


# Import Alert 66-40

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 [EMAIL \(MAILTO:?SUBJECT=IMPORT ALERT 66-40&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/CMS\\_IA/IMPORTALERT\\_189.HTML\)](mailto:?subject=IMPORT%20ALERT%2066-40&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:** 10/25/2017

**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

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

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#### AUSTRALIA

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#### Delta Laboratories Pty Ltd

8 Warringah CL , Somersby, New South Wales AUSTRALIA

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

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

56 - - - - Antibiotics (Human/Animal)

Notes:All Antibiotics; 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

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

**Date Published : 09/28/2017**

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

Date Published: 09/28/2017

#### Radpharm Scientific

57 Oatley Court , Belconnen, AUSTRALIA

66 V I P 99 Miscellaneous Patent Medicines, Etc., Human - Investigational, Small Volume Parenteral <100ml

**Date Published : 09/10/2009**

Date Published: 09/10/2009

Notes:Nexavir

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## AUSTRIA

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### Schrofner Cosmetics Gmbh

Robinigstrase 26a , Salzburg, Salzburg AUSTRIA

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

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

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

**Date Published : 10/20/2017**

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Date Published: 10/20/2017

Date Published: 10/20/2017

Date Published: 10/20/2017

Date Published: 10/20/2017

Date Published: 10/20/2017

Date Published: 10/20/2017

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## BELGIUM

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### Laboratoria Qualiphar NV

Rijksweg 9 , Bornem, Antwerp BELGIUM

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

**Date Published : 01/18/2011**

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

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## BRAZIL

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**Lima & Pergher Ind. Com. Rep Ltda**

**Date Published : 07/15/2016**

Av Airton Borges Da Silva 740 , Minas Gerais, BRAZIL

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

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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: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

#### **Lima & Pergher Industria e Comercio S/A**

Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL

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

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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 : 07/15/2016**

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Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

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## **CANADA**

#### **Aleeda Inc**

7115 Tomken Rd , Mississauga, ON CANADA

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

**Date Published : 05/29/2012**

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

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

Date Published: 05/29/2012  
Date Published: 05/29/2012

**Attix Pharmaceuticals Inc.**

184 Front St Unit 801 , Toronto, Ontario CANADA

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

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes:All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

**Date Published : 02/18/2015**

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

**Aztex Enterprises Ltd.**

5155 Fairview Street , Burlington, Ontario CANADA

53 - - - - Cosmetics

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

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

**Date Published : 10/19/2017**

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

**Aztex Enterprises Ltd.**

5155 Fairview Street , Burlington, Ontario CANADA

53 - - - - Cosmetics

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 : 10/19/2017**

Date Published: 10/19/2017

Date Published: 10/19/2017

Notes:All Drug and Drug Products  
60 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
61 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
62 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
63 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
64 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
65 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
66 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products

**Baxter Healthcare**

Unknown Street , Mississauga, ON CANADA  
55 R - - 55 Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent) Date Published: 04/10/2014  
Desc:0.9% Sodium Chloride Injection USP  
65 R - - 12 Potassic Saline (Injection) (Replenisher) Date Published: 04/10/2014  
Desc:0.9% Sodium Chloride Injection USP

**CMI Cosmetic Manufacturers Inc.**

90 Moyal Court , Concord, On CANADA  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
60 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
61 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
62 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
63 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
64 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
65 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs Date Published: 09/28/2015  
Notes:(GMP) Good Manufacturing Practices

**Cellex-C International Inc.**

9 New St , Toronto, Ontario CANADA  
53 - - - - Cosmetics Date Published: 06/02/2017  
Desc:All Drug and Drug Products  
Notes:For Industry Code 53; only drug and drug products (i.e. sunscreens) are subject to DWPE under this notice.  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/02/2017  
Notes:All Drug and Drug Products  
56 - - - - Antibiotics (Human/Animal) Date Published: 06/02/2017  
Notes:All Drug and Drug Products  
60 - - - - Human and Animal Drugs Date Published: 06/02/2017



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

**Homeocan Inc**

3025 Del Assomption , Lasalle, QC CANADA

53 - - - - Cosmetics

Desc:All Drugs and Drug Products

Notes:Problem(s); (GMP) Good Manufacturing Practices

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

Desc:All Drugs and Drug Products

Notes: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

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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

**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

**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



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

**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

**Date Published : 03/14/2014**

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

**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

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

**Date Published : 02/23/2012**

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

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**CHINA**

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**Attix Pharmaceuticals (Xiamen)**

Xiangyue Road , NO. 7 Xinganlu , Shamen, Fujian CHINA

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

Desc:All Drugs and Drug Products

**Date Published : 05/13/2016**

Date Published: 05/13/2016

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

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

**Ausmetics Daily Chemicals (Guangzhou) Co., Ltd.**

Economic And Technical , NO. 1 Jinxiulu; Huangpu , Guangzhou, Guangdong 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 : 12/20/2016**

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

**Baoying County Fukang Medical Appliance Co., Ltd.**

Trade of , Su Zhongbeilu; Baoyingxian , Yangzhou, 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

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

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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

Date Published: 09/20/2016

Date Published: 09/20/2016

Date Published: 09/20/2016

**Beijing Shunxin Meihua Bio-technical Co., Ltd.**

No 7 Fuqiandongjie , Shunyi District , Shunyiqiu, Beijingshi CHINA

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

**Date Published : 07/22/2014**

Date Published: 07/22/2014

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Date Published: 07/22/2014

Date Published: 07/22/2014

Date Published: 07/22/2014

Date Published: 07/22/2014

Date Published: 07/22/2014

Date Published: 07/22/2014

**Beijing Taiyang Pharmaceutical Industry Co Ltd**

NO 1 Shuangqiao (E) Road , Chaoyang, Beijing 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 : 04/29/2016**

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

Date Published: 04/29/2016

**Bicooya Cosmetics Limited**

NO 17 Yanhu Lu , Yiwu , Jinhua, Zhejiang CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices

**Date Published : 06/29/2017**

Date Published: 06/29/2017



Notes:All drug and drug products;(GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs  
Notes:All drug and drug products;(GMP) Good Manufacturing Practices

Date Published: 05/18/2015

**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

**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: 09/17/2010

Date Published: 09/17/2010

**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

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 : 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: 09/17/2010

Date Published: 09/17/2010

**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

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

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

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

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

**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

**Date Published : 09/30/2013**

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

**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

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

**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

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

Date Published: 08/11/2017

**Changzhou Jintan Qianyao Pharmaceutical Raw Materials**

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

Date Published: 05/04/2017

56 - - - - Antibiotics (Human/Animal)

Date Published: 05/04/2017

Notes:All Drug and Drug Products

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

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

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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

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

61 L - - 08 Heparin Sodium (Anti-Coagulant)

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

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

74 L - - 1S Heparin Coating Chemicals,

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

80 N