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs   | Date Published: 10/19/2017   |
|---|--|
| Notes: All Drug and Drug Products<br>89 / Portion of device code  | Date Published: 10/19/2017<br>Date Published: 10/19/2017   |
| Desc: All Drug and Drug Products<br>Notes: For industry code 89I; only products found to be drug products are subject to DWPE under this listing  |  |
| <b>Xiamen Origin Biotech Co. Ltd.</b><br>NO. 7 Xiang Yue Road , Xiamen Torch , Xiamen, Fujian CHINA   | Date Published : 05/13/2016  |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)<br>Desc: All Drugs and Drug Products  | Date Published: 05/13/2016   |
| Notes: (GMP) Good Manufacturing Practices<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Nates: All Drugs and Drug Bradueta/Braham(a): (CMB) Cood Manufacturing Brastings  | Date Published: 05/13/2016   |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 05/13/2016   |
| 60 Human and Animal Drugs   | Date Published: 05/13/2016   |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 05/13/2016   |
| 62 Human and Animal Drugs   | Date Published: 05/13/2016   |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 05/13/2016   |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs  | Date Published: 05/13/2016   |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs  | Date Published: 05/13/2016   |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 05/13/2016   |
| Notoo: All Drugo and Drug Producto:Problem(a): (CMD) Cood Menufacturing Practices   |  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published : 04/06/2016  |
| Xinxiang Pharmaceutical Co. Ltd.<br>NO. 30 Jianshe West Road , Beigandao , Henan, CHINA   | Date Published : 04/06/2016  |
| Xinxiang Pharmaceutical Co. Ltd.<br>NO. 30 Jianshe West Road , Beigandao , Henan, CHINA<br>53 Cosmetics<br>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, o   | Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road , Beigandao , Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> </ul>  | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road , Beigandao , Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> </ul>   | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road , Beigandao , Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> </ul>  | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road, Beigandao, Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> </ul>                                    | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road, Beigandao, Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> </ul>  | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road, Beigandao, Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>62 Human and An</li></ul>                          | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road, Beigandao, Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Human Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Onl</li></ul> | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016   |
| <ul> <li>Xinxiang Pharmaceutical Co. Ltd.</li> <li>NO. 30 Jianshe West Road, Beigandao, Henan, CHINA</li> <li>53 Cosmetics</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>54 Vit/Min/Prot/Unconv Diet(Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>56 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, or pharmaceutical intermediates) are subject to DWPE under this notice.</li> <li>62 Human and Animal</li></ul>                          | Date Published: 04/06/2016<br>cytidine, inosine, and all<br>Date Published: 04/06/2016 |

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 66 - - - -- Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. Xinxiang Tuoxin Biochemical Co. Ltd Date Published : 04/06/2016 Muye And Deyuan Road Cross Street, Xinxiang City, Henan CHINA 53 - - - - Cosmetics Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 54 - - - -- Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 56 - - - - Antibiotics (Human/Animal) Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 60 - - - -- Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 61 - - - -- Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 62 - - - - Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 63 - - - - Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 64 - - - -- Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 65 - - - - Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. 66 - - - -- Human and Animal Drugs Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice. Yangzhou Hengyuan Daily Chemical Plastic Co Ltd Date Published : 08/12/2016 Hangji Town, 7 Sitonglu; Hanjiang, Yangzhou, Jiangsu CHINA 53 / - - 01 Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products) Date Published: 08/12/2016 Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 53 J - - 02 Deodorants (underarm)(Not Antiperspirant) (Personal Cleanliness) Date Published: 08/12/2016 Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/12/2016 Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 56 - - - - Antibiotics (Human/Animal) Date Published: 08/12/2016 Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice 60 - - - -- Human and Animal Drugs Date Published: 08/12/2016 Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice 61 - - - -- Human and Animal Drugs Date Published: 08/12/2016 Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 62 - - - - Human and Animal Drugs Date Published: 08/12/2016 Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice 63 - - - - Human and Animal Drugs Date Published: 08/12/2016 Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice

| 64 Human and Animal Drugs  | Date Published: 08/12/2016  |
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| Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DW | /PE under this notice       |
| 65 Human and Animal Drugs  | Date Published: 08/12/2016  |
| Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DW | /PE under this notice       |
| 66 Human and Animal Drugs  | Date Published: 08/12/2016  |
| Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DV | /PE under this notice       |
| Yicheng Chemical Corp.   | Date Published : 08/11/2017 |
| Fuchen Garden Suite , 1-402; Xinbei District , Changzhou, Jiangsu CHINA                                |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 60 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 61 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 62 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 63 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
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| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 65 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| 66 Human and Animal Drugs  | Date Published: 08/11/2017  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     |                             |
| Yicheng Goto Pharmaceuticals Co., Ltd  | Date Published : 01/10/2018 |
| Group 1 Gaokeng , Yicheng , Xiangyang, Hubei CHINA   |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products  |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products  |                             |
| 60 Human and Animal Drugs  | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products  |                             |
| 61 Human and Animal Drugs  | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products  |                             |
| 62 Human and Animal Drugs  | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products  |                             |
| 63 Human and Animal Drugs  | Date Published: 01/10/2018  |
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| 64 Human and Animal Drugs  | Date Published: 01/10/2018  |
| Notes: All Drug and Drug Products  |                             |
| 65 Human and Animal Drugs  | Date Published: 01/10/2018  |

Date Published: 01/10/2018

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# Date Published : 05/20/2016

Date Published: 05/20/2016 Date Published: 05/20/2016 Date Published: 05/20/2016 Date Published: 05/20/2016 Date Published: 05/20/2016 Date Published: 05/20/2016

# Yunnan Hande Bio-Tech. Co. Ltd.

Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs

Notes: All Drug and Drug Products

No. 3 Jindingbeilu, Wuhua, Kunming, Yunnan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs

| Notes: All Drug and Drug Products<br>64 Human and Animal Drugs  | Date Published: 05/20/2016  |
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| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs  | Date Published: 05/20/2016  |
| Notes: All Drug and Drug Products<br>66 Human and Animal Drugs  | Date Published: 05/20/2016  |
| Notes: All Drug and Drug Products   |   |
| Zhejiang Bangli Medical Products Co., Ltd<br>Huachuan Block , 118 South of Yuegui Road , Yongkang City, Zhejiang CHINA  | Date Published : 09/09/2016   |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 09/09/2016  |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 09/09/2016  |
| 60 Human and Animal Drugs   | Date Published: 09/09/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 09/09/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 09/09/2016  |
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| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs  | Date Published: 09/09/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 09/09/2016  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |   |
| Zhejiang Casing Animal By-Products Co.,Ltd.   | Date Published : 10/18/2011   |
|   |   |
| 369 Dong Xing Road, Tonglu Economic Developing District, Hangzhou, Zhejiang Province CN-33 CHINA<br>61 L 08 Heparin Sodium (Anti-Coagulant)   | Date Published: 10/18/2011  |
| <i>61 L 08</i> Heparin Sodium (Anti-Coagulant)<br>Desc: Heparin Sodium (Anti-coagulant)   |   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> </ul>   | Date Published : 01/20/2016   |
| 61 L 08 Heparin Sodium (Anti-Coagulant)<br>Desc: Heparin Sodium (Anti-coagulant)<br><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b>  |   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> </ul>   | Date Published : 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> </ul>   | Date Published : 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> </ul>  | <b>Date Published : 01/20/2016</b><br>Date Published: 01/20/2016<br>Date Published: 01/20/2016  |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> </ul>  | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> </ul>  | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L - 08 Heparin Sodium (Anti-Coagulant)<br/>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> </ul>   | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L - 08 Heparin Sodium (Anti-Coagulant)<br/>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> </ul>  | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L - 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> </ul>   | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li>Desc: Heparin Sodium (Anti-coagulant)</li> <li>Zhejiang Hisoar Pharmaceutical Co. Ltd.</li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug</li></ul>      | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufact</li></ul>     | Date Published : 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) G</li></ul>   | Date Published : 01/20/2016<br>Date Published: 01/20/2016   |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturin</li></ul> | Date Published : 01/20/2016Date Published: 01/20/2016 |
| <ul> <li>61 L 08 Heparin Sodium (Anti-Coagulant)</li> <li><b>Zhejiang Hisoar Pharmaceutical Co. Ltd.</b></li> <li>No. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA</li> <li>55 Pharm Necess &amp; Chr For Drug/Bio</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good</li></ul> | Date Published : 01/20/2016<br>Date Published: 01/20/2016   |

| Notes: For industry code 53J; 53D and 53L; only products found to be drug products are subject to DWPE u 53 L Skin Care Prep Desc: All Drug and Drug Products  | under this listing.<br>Date Published: 12/28/2017  |
|--|--|
| Notes: For industry code 53J; 53D and 53L; only products found to be drug products are subject to DWPE t<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products   | under this listing.<br>Date Published: 12/28/2017  |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 60 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 61 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 62 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 64 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 65 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/28/2017   |
| Zhejiang Qianfei Enterprise Co. Ltd.   | Date Published : 11/24/2015  |
| No 173 Wulian Road , Yiwu , Jinhua, Zhejiang CHINA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 11/24/2015   |
| Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs   | Date Published: 11/24/2015   |
|  |  |
| Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs   |  |
| 61 Human and Animal Drugs<br>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices   | Date Published: 11/24/2015   |
| <ul> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> </ul>   |  |
| 61 Human and Animal Drugs<br>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 11/24/2015<br>Date Published: 11/24/2015   |
| <ul> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> </ul> | Date Published: 11/24/2015<br>Date Published: 11/24/2015<br>Date Published: 11/24/2015                               |
| <ul> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> </ul>  | Date Published: 11/24/2015<br>Date Published: 11/24/2015<br>Date Published: 11/24/2015<br>Date Published: 11/24/2015 |

# DENMARK

| <b>Leo Pharma A/S</b><br>Industriparken 55 , Ballerup, DENMARK   | Date Published : 03/01/2011 |
|--|-----------------------------|
| <i>61 L 35</i> Tinzaparin Sodium (Anti-Coagulant)<br>Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c. | Date Published: 03/01/2011  |
| 61 L 99 Anti-Coagulant, N.E.C.<br>Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.                    | Date Published: 03/01/2011  |
| Leo Pharmaceutical Products<br>A 8 , Copenhagen, DENMARK   | Date Published : 03/01/2011 |
| 61 L 35 Tinzaparin Sodium (Anti-Coagulant)<br>Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.        | Date Published: 03/01/2011  |
| 61 L 99 Anti-Coagulant, N.E.C.<br>Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.                    | Date Published: 03/01/2011  |
| Leo Pharmaceutical Products  | Date Published : 03/01/2011 |

Park Alle 26, Vejen, DENMARK 61 L - - 35 Tinzaparin Sodium (Anti-Coagulant) Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c. 61 L - - 99 Anti-Coagulant, N.E.C. Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

### DOMINICAN REPUBLIC

| Labocont Industrial SRL   | Date Published : 02/08/2018 |
|---|-----------------------------|
| Entrada Zona Franca, La Caleta , Autopista Las Americas Km. 19 , Santo Domingo, DOMINICAN REPUBLIC<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 02/08/2018  |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)  | Date Published: 02/08/2018  |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs  | Date Published: 02/08/2018  |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 02/08/2018  |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 02/08/2018  |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 02/08/2018  |
| Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices | Date Published: 02/08/2018  |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 02/08/2018  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 02/08/2018  |
| Notes. All brugs and brug i roducis . I robiern(s). (Givir ) Good Manulacturing i ractices  |                             |

### FRANCE

| BR SAS   | Date Published : 01/17/2018 |
|--|-----------------------------|
| 28 Rue De La Procession , Suresnes, FRANCE   |                             |
| 53 Cosmetics   | Date Published: 01/17/2018  |
| Desc: All Drug and Drug Products   |                             |
| Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.            |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u |                             |
| 60 Human and Animal Drugs  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u | nder this notice.           |
| <i>61</i> Human and Animal Drugs   | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u | nder this notice.           |
| 62 Human and Animal Drugs  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u | nder this notice.           |
| 63 Human and Animal Drugs  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u | nder this notice.           |
| 64 Human and Animal Drugs  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u | nder this notice.           |
| 65 Human and Animal Drugs  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE u | nder this notice.           |
| 66 Human and Animal Drugs  | Date Published: 01/17/2018  |
| Notes: All Drug and Drug Products;For Industry Code 53, only drug and drug products are subject to DWPE u  | nder this notice.           |
| CISBIO BIOASSAYS   | Date Published : 09/10/2009 |

Date Published: 03/01/2011

Date Published: 03/01/2011

1 route du Parc Marcel Boiteux, Codolet, Gard FRANCE 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: Selenomethionine 75 injection 60 - - - -- Human and Animal Drugs Notes: Selenomethionine 75 injection 61 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 62 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 63 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 64 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 65 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 66 - - - -- Human and Animal Drugs Notes: Selenomethionine 75 injection

### Compagnie Oris Industrie Lpib

B.P. #2 91 Gif-Sur-Yvette , Saclay, FRANCE 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: Selenomethionine 75 injection 60 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 61 - - - -- Human and Animal Drugs Notes: Selenomethionine 75 injection 62 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 63 - - - - Human and Animal Drugs Notes: Selenomethionine 75 injection 64 - - - -- Human and Animal Drugs Notes: Selenomethionine 75 injection 65 - - - - Human and Animal Drugs Notes: Selenomethionine 75 Injection 66 - - - -- Human and Animal Drugs Notes: Selenomethionine 75 injection

### Ligne St. Barth SAS

Lorient , route de Saline , St Barthelemy, Guadeloupe FRANCE 55 - - - -- Pharm Necess & Ctnr For Drug/Bio 60 - - - -- Human and Animal Drugs 61 - - - -- Human and Animal Drugs 62 - - -- Human and Animal Drugs 63 - - -- Human and Animal Drugs 64 - - -- Human and Animal Drugs 65 - - -- Human and Animal Drugs 66 - - -- Human and Animal Drugs

### **Societe Chimique Grevis**

Avenue De La Paix , Limay, FRANCE 55 - - - -- Pharm Necess & Ctnr For Drug/Bio Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 56 - - - -- Antibiotics (Human/Animal) Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 60 - - -- Human and Animal Drugs Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 61 - - -- Human and Animal Drugs Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 62 - - -- Human and Animal Drugs Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 62 - - -- Human and Animal Drugs Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 63 - - -- Human and Animal Drugs Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 63 - - -- Human and Animal Drugs Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 Date Published: 09/10/2009

### Date Published : 09/10/2009

Date Published: 09/10/2009

### Date Published : 07/08/2013

Date Published: 07/08/2013 Date Published: 07/08/2013 Date Published: 07/08/2013 Date Published: 07/08/2013 Date Published: 07/08/2013 Date Published: 07/08/2013 Date Published: 07/08/2013

### Date Published : 09/10/2009

Date Published: 09/10/2009

64 - - - -- Human and Animal Drugs
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989
65 - - - -- Human and Animal Drugs
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989
66 - - - -- Human and Animal Drugs
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989

### GERMANY

# SANUM-Kehlbeck GmbH & Co. KG

Hasseler Steinweg, 9-12, and Bahnhofstrasse 2-4, Hoya, Niedersachsen GERMANY
50 - - - - Color Additiv Food/Drug/Cosmetic
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
55 - - - Pharm Necess & Ctnr For Drug/Bio
56 - - - - Antibiotics (Human/Animal)
60 - - - Human and Animal Drugs
61 - - - Human and Animal Drugs
63 - - - Human and Animal Drugs
63 - - - Human and Animal Drugs
64 - - - Human and Animal Drugs
65 - - - Human and Animal Drugs
66 - - - - Human and Animal Drugs

### GREECE

### CHIA GH LTD.

Ag. Mina 144, Chios, GREECE 55 - - - - Pharm Necess & Ctnr For Drug/Bio 56 - - - - Antibiotics (Human/Animal) 60 - - - - Human and Animal Drugs 61 - - - - Human and Animal Drugs 63 - - - Human and Animal Drugs 64 - - - - Human and Animal Drugs 65 - - - - Human and Animal Drugs 66 - - - - Human and Animal Drugs

### HONG KONG

### Date Published : 08/31/2013 **CBSCHEM LIMITED** 13th Floor, Nan Fung Industrial City, Tuen Mun, New Territories HONG KONG 35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling Date Published: 08/31/2013 Desc: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 08/31/2013 Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/31/2013 Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 08/31/2013 Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products 61 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published : 07/08/2013

Date Published: 07/08/2013

# Date Published : 05/06/2013

Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013

| 62 Human and Animal Drugs   | Date Published: 08/31/2013    |
|---|-------------------------------|
| Notes: All drugs and drug products<br>63 Human and Animal Drugs   | Date Published: 08/31/2013    |
| Notes: All drugs and drug products<br><i>64</i> Human and Animal Drugs  | Date Published: 08/31/2013    |
| Notes: All drugs and drug products  |                               |
| 65 Human and Animal Drugs<br>Notes: All drugs and drug products   | Date Published: 08/31/2013    |
| 66 Human and Animal Drugs<br>Notes: All drugs and drug products   | Date Published: 08/31/2013    |
| 78 Gastroenterological & Urological   | Date Published: 08/31/2013    |
| Desc: All drugs and drug products<br>88 Pathology   | Date Published: 08/31/2013    |
| Desc: All drugs and drug products   |                               |
| Chan Yat Hing Medicine Factory<br>Flat 3, 9/F , Fuk Keung Industrial Bldg. , Mong Kok, Kowloon HONG KONG  | Date Published : 12/03/2015   |
| 53 Cosmetics  | Date Published: 01/07/2016    |
| Desc: All drug products declared as Cosmetic Products<br>Notes: The firm has a history of importing some of the following drug products under product code 53: Arthrit  | is Pain Relieving Cream, Pain |
| Relieving Balm, Wok Lok Pain Relieving Oil, Shuang Long Pain Relieving Oil, and Red Flower Oil, Pain Relieving Oil, Pain Relieving Po Tong Oil, and Back Pain Relieving Oil. This is not an inclusive list; therefore it products offered for import under product code 53 be thoroughly reviewed to determine if said products are d | is recommended that any       |
| DWPE under this listing.  |                               |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 12/03/2015    |
| 56 Antibiotics (Human/Animal)<br>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 12/03/2015    |
| 60 Human and Animal Drugs   | Date Published: 12/03/2015    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 12/03/2015    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 12/03/2015    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 12/03/2015    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                               |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 12/03/2015    |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 12/03/2015    |
| 66 Human and Animal Drugs   | Date Published: 12/03/2015    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                               |
| Luen Wah (HK) Medicine Ltd<br>412 Room , Paramount Building 406; 12 Ka Yip Street , Chai Wan, Hong Kong Island HONG KONG  | Date Published : 01/18/2018   |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 01/18/2018    |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 01/18/2018    |
| 60 Human and Animal Drugs   | Date Published: 01/18/2018    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 01/18/2018    |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 01/18/2018    |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices  |                               |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 01/18/2018    |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 01/18/2018    |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 01/18/2018    |
| 66 Human and Animal Drugs   | Date Published: 01/18/2018    |
|   |                               |

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

### Luen Yick Pharmaceutical Co. Ltd.

| Unit B, 7F, Phase 1 Leader Industry Ctr. , 188-202 Texaco Rd, Tsuen Wan , Kowloon, HK-NA HONG KONG |    |
|--|----|
| 55 Pharm Necess & Ctnr For Drug/Bio  | Da |
| Notes: All Drug Products   |    |
| 60 Human and Animal Drugs  | Da |
| Notes: All Drug Products   |    |
| <i>61</i> Human and Animal Drugs   | Da |
| Notes: All Drug Products   |    |
| 62 Human and Animal Drugs  | Da |
| Notes: All Drug Products   |    |
| 63 Human and Animal Drugs  | Da |
| Notes: All Drug Products   | _  |
| 64 Human and Animal Drugs  | Da |
| Notes: All Drug Products   | _  |
| 65 Human and Animal Drugs  | Da |
| Notes: All Drug Products   | _  |
| 66 Human and Animal Drugs  | Da |
| Notes: All Drug Products   |    |

### Nan San (HK) Pharmaceutical Factory Ltd.

Hoi Bun Industrial Building , 6 Wing Yip Street, Unit C1, 10/F , Kwun Tong Kowloon, Hong Kong HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products Peking Medicine Manufactory

Unit B, 7/F, Phase 1 , Leader Industry Centre , Tsuen Wan, New Territories HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug Products 65 - - - -- Human and Animal Drugs Notes: All Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug Products

### Seedings

- Date Published: 03/04/2014

### Date Published : 01/08/2018

Date Published: 01/08/2018

- Date Published: 01/08/2018
- Date Published: 01/08/2018
- Date Published: 01/08/2018
- Date Published: 01/08/2018
- Date Published: 01/08/2018
- Date Published: 01/08/2018
- Date Published: 01/08/2018
- Date Published: 01/08/2018

## Date Published : 03/04/2014

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- Date Published: 03/04/2014
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- Date Published: 03/04/2014
- Date Published: 03/04/2014
- Date Published: 03/04/2014
- Date Published: 03/04/2014
- Date Published: 03/04/2014
- Date Published : 08/31/2013

| 18 Tin Hau Rd. , Room 3, 13/F, Tower 4 , Hong Kong, Hong Kong HONG KONG  |   |
|--|---|
| 35 Gelatin/Rennet/Pudding Mix/Pie Filling  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 56 Antibiotics (Human/Animal)  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 60 Human and Animal Drugs  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 61 Human and Animal Drugs  | Date Published: 08/31/2013  |
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| 62 Human and Animal Drugs  | Date Published: 08/31/2013  |
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| 63 Human and Animal Drugs  | Date Published: 08/31/2013  |
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| 64 Human and Animal Drugs  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 65 Human and Animal Drugs  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 66 Human and Animal Drugs  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
| 78 Gastroenterological & Urological  | Date Published: 08/31/2013  |
| Notes: All drugs and drug products   |   |
|  |   |
|  | Date Published: 08/31/2013  |
| 88 Pathology   | Date Published: 08/31/2013  |
|  | Date Published: 08/31/2013  |
| 88 Pathology<br>Notes: All drugs and drug products   | Date Published: 08/31/2013<br>Date Published : 01/08/2018   |
| 88 Pathology<br>Notes: All drugs and drug products<br>Wong Lap Kwong Medicine Company Limited  |   |
| 88 Pathology<br>Notes: All drugs and drug products   |   |
| <ul> <li>88 Pathology</li> <li>Notes: All drugs and drug products</li> <li>Wong Lap Kwong Medicine Company Limited</li> <li>Flat B, 4/F , Wah Lung Industrial Building; 49-53 Wang Lung Street , Tsuen Wan, New Territories HONG KONG 55 Pharm Necess &amp; Ctnr For Drug/Bio</li> </ul>   | Date Published : 01/08/2018   |
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# HUNGARY

# Teva Pharmaceutical Works Private Limited CompanyDate Published : 05/27/2016Tancsics Mihaly ut 82 , Godollo, Pest HUNGARYDate Published: 05/27/201655 - - - - Pharm Necess & Ctnr For Drug/BioDate Published: 05/27/2016Notes: All Drugs;Problem(s): (GMP) Good Manufacturing PracticesDate Published: 05/27/201656 - - - - Antibiotics (Human/Animal)Date Published: 05/27/2016Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe: Amikacin/56D[][06;Bleomycin / 56H[][10Date Published: 05/27/201660 - - - - Human and Animal DrugsDate Published: 05/27/2016

Import Alert 66-40

| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices |
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| <i>61</i> Human and Animal Drugs                                 |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices |
| 62 Human and Animal Drugs  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices |
| 63 Human and Animal Drugs  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices |
| 64 Human and Animal Drugs  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices |
| 65 Human and Animal Drugs  |
| Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices |
| 66 Human and Animal Drugs  |
| Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices  |

# INDIA

Date Published: 05/27/2016

Date Published: 05/27/2016

| Aadivighnesh Chem PVT. LTD.   | Date Published : 05/05/2014 |
|---|-----------------------------|
| A/7 Badrinath Apartment , Simpoli Road; Borivali West , Mumbai, Maharashtra INDIA<br>56 C -  - 66 Ceftazidime (Cephalosporins)<br>Desc: Ceftazimide for Injection USP (Sterile)             | Date Published: 05/05/2014  |
| <b>Aarti Drugs Limited</b><br>Plot No. E-22, M.I.D.C., Tarapur , Palghar, Maharashtra INDIA   | Date Published : 03/23/2015 |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 03/23/2015  |
| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)  | Date Published: 03/23/2015  |
| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>60 Human and Animal Drugs  | Date Published: 03/23/2015  |
| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 03/23/2015  |
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| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices | Date Published: 03/23/2015  |
| Aarti Drugs Ltd   | Date Published : 03/23/2015 |
| G-60 Boisar MIDC Tarapur , Tal. Palghar, District Thane , Tarapur, Maharashtra INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 03/23/2015  |
| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)  | Date Published: 03/23/2015  |
| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>60 Human and Animal Drugs  | Date Published: 03/23/2015  |
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| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices<br>65 Human and Animal Drugs  | Date Published: 03/23/2015  |

| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices   |  |
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| 66 Human and Animal Drugs   | Date Published: 03/23/2015   |
| Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices   |  |
| Akorn India PVT   | Date Published : 08/21/2015  |
| 5/2 5/3 Khasra 5/1 , Paonta Sahib, Himachal Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 08/21/2015   |
| Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices  |  |
| 60 Human and Animal Drugs<br>Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices   | Date Published: 08/21/2015   |
| 61 Human and Animal Drugs   | Date Published: 08/21/2015   |
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| 63 Human and Animal Drugs<br>Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices   | Date Published: 08/21/2015   |
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| 66 Human and Animal Drugs   | Date Published: 08/21/2015   |
| Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices  |  |
| Amsal Chem Pvt. Ltd.<br>A-1/401-402-403, GIDC , Ankleshwar, Gujarat, INDIA  | Date Published : 04/11/2013  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 04/11/2013   |
| 56 Antibiotics (Human/Animal)   | Date Published: 04/11/2013   |
| 60 Human and Animal Drugs   | Date Published: 04/11/2013   |
| 61 Human and Animal Drugs   | Date Published: 04/11/2013   |
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| 65 Human and Animal Drugs   | Date Published: 04/11/2013   |
| 66 Human and Animal Drugs   | Date Published: 04/11/2013   |
| Apotex Research Private Limited   | Date Published : 04/12/2018  |
| Plots 1 and 2, Bommasandra Ind. Area , Jigani Link Rd; 4th Phase , Bangalore, Karnataka INDIA   |  |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 04/12/2018   |
|   |  |
| 56 Antibiotics (Human/Animal)   | Data Dublishadi 01/10/2010   |
| Natas, All Antibiotics, Decklow(s), (CMD) Coord Manufacturing Department  | Date Published: 04/12/2018   |
| Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices  |  |
| 60 Human and Animal Drugs   | Date Published: 04/12/2018<br>Date Published: 04/12/2018   |
| 60 Human and Animal Drugs<br>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 04/12/2018   |
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| <ul> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs; These products are excluded from DWPE: Riluzole tablets (62J[][]16) and Abacavir tablets shortage concerns.</li> </ul>  | Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>s (62V[][]17) due to potential drug  |
| <ul> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs; These products are excluded from DWPE: Riluzole tablets (62J[][16) and Abacavir tablets</li> </ul>  | Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018   |
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| <ul> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs; These products are excluded from DWPE: Riluzole tablets (62J[[[16]) and Abacavir tablets</li> <li>shortage concerns.</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> </ul>  | Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>(62V[]]17) due to potential drug<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018                         |
| <ul> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs; These products are excluded from DWPE: Riluzole tablets (62J[[]16) and Abacavir tablets</li> <li>shortage concerns.</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>68 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>69 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (Figure Bood Manufactu</li></ul> | Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>(62V[]]17) due to potential drug<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018<br>Date Published: 04/12/2018                         |
| <ul> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs; These products are excluded from DWPE: Riluzole tablets (62J[][16) and Abacavir tablets</li> <li>shortage concerns.</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>68 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> </ul>   | Date Published: 04/12/2018<br>Date Published: 04/12/2018 |

| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs  | Date Published: 12/19/2016                               |
|---|--|
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 12/19/2016                               |
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 12/19/2016                               |
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 12/19/2016                               |
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs  | Date Published: 12/19/2016                               |
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs  | Date Published: 12/19/2016                               |
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 12/19/2016                               |
| Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices   |  |
| Canton Laboratories Pvt. Ltd.   | Date Published : 04/10/2014                              |
| 110 A & B Gidc Estate , Makarpura Road , Vadodara, Gujarat INDIA<br><i>54 B</i> Mineral   | Date Published: 04/10/2014                               |
| Desc: All Drugs and Drug Products   |  |
| Notes: Problem(s) (GMP) Good Manufacturing Practices<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 04/10/2014                               |
| Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;  | Data Dubliahadi 01/10/2011                               |
| 60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;   | Date Published: 04/10/2014                               |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;   | Date Published: 04/10/2014                               |
| 62 Human and Animal Drugs   | Date Published: 04/10/2014                               |
| Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;<br>63 Human and Animal Drugs   | Date Published: 04/10/2014                               |
| Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs   | Date Published: 04/10/2014                               |
| Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;<br>65 Human and Animal Drugs   | Date Published: 04/10/2014                               |
| Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;  |  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products Problem(s) (GMP) Good Manufacturing Practices ;   | Date Published: 04/10/2014                               |
| Emcure Pharmaceuticals Limited  | Date Published : 07/13/2015                              |
| Plot No. P-1 & P-2 , It-Bt Park Phase Ii, Midc, Hinjwadi , Hinjwadi, Pune, Maharashtra INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 07/13/2015                               |
| Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices   | Date i ublished. 07/13/2013                              |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are exclude   | Date Published: 07/13/2015<br>d from dwpe: Amikacin inj, |
| antibiotic / 56D[][]06  |  |
| 60 Human and Animal Drugs<br>Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/13/2015                               |
| 61 Human and Animal Drugs<br>Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are exclude   | Date Published: 07/13/2015                               |
| Antiemetic (for nausea/vomiting)/61T[][]26 Prochlorperazine inj, Antiemetic (for nausea/vomiting)/ 61T[][]14 Me   |  |
| and antiemetic / 61T[][]12<br>62 Human and Animal Drugs   | Date Published: 07/13/2015                               |
| Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluder treats/prevents osteoporosis / 62A[][]05 Cidofovir inj, treats eye infection in HIV patients / 62V[][]21 Carmustine |  |
| 62V[][]24   |  |
| 63 Human and Animal Drugs<br>Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/13/2015                               |
| 64 Human and Animal Drugs<br>Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices  | Date Published: 07/13/2015                               |
| 65 Human and Animal Drugs   | Date Published: 07/13/2015                               |
| Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 07/13/2015                               |
|   |  |

Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Haloperidol inj, Antipsychotic / 66M[][]98

| Anupsychouc / 66MUU98  |  |
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| Fleming Laboratories Limited<br>48 Temple Rock Enclave , Tarbund Road; Plot No; Bhowanpalli , Secunderabad, Telangana INDIA  | Date Published : 04/11/2011  |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug Products  | Date Published: 04/11/2011   |
| 73 Anesthesiology<br>Notes: All Drug Products  | Date Published: 04/11/2011   |
| 74 Cardiovascular  | Date Published: 04/11/2011   |
| Notes: All Drug Products<br>76 Dental  | Date Published: 04/11/2011   |
| Notes: All Drug Products<br>77 Ear,Nose And Throat   | Date Published: 04/11/2011   |
| Notes: All Drug Products<br>78 Gastroenterological & Urological  | Date Published: 04/11/2011   |
| Notes: All Drug Products<br>79 General & Plastic Surgery   | Date Published: 04/11/2011   |
| Notes: All Drug Products<br>80 General Hospital/Personal Use   | Date Published: 04/11/2011   |
| Notes: All Drug Products   |  |
| 84 Neurological<br>Notes: All Drug Products  | Date Published: 04/11/2011   |
| 85 Obstetrical & Gynecological<br>Notes: All Drug Products   | Date Published: 04/11/2011   |
| 86 Ophthalmic<br>Notes: All Drug Products  | Date Published: 04/11/2011   |
| 87 Orthopedic<br>Notes: All Drug Products  | Date Published: 04/11/2011   |
| 89 Physical Medicine   | Date Published: 04/11/2011   |
| Notes: All Drug Products<br>90 Radiological  | Date Published: 04/11/2011   |
| Notes: All Drug Products   |  |
|  |  |
| Fleming Laboratories Ltd.<br>Survey No. 270, Kanukunta Road, Nawabpet Village, Medak District, Hyderabad, Telangana Pradesh INDIA.   | Date Published : 10/20/2017  |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published : 10/20/2017<br>Date Published: 10/20/2017  |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)  |  |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs  | Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctrr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctrr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs  | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017<br>Date Published: 10/20/2017   |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug A Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug A Drug Products<br>65 Human A Anima | Date Published: 10/20/2017<br>Date Published: 10/20/2017                               |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67   | Date Published: 10/20/2017<br>Date Published: 10/20/2017                               |
| Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>60 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>61 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>67   | Date Published: 10/20/2017<br>Date Published: 10/20/2017 |

| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs                      | Date Published: 03/05/2018  |
|---|-----------------------------|
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      | Date Published: 03/05/2018  |
| 63 Human and Animal Drugs   | Date Published: 03/05/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs                      | Date Published: 03/05/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs                      | Date Published: 03/05/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                             |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      | Date Published: 03/05/2018  |
| Health Biotech Limited  | Date Published : 04/03/2018 |
| District Solan , Nalgarh Road , Baddi, Himachal Pradesh INDIA   |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices           | Date Published: 04/03/2018  |
| 56 Antibiotics (Human/Animal)   | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs                     | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     | Date Published: 04/03/2018  |
| 62 Human and Animal Drugs   | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs                     | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices  | Date 1 ubisited. 04/03/2010 |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     | Date Published: 04/03/2018  |
| 65 Human and Animal Drugs   | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices  | Data Dubliahadi 04/02/2010  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                     | Date Published: 04/03/2018  |
| Health Biotech Limited  | Date Published : 04/03/2018 |
| S.C.O. 162-164, Indian Airlines Building, Top Floor , Sector 34-A , Chandigarh, Punjab INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date i ublished. 04/05/2010 |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                  | Date Published: 04/03/2018  |
| 60 Human and Animal Drugs   | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Data Dubliahadi 04/02/2010  |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                      | Date Published: 04/03/2018  |
| 62 Human and Animal Drugs   | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs                      | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                             |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices               | Date Published: 04/03/2018  |
| 65 Human and Animal Drugs   | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs                      | Date Published: 04/03/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   |                             |
| lpca Laboratories LTd   | Date Published : 03/24/2015 |
| 1 Pharma Zone , Pithampur, Madhya Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 03/24/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |                             |
| 60 Human and Animal Drugs   | Date Published: 03/24/2015  |

Notes: All Drugs;(GMP) Good Manufacturing Practices

| 61 Human and Animal Drugs   | Date Published: 03/24/2015   |
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| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |  |
| 64 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices  | Date Published: 03/24/2015   |
| 65 Human and Animal Drugs   | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |  |
| Ipca Laboratories Limited   | Date Published : 03/24/2015  |
| Plot No. 65 And 99, Danudyog , Ind. Estate, Piparia , Silvasa (D And Nh), INDIA   |  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 03/24/2015   |
| Notes: All Drugs;GMP) Good Manufacturing Practices;<br>60 Human and Animal Drugs  | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |  |
| 61 Human and Animal Drugs   | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   | Date Fublished. 03/24/2013   |
| 63 Human and Animal Drugs   | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices;  |  |
| 64 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices  | Date Published: 03/24/2015   |
| 65 Human and Animal Drugs   | Date Published: 03/24/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |  |
| 66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices  | Date Published: 03/24/2015   |
| Notes. All Drugs, (GMF) Good Manufacturing Fractices  |  |
|   |  |
| Ipca Laboratories Limited   | Date Published : 01/22/2015  |
| Village Sejavta , Ratlam, Madhya Pradesh INDIA  |  |
|   | Date Published : 01/22/2015<br>Date Published: 01/22/2015  |
| Village Sejavta , Ratlam, Madhya Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;<br>56 Antibiotics (Human/Animal)  |  |
| Village Sejavta , Ratlam, Madhya Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;<br>56 Antibiotics (Human/Animal)<br>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 01/22/2015<br>Date Published: 01/22/2015   |
| Village Sejavta , Ratlam, Madhya Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;<br>56 Antibiotics (Human/Animal)<br>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs  | Date Published: 01/22/2015   |
| Village Sejavta , Ratlam, Madhya Pradesh INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;<br>56 Antibiotics (Human/Animal)<br>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 01/22/2015<br>Date Published: 01/22/2015   |
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| <ul> <li>Village Sejavta , Ratlam, Madhya Pradesh INDIA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> </ul>   | Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Chloroquine Phosphate API/61A[]  |
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| <ul> <li>Village Sejavta , Ratlam, Madhya Pradesh INDIA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>68</li></ul> | Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Chloroquine Phosphate API/61A[]<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>WPE: Furosemide/64BQS24<br>Date Published: 01/22/2015   |
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| <ul> <li>Village Sejavta , Ratlam, Madhya Pradesh INDIA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices</li> <li>68</li></ul> | Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Chloroquine Phosphate API/61A[]<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>WPE: Furosemide/64BQS24<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015   |
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| <ul> <li>Village Sejavta , Ratlam, Madhya Pradesh INDIA</li> <li>55 Pharm Necess &amp; Cthr For Drug/Bio</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;This product is excluded from DWPE:</li> <li>[]06</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices;</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from D</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All drug and drug products</li> <li>54</li></ul>  | Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Chloroquine Phosphate API/61A[]<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>WPE: Furosemide/64BQS24<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2015<br>Date Published: 01/22/2013<br>Date Published: 01/22/2013 |
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| 56 Antibiotics (Human/Animal)   | Date Published: 07/10/2013  |
|---|-----------------------------|
| Notes: All drug and drug products<br>60 Human and Animal Drugs  | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| 61 Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products<br>62 Human and Animal Drugs  | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| 63 Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products<br><i>64</i> Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| 65 Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products<br>66 Human and Animal Drugs  | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| Kim Chemicals Private Ltd.  | Date Published : 08/21/2017 |
| Plot No. G-13/16, Midc, Taloja , Taloja, Raigad, Maharashtra INDIA  |                             |
| 53 Cosmetics  | Date Published: 08/21/2017  |
| Desc: All Drug and Drug Products<br>Notes: For Industry Code 53; only drug and drug products (i.e. petroleum jelly; etc.) are subject to DWPE under | r this notice               |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 08/21/2017  |
| Notes: All Drug and Drug Products   |                             |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products  | Date Published: 08/21/2017  |
| 60 Human and Animal Drugs   | Date Published: 08/21/2017  |
| Notes: All Drug and Drug Products   | Data Dublishad, 00/04/2017  |
| 61 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 08/21/2017  |
| 62 Human and Animal Drugs   | Date Published: 08/21/2017  |
| Notes: All Drug and Drug Products   | Data Dublishad, 00/04/2017  |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 08/21/2017  |
| 64 Human and Animal Drugs   | Date Published: 08/21/2017  |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs  | Date Published: 08/21/2017  |
| Notes: All Drug and Drug Products   | Date Fublished. 00/21/2017  |
| 66 Human and Animal Drugs   | Date Published: 08/21/2017  |
| Notes: All Drug and Drug Products   |                             |
| Konduskar Laboratories Pvt Ltd  | Date Published : 07/10/2013 |
| T-47 Kagel Hatkanangale Five Star, MIDC , Talandage (Village) , Tal Kagal, Maharashtra INDIA<br>50 Color Additiv Food/Drug/Cosmetic                 | Date Published: 07/10/2013  |
| Desc: All drug and drug products  |                             |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)   | Date Published: 07/10/2013  |
| Desc: All drug and drug products<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| 56 Antibiotics (Human/Animal)<br>Desc: All drug and drug products   | Date Published: 07/10/2013  |
| 60 Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| <i>61</i> Human and Animal Drugs<br>Notes: All drug and drug products   | Date Published: 07/10/2013  |
| 62 Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| 63 Human and Animal Drugs<br>Notes: All drug and drug products  | Date Published: 07/10/2013  |
| 64 Human and Animal Drugs   | Date Published: 07/10/2013  |
| Notes: All drug and drug products   |                             |
| 65 Human and Animal Drugs   | Date Published: 07/10/2013  |
|   |                             |

Notes: All drug and drug products 66 - - - - Human and Animal Drugs Notes: All drug and drug products

### **Mahendra Chemicals**

B - 1 217 218 2 G I D C Estate , Ahmedabad, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - -- Human and Animal Drugs Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Notes: All Drugs: All Antibiotics: (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices

### Malladi Drugs & Pharmaceuticals Ltd.

Plot 67, 68, Sipcot Industrial Complex, Vellore, Ranipet, Tamil Nadu INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products

### Marck Biosciences Ltd.

Plot No. 876, N.H. - 8 , Vill: Hariyala, Tal: Matar , Kheda, Gujarat INDIA 55 - - - -- Pharm Necess & Ctnr For Drug/Bio
Notes: All Drug Products
60 - - - -- Human and Animal Drugs
Notes: All Drug Products
61 - - -- Human and Animal Drugs
Notes: All Drug Products
62 - - -- Human and Animal Drugs
Notes: All Drug Products
63 - - -- Human and Animal Drugs
Notes: All Drug Products
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Notes: All Drug Products
65 - - -- Human and Animal Drugs
Notes: All Drug Products

Date Published: 07/10/2013

### Date Published : 08/25/2017

### Date Published: 08/25/2017

### Date Published : 12/13/2017

# Date Published: 12/13/2017

### Date Published : 03/12/2014

Date Published: 03/12/2014

66 - - - -- Human and Animal Drugs Notes: All Drug Products

### Megafine Pharma (P) Limited

48 - 51/201 Plot No 31 - 35 , Lakhamapur, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products

### **Nivedita Chemicals P ITd**

A14 MIDC Andheri East, Mumbai, IN-MH INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: Chlorpheniramine maleate 60 - - - -- Human and Animal Drugs Notes: Chlorpheniramine maleate 61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate 61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate 61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Desc: Pyrilamine maleate Pyrilamine maleate USP 61 X - - 99 Anti-Histaminic N.E.C. Desc: Pyrilamine maleate Pyrilamine maleate USP 61 - - - -- Human and Animal Drugs Notes: Chlorpheniramine maleate 62 - - - - Human and Animal Drugs Notes: Chlorpheniramine maleate 63 - - - -- Human and Animal Drugs Notes: Chlorpheniramine maleate 64 - - - -- Human and Animal Drugs Notes: Chlorpheniramine maleate 65 - - - - Human and Animal Drugs Notes: Chlorpheniramine maleate 66 - - - -- Human and Animal Drugs Notes: Chlorpheniramine maleate

### **Nivedita Chemicals Pvt. Ltd.** A - 14 Maharashtra , M i d C; Andheri East , Mumbai, Maharashtra INDIA 55 - - - -- Pharm Necess & Ctnr For Drug/Bio Notes: Chlorpheniramine maleate 60 - - - -- Human and Animal Drugs Notes: Chlorpheniramine maleate 61 X - 08 Chlorpheniramine Maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate 61 X - 29 Pyrilamine Maleate (Anti-Histaminic) Desc: Pyrilamine maleate Pyrilamine maleate USP 61 X - 29 Pyrilamine Maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate 01 X - 29 Pyrilamine maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate (Anti-Histaminic) Desc: Chlorpheniramine maleate 01 X - 29 Pyrilamine Maleate (Anti-Histaminic)

Date Published: 03/12/2014

### Date Published : 10/14/2015

Date Published: 10/14/2015

### Date Published : 11/23/2011

Date Published: 11/23/2011

### Date Published : 11/23/2011

Date Published: 11/23/2011

| Desc: Pyrilamine maleate Pyrilamine maleate USP   |   |
|---|---|
| <i>61</i> Human and Animal Drugs  | Date Published: 11/23/2011  |
| Notes: Chlorpheniramine maleate   |   |
| 62 Human and Animal Drugs   | Date Published: 11/23/2011  |
| Notes: Chlorpheniramine maleate<br>63 Human and Animal Drugs  | Date Published: 11/23/2011  |
| Notes: Chlorpheniramine maleate   | Date Fublished. Th/20/2011  |
| 64 Human and Animal Drugs   | Date Published: 11/23/2011  |
| Notes: Chlorpheniramine maleate   |   |
| 65 Human and Animal Drugs   | Date Published: 11/23/2011  |
| Notes: Chlorpheniramine maleate   |   |
| 66 Human and Animal Drugs   | Date Published: 11/23/2011  |
| Notes: Chlorpheniramine maleate   |   |
| Pan Drugs Limited   | Date Published : 12/08/2015   |
| 192 G I D C Makarpura Industrial Estate , M I Estate , Vadodara, Gujarat INDIA  |   |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |   |
| 56 Antibiotics (Human/Animal)   | Date Published: 12/08/2015  |
| Notes: All Antibiotics;(GMP) Good Manufacturing Practices   |   |
| 60 Human and Animal Drugs   | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   | Date Published: 12/08/2015  |
| 61 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices  | Date Published: 12/08/2015  |
| 62 Human and Animal Drugs   | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |   |
| 63 Human and Animal Drugs   | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |   |
| <i>64</i> Human and Animal Drugs  | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   |   |
| 65 Human and Animal Drugs   | Date Published: 12/08/2015  |
|   |   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   | Data Dublishadi 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices   | Date Published: 12/08/2015  |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br><b>Pan Drugs Ltd.</b>  | Date Published: 12/08/2015<br>Date Published : 05/05/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br><b>Pan Drugs Ltd.</b><br>167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA  | Date Published : 05/05/2015   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br><b>Pan Drugs Ltd.</b><br>167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio   |   |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br><b>Pan Drugs Ltd.</b><br>167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs;(GMP) Good Manufacturing Practices  | Date Published : 05/05/2015<br>Date Published: 05/05/2015   |
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| <ul> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li><b>Pan Drugs Ltd.</b></li> <li>167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Antibiotics;(GMP) Good Manufacturing Practices</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufacturing Practices</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drugs;(GMP) Good Manufactu</li></ul>                                     | Date Published : 05/05/2015<br>Date Published: 05/05/2015 |
| Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br><b>Pan Drugs Ltd.</b><br>167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Antibiotics;(GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs<br>Notes: All Drugs;(GMP) Good Manufacturing Practices<br>64  | Date Published : 05/05/2015<br>Date Published: 05/05/2015 |

Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
60 - - - -- Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
61 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
62 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
63 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
63 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
64 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
65 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
65 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
66 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
66 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices
66 - - - - Human and Animal Drugs
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices

### **RPG Life Sciences Limited**

### 25, M.I.D.C. Land, Thane-Belapur Road , Thane, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic 55 - - - - Pharm Necess & Ctnr For Drug/Bio

- 56 - -- Antibiotics (Human/Animal)
- 60 - -- Human and Animal Drugs
- 61 - -- Human and Animal Drugs
- 62 - -- Human and Animal Drugs
- 63 - -- Human and Animal Drugs
- 64 - -- Human and Animal Drugs
- 65 - -- Human and Animal Drugs
- 66 - -- Human and Animal Drugs

### **Reine Lifescience**

Plot No-5901, B H Sajjan India Limited , GIDC Industrial Estate, Dist. Bharuch , Ankleshwar, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 60 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP)

Date Published: 09/11/2015

### Date Published : 06/11/2013

Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013 Date Published: 06/11/2013

### Date Published : 06/10/2013

Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013 Date Published: 06/10/2013

### Date Published : 03/30/2018

Date Published: 03/30/2018

- Date Published: 03/30/2018
- Date Published: 03/30/2018

| Sal Pharma   | Date Published : 02/15/2017                              |
|--|--|
| 1-7-176 Bakaram , Hyderabad, Andhra Pradesh INDIA  |  |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  | Data Dublishadi 02/15/2017                               |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 02/15/2017                               |
| 60 Human and Animal Drugs  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  | Date i ublished. 02/13/2017                              |
| 61 Human and Animal Drugs  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  |  |
| 62 Human and Animal Drugs  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  |  |
| 63 Human and Animal Drugs  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  |  |
| 64 Human and Animal Drugs  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  |  |
| 65 Human and Animal Drugs  | Date Published: 02/15/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                  | Data Bublishad: 02/15/2017                               |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices     | Date Published: 02/15/2017                               |
| Notes. All Drugs and Drug Products, Problem(s). (Giver ) Good Manufacturing Practices                              |  |
| Sentiss Pharma Pvt. Ltd.   | Date Published : 06/20/2013                              |
| Village Khera Nihla , Tehsil Nalargarh , District Solan, Himachal Pradesh INDIA                                    |  |
| 50 Color Additiv Food/Drug/Cosmetic  | Date Published: 06/20/2013                               |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 06/20/2013                               |
| 56 Antibiotics (Human/Animal)  | Date Published: 06/20/2013                               |
| 60 Human and Animal Drugs  | Date Published: 06/20/2013                               |
| 61 Human and Animal Drugs  | Date Published: 06/20/2013                               |
| 62 Human and Animal Drugs  | Date Published: 06/20/2013                               |
| 63 Human and Animal Drugs<br>64 Human and Animal Drugs   | Date Published: 06/20/2013<br>Date Published: 06/20/2013 |
| 65 Human and Animal Drugs  | Date Published: 06/20/2013<br>Date Published: 06/20/2013 |
| 66 Human and Animal Drugs  | Date Published: 06/20/2013                               |
| 86 Ophthalmic  | Date Published: 06/20/2013                               |
|  | 2 4.0 1 42.00.004 00,20,2010                             |
| Smruthi Organics Limited   | Date Published : 06/03/2013                              |
| Plot No. A-27, MIDC, Chincholi , Solapur District, Maharashtra, Maharashtra State INDIA                            |  |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 06/03/2013                               |
| 60 Human and Animal Drugs  | Date Published: 06/03/2013                               |
| 61 Human and Animal Drugs  | Date Published: 06/03/2013                               |
| 62 Human and Animal Drugs<br>63 Human and Animal Drugs   | Date Published: 06/03/2013<br>Date Published: 06/03/2013 |
| 64 Human and Animal Drugs  | Date Published: 06/03/2013                               |
| 65 Human and Animal Drugs  | Date Published: 06/03/2013                               |
| 66 Human and Animal Drugs  | Date Published: 06/03/2013                               |
| <b>U</b>   |  |
| Sri Krishna Pharmaceuticals Ltd Unit II  | Date Published : 08/13/2015                              |
| A-35, Ida, Nacharam , Hyderabad, Andhra Pradesh, INDIA   |  |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 08/13/2015                               |
| Notes: All Drugs   |  |
| 60 Human and Animal Drugs  | Date Published: 08/13/2015                               |
| Notes: All Drugs<br>61 Human and Animal Drugs  | Date Published: 08/13/2015                               |
| Notes: All Drugs   | Date 1 ublished. 00/15/2015                              |
| 62 Human and Animal Drugs  | Date Published: 08/13/2015                               |
| Notes: All Drugs   |  |
| 63 Human and Animal Drugs  | Date Published: 08/13/2015                               |
| Notes: All Drugs   |  |
| 64 Human and Animal Drugs  | Date Published: 08/13/2015                               |
| Notes: All Drugs   |  |
| 65 Human and Animal Drugs  | Date Published: 08/13/2015                               |
| Notes: All Drugs;This product is excluded from dwpe: Sodium Phenylbutyrate granules/65C[][]09                      |  |
|  |  |

| 66 Human and Animal Drugs<br>Notes: All Drugs  | Date Published: 08/13/2015  |
|--|-----------------------------|
| <b>Srikem Laboratories Pvt. Ltd.</b><br>Plot No. 17/24, Midc Taloja , Navi Mumbai, Maharashtra INDIA                           | Date Published : 07/06/2016 |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices         | Date Published: 07/06/2016  |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices               | Date Published: 07/06/2016  |
| 60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| 64 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices                   | Date Published: 07/06/2016  |
| <b>Stericon Pharma Pvt. Ltd.</b><br>No. 9, Sub Layout Of Plot 9 , 1st Phase Bommasandra Ind. Area , Bangalore, Karnataka INDIA | Date Published : 01/13/2011 |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 60 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 61 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 62 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 63 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 64 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 65 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |
| 66 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 01/13/2011  |

# Sun Pharmaceutical Industries (prev. Ranbaxy)

3 Industrial Area, Dewas, Madhya Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import. 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import. 60 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import. 61 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import. 62 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import. 63 - - - -- Human and Animal Drugs Date Published: 09/10/2009

Date Published : 09/10/2009

| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle<br>DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>64 Human and Animal Drugs<br>Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle<br>DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>65 Human and Animal Drugs<br>Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle<br>DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>65 Human and Animal Drugs<br>Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle<br>DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>66 Human and Animal Drugs<br>Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle<br>DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>66 Human and Animal Drugs | Date Published: 09/10/2009<br>ovir API. Districts should contat<br>Date Published: 09/10/2009<br>ovir API. Districts should contat<br>Date Published: 09/10/2009 |
|---|--|
| Sun Pharmaceutical Industries (prev. Ranbaxy)   | Date Published : 09/10/2009  |
| Tehsil , Simour District , Paonta Sahib, Himachal Pradesh INDIA   |  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclo DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.   | ovir API. Districts should contat  |
| 56 Antibiotics (Human/Animal)   | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   |  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.   |  |
| 60 Human and Animal Drugs   | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   | ovir API. Districts should contat  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>61 Human and Animal Drugs  | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   |  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.   |  |
| 62 Human and Animal Drugs   | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   | ovir API. Districts should contat  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>63 Human and Animal Drugs  | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   |  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.   |  |
| <i>64</i> Human and Animal Drugs  | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   | ovir API. Districts should contat  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.<br>65 Human and Animal Drugs  | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   |  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.   |  |
| 66 Human and Animal Drugs   | Date Published: 09/10/2009   |
| Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Gancicle   | ovir API. Districts should contat  |
| DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.   |  |
| Sun Pharmaceutical Industries Limited - Karkhadi  | Date Published : 03/12/2014  |
| Plot No. 817/A, Village - Karkhadi , Taluka - Padra District , Vadodara, Gujarat, INDIA   |  |
| 60 Human and Animal Drugs<br>Desc: All Human Drug Products  | Date Published: 03/12/2014   |
| 61 Human and Animal Drugs   | Date Published: 03/12/2014   |
| Desc: All Human Drug Products   |  |
| 62 Human and Animal Drugs   | Date Published: 03/12/2014   |
| Desc: All Human Drug Products   |  |
| 63 Human and Animal Drugs<br>Desc: All Human Drug Products  | Date Published: 03/12/2014   |
| 64 Human and Animal Drugs   | Date Published: 03/12/2014   |
| Desc: All Human Drug Products   |  |
| 65 Human and Animal Drugs   | Date Published: 03/12/2014   |
| Desc: All Human Drug Products   | Data Dublichade 02/42/2044   |
| 66 Human and Animal Drugs<br>Desc: All Human Drug Products  | Date Published: 03/12/2014   |
| Dese. An Human Drug Froducts  |  |
| Unique Chemicals<br>Shir Mahana Canadii, Thana Balanur Baadi, Navi Mumhai, Mahanashtra INDIA  | Date Published : 06/28/2013  |

# **Unique Chemicals**

Shiv Mahape Gansoli , Thane Belapur Road , Navi Mumbai, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic

Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Notes: All drugs and drug products 61 - - - -- Human and Animal Drugs Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Notes: All drugs and drug products 64 - - - -- Human and Animal Drugs Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Notes: All drugs and drug products 66 - - - -- Human and Animal Drugs Notes: All drugs and drug products

### Vignesh Life Science Pvt Ltd

202 Sarada Residency , H - 26 , Madhura Nagar Ameerpet , Hyderabad, Tamil Nadu INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Desc: All drugs and drug products 54 - - - -- Vit/Min/Prot/Unconv Diet(Human/Animal) Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Desc: All drugs and drug products 60 - - - -- Human and Animal Drugs Notes: All drugs and drug products 61 - - - - Human and Animal Drugs Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Notes: All drugs and drug products 64 - - - - Human and Animal Drugs Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Notes: All drugs and drug products 66 - - - -- Human and Animal Drugs Notes: All drugs and drug products

# Vignesh Life Sciences Pvt., Ltd.

93 & 94 P Mundargi Industrial Estate , Bellary Karnataka, INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Desc: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Notes: All drugs and drug products 61 - - - -- Human and Animal Drugs Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Notes: All drugs and drug products 63 - - - - Human and Animal Drugs

Date Published: 06/28/2013

### Date Published : 06/28/2013

Date Published: 06/28/2013

Date Published: 06/28/2013 Date Published: 06/28/2013

Date Published: 06/28/2013

Date Published: 06/28/2013

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Date Published: 06/28/2013

Date Published: 06/28/2013

Date Published: 06/28/2013

### Date Published : 06/28/2013

Date Published: 06/28/2013

| Notes: All drugs and drug products  |                             |
|---|-----------------------------|
| 64 Human and Animal Drugs   | Date Published: 06/28/2013  |
| Notes: All drugs and drug products  |                             |
| 65 Human and Animal Drugs   | Date Published: 06/28/2013  |
| Notes: All drugs and drug products  |                             |
| 66 Human and Animal Drugs   | Date Published: 06/28/2013  |
| Notes: All drugs and drug products  |                             |
| Vikshara Trading & Investments Ltd.   | Date Published : 02/08/2017 |
| Odhav Road , Ahmedabad, Gujarat INDIA   |                             |
| 53 Cosmetics  | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to D |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;.<br>56 Antibiotics (Human/Animal)                                  | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;  | Date 1 ublished: 02/00/2017 |
| 60 Human and Animal Drugs   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;  |                             |
| 61 Human and Animal Drugs   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;  |                             |
| 62 Human and Animal Drugs   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;<br>63 Human and Animal Drugs                                       | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;  | Date Fublished: 02/06/2017  |
| 64 Human and Animal Drugs   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;  |                             |
| 65 Human and Animal Drugs   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;.   |                             |
| 66 Human and Animal Drugs   | Date Published: 02/08/2017  |
| Notes: All Drug and Drug Products;  |                             |
| Wockhardt Limited   | Date Published : 05/22/2013 |
| H - 14/2 Plot , Biotech Park , Karodi, Maharashtra INDIA  |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products;<br>56 Antibiotics (Human/Animal)                                  | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products;   | Date 1 ublished. 03/22/2013 |
| 60 Human and Animal Drugs   | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products;   |                             |
| <i>61</i> Human and Animal Drugs  | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products;   |                             |
| 62 Human and Animal Drugs   | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products Except Enalapril Maleate (62O[[[]28)<br>63 Human and Animal Drugs  | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products;   | Date Fublished. 00/22/2010  |
| 64 Human and Animal Drugs   | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products  |                             |
| 65 Human and Animal Drugs   | Date Published: 05/22/2013  |
| Notes: All Drugs and drug products  | Data Dubliahadi 05/22/2042  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and drug products;                                      | Date Published: 05/22/2013  |
|   |                             |
| Wockhardt Limited   | Date Published : 11/26/2013 |
| L-1, MIDC Area, Jalgaon Road 43 , Chikalthana , Aurangabad, Maharashtra INDIA                         |                             |
| <i>50</i> Color Additiv Food/Drug/Cosmetic<br>Desc: All Drug and Drug Products                        | Date Published: 09/28/2016  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 11/26/2013  |
| Notes: All Drug and Drug Products   |                             |
| 56 Antibiotics (Human/Animal)   | Date Published: 09/28/2016  |
| Desc: All Drug and Drug Products  |                             |
| 60 Human and Animal Drugs   | Date Published: 11/26/2013  |
| Notes: All Drug and Drug Products   |                             |
|   |                             |

| 61 Human and Animal Drugs   | Date Published: 11/26/2013                             |
|---|--|
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs<br>Notes: All Drug and Drug Products; * Notes: These products are excluded from DWPE: Enalapril Maleate (Ant<br>(62OCA28, 62OCS28) | Date Published: 11/26/2013<br>ihypertensive - part II) |
| 63 Human and Animal Drugs   | Date Published: 11/26/2013                             |
| Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 11/26/2013                             |
| 65 Human and Animal Drugs   | Date Published: 11/26/2013                             |
| Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 11/26/2013                             |
| Wockhardt, Ltd.   | Date Published : 08/05/2016                            |
| Plot 138 GIDC Industrial , Bulk Drug Division, Dist. Bharuch , Ankleshwar, INDIA<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products                                      | Date Published: 08/05/2016                             |
| 56 Antibiotics (Human/Animal)   | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products;<br>60 Human and Animal Drugs   | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products<br>61 Human and Animal Drugs  | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs  | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products<br>63 Human and Animal Drugs  | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products<br>64 Human and Animal Drugs  | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs  | Date Published: 08/05/2016                             |
| Notes: All Drug and Drug Products<br>66 Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 08/05/2016                             |
| Yag Mag Labs Private Limited  | Date Published : 09/13/2011                            |
| Survey No. 10, Gaddapotharam Village , Jinnaram Mandal , Medak District, Telangana INDIA<br>60 L -  -  69 Tramadol HCI (Analgesic)<br>Desc: Tramadol HCI (Analgesic)                              | Date Published: 09/13/2011                             |
| 60 L 99 Analgesic, N.E.C.   | Date Published: 09/13/2011                             |
| Desc: Tramadol HCI (Analgesic)<br><i>64 H 02</i> Guaifenesin (Expectorant)<br>Desc: Guaifensein (Expectorant)   | Date Published: 09/13/2011                             |

# IRELAND

| Europharma Concepts Limited<br>Kilbeggan Road, Clara , Tullamore, County Offaly IRELAND                            | Date Published : 02/22/2018 |
|--|-----------------------------|
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 02/22/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal) | Date Published: 02/22/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs     | Date Published: 02/22/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs     | Date Published: 02/22/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs     | Date Published: 02/22/2018  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 63 Human and Animal Drugs        | Date Published: 02/22/2018  |

| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                            |
|--|----------------------------|
| 64 Human and Animal Drugs  | Date Published: 02/22/2018 |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                            |
| 65 Human and Animal Drugs  | Date Published: 02/22/2018 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                            |
| 66 Human and Animal Drugs  | Date Published: 02/22/2018 |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices |                            |
|  |                            |

# ITALY

| BBCOS srl  | Date Published : 11/27/2017  |
|--|--|
| Via Del Lavoro 37 , Cherasco, Cuneo ITALY  |  |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products   | Date Published: 11/27/2017   |
| 56 Antibiotics (Human/Animal)  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  | Date Fublished. 11/27/2017   |
| 60 Human and Animal Drugs  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  |  |
| 61 Human and Animal Drugs  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  |  |
| 62 Human and Animal Drugs  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  |  |
| 63 Human and Animal Drugs  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products<br>64 Human and Animal Drugs   | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  | Date Fublished. 11/21/2017   |
| 65 Human and Animal Drugs  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  |  |
| 66 Human and Animal Drugs  | Date Published: 11/27/2017   |
| Notes: All Drug and Drug Products  |  |
|  |  |
| Topchem SRL  | Date Published : 09/10/2009  |
| Viale Andrea Doria 17 , Milano, MI ITALY   |  |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published : 09/10/2009<br>Date Published: 09/10/2009  |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992  | Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)   |  |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992   | Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs  | Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992   | Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992   | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs  | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992  | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs   | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992  | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009                               |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>64 Human and Animal Drugs  | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009   |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>64 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992   | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009                               |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>64 Human and Animal Drugs  | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009 |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>64 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>64 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>65 Human and Animal Drugs                                   | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009 |
| Viale Andrea Doria 17 , Milano, MI ITALY<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All bulk drugs 8/4/1992<br>56 Antibiotics (Human/Animal)<br>Notes: All bulk drugs 8/4/1992<br>60 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>61 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>62 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>63 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>64 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>65 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992<br>65 Human and Animal Drugs<br>Notes: All bulk drugs 8/4/1992 | Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009<br>Date Published: 09/10/2009 |

JAMAICA

# P.A. Benjamin Manufacturing Company Limited 95-97 East Street , Kingston, JM-01 JAMAICA

Date Published : 08/29/2012

55 - - - - Pharm Necess & Ctnr For Drug/Bio

- 60 - -- Human and Animal Drugs
- 61 - -- Human and Animal Drugs
- 62 - -- Human and Animal Drugs
- 63 - -- Human and Animal Drugs
- 64 - -- Human and Animal Drugs
- 65 - -- Human and Animal Drugs
- 66 - -- Human and Animal Drugs

JAPAN

Asada Milling Co., Ltd. Date Published : 02/13/2013 253 Obata Kanra-machi, Kanra-gun, Gunma-ken JAPAN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/13/2013 Notes: All Drugs Products 60 - - - -- Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 61 - - - -- Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 62 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 63 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 64 - - - -- Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 65 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 66 - - - -- Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products Date Published : 10/25/2017 Daito Kasei Kogyo Co Ltd 441, Kidani, Bizen, Okayama JAPAN 53 - - - - Cosmetics Date Published: 10/25/2017 Desc: Cosmetics Notes: Problem(s); (GMP) Good Manufacturing Practices; For Industry Code 53; only drug and drug products are subject to DWPE under this notice 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 60 - - - -- Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices Kanebo Cosmetics Inc. Date Published : 05/06/2013 Odawara-shi Kanagawa 28, Kotobuki-Cho, Odawara, Kanagawa JAPAN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/06/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 05/06/2013

Date Published: 08/29/2012

60 - - - -- Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - -- Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - -- Human and Animal Drugs

Date Published: 05/06/2013 Date Published: 05/06/2013

# 65 - - - -- Human and Animal Drugs 66 - - - -- Human and Animal Drugs

# KOREA, REPUBLIC OF (SOUTH)

| Amaros Co., Ltd   | Date Published : 08/23/2017                              |
|---|--|
| 560 Dunchondae-Ro; Jungwon , Seongnam, Gyeonggi KOREA, REPUBLIC OF (SOUTH)<br>53 Cosmetics  | Date Published: 08/23/2017                               |
| Desc: All Drug and Drug Products  |  |
| Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.   |  |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   |  |
| 56 Antibiotics (Human/Animal)   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs  | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   |  |
| 61 Human and Animal Drugs   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   |  |
| 62 Human and Animal Drugs   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   | D-t- D-t-1-t-t-00/00/0047                                |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 08/23/2017                               |
| 64 Human and Animal Drugs   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   |  |
| 65 Human and Animal Drugs   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   |  |
| 66 Human and Animal Drugs   | Date Published: 08/23/2017                               |
| Notes: All Drug and Drug Products   |  |
| Cosmecca Korea Co., Ltd.  | Date Published : 01/08/2018                              |
| 17-12 Daegeumro196beon-Gil, Daeso-Myeon, Eumseong-Gun, Cungceongbug-do KOREA, REPUBLIC C  | OF (SOUTH)   |
| 53 Cosmetics  | Date Published: 01/08/2018                               |
| Desc: All Drug and Drug Products  |  |
| Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.   | Data Dubliahad. 01/00/2010                               |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products  | Date Published: 01/08/2018                               |
| 56 Antibiotics (Human/Animal)   | Date Published: 01/08/2018                               |
| Notes: All Drug and Drug Products   |  |
| 60 Human and Animal Drugs   | Date Published: 01/08/2018                               |
| Notes: All Drug and Drug Products   |  |
| 61 Human and Animal Drugs   | Date Published: 01/08/2018                               |
| Notes: All Drug and Drug Products   |  |
| 62 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 01/08/2018                               |
| NOIES. AILDIUG AUG DIUG FIGUUGIS  |  |
| • •   | Date Published: 01/08/2018                               |
| 63 Human and Animal Drugs   | Date Published: 01/08/2018                               |
| 63 Human and Animal Drugs   | Date Published: 01/08/2018<br>Date Published: 01/08/2018 |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products  |  |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs   |  |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>64 Human and Animal Drugs<br>Notes: All Drug and Drug Products<br>65 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 01/08/2018<br>Date Published: 01/08/2018 |
| <ul> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> </ul> | Date Published: 01/08/2018                               |
| <ul> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> </ul> | Date Published: 01/08/2018<br>Date Published: 01/08/2018 |
| <ul> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> </ul>                                    | Date Published: 01/08/2018<br>Date Published: 01/08/2018 |

| Seobuk-Gu , 47 Handeul 1-ro , Seobuk-gu, Cheonan-si, Chungcheongnam-do KOREA, REPUBLIC OF            |                             |
|--|-----------------------------|
| 53 Cosmetics   | Date Published: 05/11/2017  |
| Desc: All Drug and Drug Products   |                             |
| Notes: For Industry Codes 53 & 77; only drug and drug products are subject to DWPE under this notice | e.                          |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  |                             |
| 60 Human and Animal Drugs  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products<br><i>61</i> Human and Animal Drugs                                | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  | Date Fublished: 03/11/2017  |
| 62 Human and Animal Drugs  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  |                             |
| 63 Human and Animal Drugs  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  |                             |
| 64 Human and Animal Drugs  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  |                             |
| 65 Human and Animal Drugs  | Date Published: 05/11/2017  |
| Notes: All Drug and Drug Products  |                             |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products                                       | Date Published: 05/11/2017  |
| 77 Ear,Nose And Throat   | Date Published: 05/11/2017  |
| Desc: All Drug and Drug Products   | Date Fublished: 03/11/2017  |
| Notes: For Industry Codes 53 & 77; only drug and drug products are subject to DWPE under this notice | e.                          |
|  |                             |
| Hanbul Cosmetics Co., Ltd  | Date Published : 03/08/2018 |
| 62 Daeseongro547beon-Gil, Samseong-myeon, Eumseong-gun, Cungceongbug-do KOREA, REPUB                 | , ,                         |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 |                             |
| 56 Antibiotics (Human/Animal)  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs    | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 | Date Published. 05/06/2016  |
| 61 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 |                             |
| 62 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 |                             |
| 63 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 |                             |
| 64 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 |                             |
| 65 Human and Animal Drugs  | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs    | Date Published: 03/08/2018  |
| Notes: All Drug and Drug Products;(GMP) Good Manufacturing Practices                                 | Date Published. 03/06/2016  |
|  |                             |
| K J I Industrial Co., Ltd.   | Date Published : 09/04/2013 |
| 29 Gyeseok-ro, Dong-myeon , Yangsan-si, Gyeongsangnam-do, KOREA, REPUBLIC OF (SOUTH)                 |                             |
| 53 Cosmetics   | Date Published: 09/04/2013  |
| Desc: All drugs and drug products  |                             |
| 54 Vit/Min/Prot/Unconv Diet(Human/Animal)  | Date Published: 09/04/2013  |
| Desc: All drugs and drug products<br><i>55</i> Pharm Necess & Ctnr For Drug/Bio                      | Date Published: 09/04/2013  |
| Notes: All drugs and drug products   |                             |
| 60 Human and Animal Drugs  | Date Published: 09/04/2013  |
| Notes: All drugs and drug products   |                             |
| 61 Human and Animal Drugs  | Date Published: 09/04/2013  |
| Notes: All drugs and drug products   |                             |
| 62 Human and Animal Drugs  | Date Published: 09/04/2013  |
| Notes: All drugs and drug products   |                             |
| 63 Human and Animal Drugs  | Date Published: 09/04/2013  |
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| Notes: All drugs and drug products<br>64 Human and Animal Drugs  | Date Published: 09/04/2013   |
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| Notes: All drugs and drug products   | Date Fublished: 03/04/2013   |
| 65 Human and Animal Drugs  | Date Published: 09/04/2013   |
| Notes: All drugs and drug products   |  |
| 66 Human and Animal Drugs  | Date Published: 09/04/2013   |
| Notes: All drugs and drug products<br>80 General Hospital/Personal Use   | Date Published: 09/06/2013   |
| Desc: All Drugs and Drug Products  | Date i ublished. 03/00/2013  |
| 81 Hematology  | Date Published: 09/04/2013   |
| Desc: All drugs and drug products  |  |
| 89 Physical Medicine   | Date Published: 09/04/2013   |
| Desc: All drugs and drug products  |  |
| LG Chem, Ltd.  | Date Published : 05/06/2013  |
| 129 Seogam-Ro , Igsan-Si, Jeonrabug-do KOREA, REPUBLIC OF (SOUTH)  |  |
| 50 Color Additiv Food/Drug/Cosmetic<br>53 Cosmetics  | Date Published: 05/06/2013   |
| 55 Cosmetics<br>55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 05/06/2013<br>Date Published: 05/06/2013   |
| 56 Antibiotics (Human/Animal)  | Date Published: 05/06/2013   |
| 60 Human and Animal Drugs  | Date Published: 05/06/2013   |
| 61 Human and Animal Drugs  | Date Published: 05/06/2013   |
| 62 Human and Animal Drugs  | Date Published: 05/06/2013   |
| 63 Human and Animal Drugs<br>64 Human and Animal Drugs   | Date Published: 05/06/2013<br>Date Published: 05/06/2013   |
| 65 Human and Animal Drugs  | Date Published: 05/06/2013   |
| 66 Human and Animal Drugs  | Date Published: 05/06/2013   |
| 80 General Hospital/Personal Use   | Date Published: 05/06/2013   |
| Nowcos Co Ltd  | Date Published : 12/27/2017  |
| 53714 Segyo Dong , Pyeongtaek, KOREA, REPUBLIC OF (SOUTH)  |  |
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| 50 Color Additiv Food/Drug/Cosmetic  | Date Published: 12/27/2017   |
| 50 Color Additiv Food/Drug/Cosmetic<br>Desc: All Drug and Drug Products  | Date Published: 12/27/2017   |
| 50 Color Additiv Food/Drug/Cosmetic<br>Desc: All Drug and Drug Products<br>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.   |  |
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| <ul> <li>50 Color Additiv Food/Drug/Cosmetic</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>53 Cosmetics</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>68 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>69 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61</li></ul>   | Date Published: 12/27/2017<br>Date Published: 12/27/2017 |
| <ul> <li>50 Color Additiv Food/Drug/Cosmetic</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>53 Cosmetics</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>68 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>69 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Produc</li></ul>   | Date Published: 12/27/2017<br>Date Published: 12/27/2017                               |
| <ul> <li>50 Color Additiv Food/Drug/Cosmetic</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>53 Cosmetics</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products</li> <li>S6 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>76 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>76 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>76 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>76</li></ul>   | Date Published: 12/27/2017<br>Date Published: 12/27/2017 |
| <ul> <li>50 Color Additiv Food/Drug/Cosmetic</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>53 Cosmetics</li> <li>Desc: All Drug and Drug Products</li> <li>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.</li> <li>55 Pharm Necess &amp; Ctnr For Drug/Bio</li> <li>Notes: All Drug and Drug Products</li> <li>56 Antibiotics (Human/Animal)</li> <li>Notes: All Drug and Drug Products</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>62 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>63 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>64 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>65 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>66 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>67 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>68 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>69 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>60 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Products</li> <li>61 Human and Animal Drugs</li> <li>Notes: All Drug and Drug Produc</li></ul>   | Date Published: 12/27/2017<br>Date Published: 12/27/2017 |

| Desc: All Drug and Drug Products  |                             |
|---|-----------------------------|
| Notes: For Industry Codes 50 and 53, only drug and drug products are subject to DWPE under this notice.                                     | Data Dubliahadu 19/97/9017  |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 56 Antibiotics (Human/Animal)   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/27/2017  |
| 62 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>63 Human and Animal Drugs  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 64 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 65 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>66 Human and Animal Drugs  | Data Dubliahadu 12/27/2017  |
| Notes: All Drug and Drug Products   | Date Published: 12/27/2017  |
| Nowcos Co., Ltd   | Date Published : 12/27/2017 |
| 339-853 Jeon Ui Local Industrial Zo0sin , Yeon Gi-gun Chung Nam, KOREA, REPUBLIC OF (SOUTH)   |                             |
| 50 Color Additiv Food/Drug/Cosmetic<br>Desc: All Drug and Drug Products   | Date Published: 12/27/2017  |
| Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.                                     |                             |
| 53 Cosmetics<br>Desc: All Drug and Drug Products  | Date Published: 12/27/2017  |
| Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.                                     |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 56 Antibiotics (Human/Animal)   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 61 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 64 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| Nowcos Co., Ltd.  | Date Published : 12/27/2017 |
| 37 Ayamok-gil , Sojeong-myeon , Sejong, KOREA, REPUBLIC OF (SOUTH)  | Date Published . 12/2//2017 |
| 50 Color Additiv Food/Drug/Cosmetic   | Date Published: 12/27/2017  |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. |                             |
| 53 Cosmetics  | Date Published: 12/27/2017  |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 60 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
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| <i>61</i> Human and Animal Drugs  | Date Published: 12/27/2017  |
|---|-----------------------------|
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs  | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 64 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 65 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 66 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| Nowcos Nots   | Date Published : 12/27/2017 |
| 371-17 Byc Highway , Seoul, KOREA, REPUBLIC OF (SOUTH)  |                             |
| <i>50</i> Color Additiv Food/Drug/Cosmetic<br>Desc: All Drug and Drug Products  | Date Published: 12/27/2017  |
| Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notic                                     | ce.                         |
| 53 Cosmetics  | Date Published: 12/27/2017  |
| Desc: All Drug and Drug Products<br>Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notic |                             |
| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 60 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products   | Date Published: 12/27/2017  |
| 62 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 64 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| 65 Human and Animal Drugs<br>Notes: All Drug and Drug Products  | Date Published: 12/27/2017  |
| 66 Human and Animal Drugs   | Date Published: 12/27/2017  |
| Notes: All Drug and Drug Products   |                             |
| Seindni Co., Ltd.   | Date Published : 08/23/2017 |
| Seongbuk-gu , 610-304 16, Gireum-ro , Seoul, KOREA, REPUBLIC OF (SOUTH)   | Data Dubliahadi 00/22/2017  |
| 55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices                             | Date Published: 08/23/2017  |
| 56 Antibiotics (Human/Animal)   | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs                                       | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices  | Date Fublished. 00/25/2017  |
| 61 Human and Animal Drugs   | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs                                       | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices  | Date Fublished. 00/25/2017  |
| 63 Human and Animal Drugs   | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices<br><i>64</i> Human and Animal Drugs                                | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices  |                             |
| 65 Human and Animal Drugs   | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs                                       | Date Published: 08/23/2017  |
| Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices  |                             |
|   |                             |

# MEXICO

| Farma Quimia S.A. de C.V.  | Date Published : 02/23/2012 |
|--|-----------------------------|
| Av Andre Marie Ampere No 11, Parque Industrial Cuamatla, Cuautitlan Izcalli, Mex MEXICO<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug Products | Date Published: 02/23/2012  |
| 56 Antibiotics (Human/Animal)  | Date Published: 02/23/2012  |
| Notes: All Drug Products<br>60 Human and Animal Drugs  | Date Published: 02/23/2012  |
| Notes: All Drug Products<br>61 Human and Animal Drugs  | Date Published: 02/23/2012  |
| Notes: All Drug Products<br>62 Human and Animal Drugs  | Date Published: 02/23/2012  |
| Notes: All Drug Products<br>63 Human and Animal Drugs  | Date Published: 02/23/2012  |
| Notes: All Drug Products   |                             |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 02/23/2012  |
| 65 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 02/23/2012  |
| 66 Human and Animal Drugs<br>Notes: All Drug Products  | Date Published: 02/23/2012  |
| PROSANA DISTRIBUCIONES SA DE CV  | Date Published : 07/12/2017 |
| Calle Oriente 225 97-1, Col. Agricola Oriental, Iztacalco, Ciudad De Mexico, Ciudad de Mexico MEXICO<br>55 Pharm Necess & Ctnr For Drug/Bio                | Date Published: 07/12/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)   | Date Published: 07/12/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>60 Human and Animal Drugs   | Date Published: 07/12/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs   | Date Published: 07/12/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs   | Date Published: 07/12/2017  |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  |                             |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 07/12/2017  |
| <i>64</i> Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices                                      | Date Published: 07/12/2017  |
| 65 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 07/12/2017  |
| 66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 07/12/2017  |
| Prosintesis S.A. de C.V.   | Date Published : 06/17/2015 |
| Avenida Educacion S/N , Jilotzingo , Pueblo Santa Maria Mazatla, Mexico MEXICO<br>55 Pharm Necess & Ctnr For Drug/Bio                                      | Date Published: 06/17/2015  |
| Notes: Problems: (GMP) Good Manufacturing Practices  |                             |
| 56 Antibiotics (Human/Animal)<br>Notes: Problems: (GMP) Good Manufacturing Practices   | Date Published: 06/17/2015  |
| <i>60</i> Human and Animal Drugs<br>Notes: Problems: (GMP) Good Manufacturing Practices  | Date Published: 06/17/2015  |
| 61 Human and Animal Drugs<br>Notes: Problems: (GMP) Good Manufacturing Practices   | Date Published: 06/17/2015  |
| 62 Human and Animal Drugs  | Date Published: 06/17/2015  |
| Notes: Problems: (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs   | Date Published: 06/17/2015  |
| Notes: Problems: (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs   | Date Published: 06/17/2015  |
| Notes: Problems: (GMP) Good Manufacturing Practices  |                             |

65 - - - -- Human and Animal Drugs Notes: Problems: (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Notes: Problems: (GMP) Good Manufacturing Practices Date Published: 06/17/2015

Date Published: 06/17/2015

# NEW ZEALAND

| Jaychem Industries Ltd  | Date Published : 12/22/2014    |
|---|--------------------------------|
| 3 Kordel Place , East Tamaki , Auckland, NEW ZEALAND<br>55 Pharm Necess & Ctnr For Drug/Bio | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products   | Dato i abilolitoa: 12,22,201 i |
| 56 Antibiotics (Human/Animal)   | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs                              | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products   |                                |
| <i>61</i> Human and Animal Drugs<br>Notes: All Drug and Drug Products                       | Date Published: 12/22/2014     |
| 62 Human and Animal Drugs   | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products   |                                |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products                              | Date Published: 12/22/2014     |
| 64 Human and Animal Drugs   | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products<br>65 Human and Animal Drugs                              | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products   | Date Fublished. 12/22/2014     |
| 66 Human and Animal Drugs   | Date Published: 12/22/2014     |
| Notes: All Drug and Drug Products   |                                |

# SINGAPORE

| Licht Far East (S) Pte Ltd  | Date Published : 03/28/2014 |
|---|-----------------------------|
| 2 Woodlands Sector 1 , #05-04 , Singapore, SINGAPORE<br>55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices | Date Published: 03/28/2014  |
| 60 Human and Animal Drugs   | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>61 Human and Animal Drugs  | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>62 Human and Animal Drugs  | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>63 Human and Animal Drugs  | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>64 Human and Animal Drugs  | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>65 Human and Animal Drugs  | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs  | Date Published: 03/28/2014  |
| Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices   |                             |

## SOUTH AFRICA

# **Clover Production**

| 200 Constantia Drive , Weltevreden Park , johannesburg, ZA-GT SOUTH AFRICA<br>55 Pharm Necess & Ctnr For Drug/Bio | Date Published: 09/17/2010 |
|---|----------------------------|
| Notes: All sterile drug products<br>56 Antibiotics (Human/Animal)   | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br>60 Human and Animal Drugs   | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br><i>61</i> Human and Animal Drugs  | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br>62 Human and Animal Drugs   | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br>63 Human and Animal Drugs   | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br>64 Human and Animal Drugs   | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br>65 Human and Animal Drugs   | Date Published: 09/17/2010 |
| Notes: All sterile drug products<br>66 Human and Animal Drugs   | Date Published: 09/17/2010 |
| Notes: All sterile drug products  |                            |

SPAIN

| Casmara Cosmetics, S.A.  | Date Published : 10/12/2017          |
|--|--------------------------------------|
| No. 29 y 31 , Calle Ciudad de Liria , Paterna, Valencia SPAIN  |                                      |
| 53 Cosmetics   | Date Published: 10/18/2017           |
| Desc: Cosmetics  |                                      |
| Notes: Problem(s); (GMP) Good Manufacturing Practices; For Industry Code 53; only drug and drug pro-<br>notice | ducts are subject to DWPE under this |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 56 Antibiotics (Human/Animal)  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 60 Human and Animal Drugs  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| <i>61</i> Human and Animal Drugs   | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 62 Human and Animal Drugs  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 63 Human and Animal Drugs  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 64 Human and Animal Drugs  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 65 Human and Animal Drugs  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| 66 Human and Animal Drugs  | Date Published: 10/12/2017           |
| Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices                             |                                      |
| Dysers S.A.L.  | Date Published : 09/10/2009          |
| Depositos 12, Segovia, SPAIN   |                                      |
| 55 Pharm Necess & Ctnr For Drug/Bio  | Date Published: 09/10/2009           |
| Notes: Non-sterile bulk drug products 5/1/1992   |                                      |
| 56 Antibiotics (Human/Animal)  | Date Published: 09/10/2009           |
| Notes: Non-sterile bulk drug products 5/1/1992   | Date Published: 09/10/2009           |
| 60 Human and Animal Drugs  | Date Published. 09/10/2009           |
| Notes: Non-sterile bulk drug products 5/1/1992<br>61 Human and Animal Drugs                                    | Date Published: 09/10/2009           |
| Notes: Non-sterile bulk drug products 5/1/1992   | Date Fublished. 03/10/2009           |
| 62 Human and Animal Drugs  | Date Published: 09/10/2009           |
| vz Human and Ammai Drugs   | Date Fublished. 03/10/2009           |
|  |                                      |

Date Published : 09/17/2010

| Notes: Non-sterile bulk drug products 5/1/1992 |
|--|
| 63 Human and Animal Drugs                      |
| Notes: Non-sterile bulk drug products 5/1/1992 |
| 64 Human and Animal Drugs                      |
| Notes: Non-sterile bulk drug products 5/1/1992 |
| 65 Human and Animal Drugs                      |
| Notes: Non-sterile bulk drug products 5/1/1992 |
| 66 Human and Animal Drugs                      |
| Notes: Non-sterile bulk drug products 5/1/1992 |

### Jabones Pardo S.A.

Calle Sierra Nevada 1, Fuenlabrada, Madrid SPAIN 53 - - - - Cosmetics Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Desc: All drugs and drug products 60 - - - -- Human and Animal Drugs Notes: All drugs and drug products 61 - - - -- Human and Animal Drugs Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Notes: All drugs and drug products 64 - - - -- Human and Animal Drugs Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Notes: All drugs and drug products 66 - - - -- Human and Animal Drugs Notes: All drugs and drug products

### Natura Bisse International, Inc.

Artesans, Parque Tecnologico Del Valles, Cerdanyola Del Valles, Barcelona SPAIN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

### TAIWAN

### Beanne Chemical Co. No. 28, Lane 456, Fongihou Road , Shengang District , Taichung City, TAIWAN 50 - - - - Color Additiv Food/Drug/Cosmetic

Date Published : 09/28/2012

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published : 10/01/2013

Date Published: 10/01/2013

Date Published : 10/28/2016

Date Published: 09/28/2012

| Desc: All drug and drug products |
|----------------------------------|
| 53 Cosmetics                     |
| Desc: All drug and drug products |
| 56 Antibiotics (Human/Animal)    |
| Desc: All drug and drug products |

### Polaroisin International Co., Ltd.

Xinzhuang District, NO 173, 10 F; Siyuan Rd., New Taipei City, TAIWAN 53 L - - -- Skin Care Prep Desc: All Drug and Drug Products Notes: For industry code 53L; only products found to be drug products are subject to DWPE under this listing 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug and Drug Products

### Taiwan Three Mast Pharmaceutical Co., Ltd.

3 Jingzhong Rd. , Tainan City, TAIWAN
55 - - - -- Pharm Necess & Ctnr For Drug/Bio
60 - - - -- Human and Animal Drugs
61 - - - -- Human and Animal Drugs
62 - - - -- Human and Animal Drugs
63 - - - -- Human and Animal Drugs
64 - - - -- Human and Animal Drugs
65 - - - -- Human and Animal Drugs
66 - - - -- Human and Animal Drugs

### THAILAND

| PAN RAJDHEVEE GROUP PUBLIC COMPANY LIMITED   | Date Published : 03/10/2015 |
|--|-----------------------------|
| 50/234-275 MOO 3, LAT SA WAI, LAM LUK KA , Lam Luk Ka, Pathum Thani THAILAND<br>53 Cosmetics | Date Published: 03/10/2015  |
| Notes: All Drug and Drug Products<br>55 Pharm Necess & Ctnr For Drug/Bio                     | Date Published: 03/10/2015  |
| Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)                           | Date Published: 03/10/2015  |
| Notes: All Drug and Drug Products<br>60 Human and Animal Drugs                               | Date Published: 03/10/2015  |
| Notes: All Drug and Drug Products<br>61 Human and Animal Drugs                               | Date Published: 03/10/2015  |
| Notes: All Drug and Drug Products<br>62 Human and Animal Drugs                               | Date Published: 03/10/2015  |
| Notes: All Drug and Drug Products  | Date Published: 03/10/2015  |
| 63 Human and Animal Drugs<br>Notes: All Drug and Drug Products                               |                             |

Date Published: 09/28/2012

Date Published: 09/28/2012

Date Published : 01/08/2018

Date Published: 01/08/2018

Date Published : 09/04/2012

Date Published: 09/04/2012

| Notes: All Drug and Drug ProductsDate Published: 03/10/201565 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201566 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015PCIC Co., Ltd.Date Published: 03/10/2015Lam Luk Ka , 73 Moo 12, Pracharaduthid Rd. , Bang Phli, Samut Prakan THAILANDDate Published: 03/10/201553 CosmeticsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Sotes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug Products  | 64 Human and Animal Drugs         | Date Published: 03/10/2015    |
|---|-----------------------------------|-------------------------------|
| 66 Human and Animal Drugs<br>Notes: All Drug and Drug ProductsDate Published: 03/10/2015PCIC Co., Ltd.<br>Lam Luk Ka, 73 Moo 12, Pracharaduthid Rd., Bang Phli, Samut Prakan THAILAND<br>53 Cosmetics<br>Notes: All Drug and Drug Products<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug and Drug Products<br>56 Antibiotics (Human/Animal)<br>Notes: All Drug and Drug Products<br>56 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>60 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>61 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>62 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>63 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>61 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>62 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>63 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>63 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug Products<br>63 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug Pro | 5 5                               | Date Published: 03/10/2015    |
| Notes: All Drug and Drug ProductsDate Published : 03/10/2015Lam Luk Ka , 73 Moo 12, Pracharaduthid Rd. , Bang Phli, Samut Prakan THAILANDDate Published : 03/10/201553 CosmeticsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201555 Pharm Necess & Ctnr For Drug/BioDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201556 Antibiotics (Human/Animal)Date Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201560 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201561 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201562 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/2015 <td>Notes: All Drug and Drug Products</td> <td></td>  | Notes: All Drug and Drug Products |                               |
| PCIC Co., Ltd.Date Published : 03/10/2015Lam Luk Ka , 73 Moo 12, Pracharaduthid Rd. , Bang Phli, Samut Prakan THAILANDDate Published : 03/10/201553 CosmeticsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201555 Pharm Necess & Ctnr For Drug/BioDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201556 Antibiotics (Human/Animal)Date Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201560 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201561 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201562 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/201563 Human and Animal DrugsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/2015Notes: All Drug and Drug ProductsDate Published : 03/10/2015Notes   | 66 Human and Animal Drugs         | Date Published: 03/10/2015    |
| Lam Luk Ka , 73 Moo 12, Pracharaduthid Rd. , Bang Phli, Samut Prakan THAILAND53 CosmeticsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201555 Pharm Necess & Ctnr For Drug/BioDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201556 Antibiotics (Human/Animal)Date Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   | Notes: All Drug and Drug Products |                               |
| 53 CosmeticsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201555 Pharm Necess & Ctnr For Drug/BioDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201556 Antibiotics (Human/Animal)Date Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   | PCIC Co., Ltd.                    | Date Published : 03/10/2015   |
| Notes: All Drug and Drug ProductsDate Published: 03/10/201555 Pharm Necess & Ctnr For Drug/BioDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201556 Antibiotics (Human/Animal)Date Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   |                                   | ND                            |
| 55 Pharm Necess & Ctnr For Drug/BioDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201556 Antibiotics (Human/Animal)Date Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015   |                                   | Date Published: 03/10/2015    |
| Notes: All Drug and Drug ProductsDate Published: 03/10/201556 Antibiotics (Human/Animal)Date Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015  |                                   |                               |
| 56 Antibiotics (Human/Animal)Date Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015  | •                                 | Date Published: 03/10/2015    |
| Notes: All Drug and Drug ProductsDate Published: 03/10/201560 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015  |                                   |                               |
| 60 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Kotes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   |                                   | Date Published: 03/10/2015    |
| Notes: All Drug and Drug ProductsDate Published: 03/10/201561 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015  |                                   |                               |
| 61 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   |                                   | Date Published: 03/10/2015    |
| Notes: All Drug and Drug ProductsDate Published: 03/10/201562 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   |                                   |                               |
| 62 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015  | -                                 | Date Published: 03/10/2015    |
| Notes: All Drug and Drug ProductsDate Published: 03/10/201563 Human and Animal DrugsDate Published: 03/10/2015Notes: All Drug and Drug ProductsDate Published: 03/10/2015   |                                   |                               |
| 63 Human and Animal Drugs       Date Published: 03/10/2015         Notes: All Drug and Drug Products       Date Published: 03/10/2015   |                                   | Date Published: 03/10/2015    |
| Notes: All Drug and Drug Products   | 8 8                               |                               |
|   | -                                 | Date Published: 03/10/2015    |
|   |                                   | Data Dublishadi 02/10/2015    |
| -   | -                                 | Date Published. 03/10/2013    |
| Notes: All Drug and Drug Products 65 Human and Animal Drugs Date Published: 03/10/2015  |                                   | Data Dublished: 02/10/2015    |
| 65 Human and Animal Drugs       Date Published: 03/10/2015         Notes: All Drug and Drug Products       Date Published: 03/10/2015   |                                   | Date Published. 03/10/2013    |
| 66 Human and Animal Drugs Date Published: 03/10/2015  |                                   | Date Published: 02/10/2015    |
| Notes: All Drug and Drug Products   |                                   | Date 1 ubilistied. 05/10/2015 |

# **TRINIDAD & TOBAGO**

|  | Date Published : 11/28/2017                              |
|--|--|
| ICL Drive Bhagowtie Trace , San Juan, TRINIDAD & TOBAGO<br>53 / - 02 Mouthwashes and Breath Fresheners (Liquids and Sprays), without Fluoride (Oral Hygiene Products)<br>Desc: Mouthwashes and Breath Fresheners | Date Published: 11/28/2017                               |
| Notes: For Product Code 53I[][]02; only drug and drug products are subject to DWPE under this notice 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 11/28/2017                               |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>56 Antibiotics (Human/Animal)<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices          | Date Published: 11/28/2017                               |
| 60 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 11/28/2017                               |
| 61 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 11/28/2017                               |
| 62 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 11/28/2017                               |
| 63 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices   | Date Published: 11/28/2017                               |
| 64 Human and Animal Drugs<br>65 Human and Animal Drugs<br>Natasi All Drugs and Drug ProductorProblem(c): (CMP) Coord Manufacturing Prostings   | Date Published: 11/28/2017<br>Date Published: 11/28/2017 |
| Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices<br>66 Human and Animal Drugs<br>Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices              | Date Published: 11/28/2017                               |

# TUNISIA

# Unite de Fabrication de Medicaments SA

Zone Industrielle , Kalaa El Kebira , Sousse, Sousse TUNISIA 65 F - - 06 Water, Purified (Eyewash) Desc: Cederroth Emergency Eye Wash

# TURKEY

### Ansa UNKNOWN , Izmit, TURKEY 56 - - - - Antibiotics (Human/Animal)

### Mustafa Nevzat Ilac Sanayii, A.S.

Cobancesme Mah., Sanayi Cad., Bahcelievler, Istanbul TURKEY 55 - - - - Pharm Necess & Ctnr For Drug/Bio 56 - - - - Antibiotics (Human/Animal) Notes: All drug and drug products GPI=DR; 56[[[]] 60 - - - - Human and Animal Drugs 61 - - - Human and Animal Drugs 62 - - - Human and Animal Drugs 63 - - - Human and Animal Drugs 64 - - - - Human and Animal Drugs 65 - - - - Human and Animal Drugs 66 - - - - Human and Animal Drugs

Date Published : 02/03/2015

Date Published: 02/03/2015

# Date Published : 09/10/2009

Date Published: 09/10/2009

## Date Published : 04/16/2013

Date Published: 04/16/2013 Date Published: 04/16/2013

Date Published: 04/16/2013 Date Published: 04/16/2013 Date Published: 04/16/2013 Date Published: 04/16/2013 Date Published: 04/16/2013 Date Published: 04/16/2013 Date Published: 04/16/2013

# UNITED ARAB EMIRATES

| Julphar Gulf Pharmaceutical Industries  | Date Published : 01/31/2012 |
|---|-----------------------------|
| Digdaga , Airport Road , Ra's al Khaymah, UNITED ARAB EMIRATES<br>55 Pharm Necess & Ctnr For Drug/Bio<br>Notes: All Drug Products | Date Published: 01/31/2012  |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 60 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 61 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 62 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 63 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 64 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 65 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| 66 Human and Animal Drugs<br>Notes: All Drug Products   | Date Published: 01/31/2012  |
| Notes: All Drug Products  |                             |

# UNITED KINGDOM

| Hampshire Chemicals, Ltd.  | Date Published : 09/10/2009 |
|--|-----------------------------|
| Seal Sands Road , Middlesborough, Cleveland UNITED KINGDOM<br>56 S Antibiotics (Human/Animal), Active Pharm Ingred/Chems for Further Manuf | Date Published: 09/10/2009  |
| Notes: All bulk pharmaceuticals 1/26/1996<br>60 S Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf                      | Date Published: 09/10/2009  |

| Date Published: 09/10/2009 |
|----------------------------|
|                            |
| Date Published: 09/10/2009 |
|                            |
|                            |

# VENEZUELA

|   | Date Published : 05/14/2010   |
|---|-------------------------------|
| CTO. EMPRESARIAL "RS", CALLE 6 , ZONA INDUSTRIAL LA URBINA , Caracas, VE-NOTA VENEZUELA |                               |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug Products                               | Date Published: 05/14/2010    |
| 73 Anesthesiology   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 74 Cardiovascular   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 76 Dental   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 77 Ear,Nose And Throat  | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 78 Gastroenterological & Urological   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 79 General & Plastic Surgery  | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 30 General Hospital/Personal Use  | Date Published: 05/14/2010    |
| Notes: All Drug Products  | Data Dubliahad, 05/11/2010    |
| 34 Neurological<br>Notes: All Drug Products   | Date Published: 05/14/2010    |
| 35 Obstetrical & Gynecological  | Date Published: 05/14/2010    |
| Notes: All Drug Products  | Date 1 ublished. 00/14/2010   |
| 36 Ophthalmic   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 37 Orthopedic   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 39 Physical Medicine  | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
| 90 Radiological   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
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| 55 Pharm Necess & Ctnr For Drug/Bio   | Date Published: 05/14/2010    |
| Notes: All Drug Products  | Data Dubliahadi 05/11/2010    |
| 56 Antibiotics (Human/Animal)<br>Notes: All Drug Products                               | Date Published: 05/14/2010    |
| 50 Human and Animal Drugs   | Date Published: 05/14/2010    |
| Notes: All Drug Products  | Date 1 ubilistied. 00/14/2010 |
| 61 Human and Animal Drugs   | Date Published: 05/14/2010    |
| Notes: All Drug Products  |                               |
|   |                               |
| 62 Human and Animal Drugs   | Date Published: 05/14/2010    |

63 - - - -- Human and Animal Drugs Notes: All Drug Products 64 - - - -- Human and Animal Drugs Notes: All Drug Products 65 - - - -- Human and Animal Drugs Notes: All Drug Products 66 - - - -- Human and Animal Drugs Notes: All Drug Products Date Published: 05/14/2010

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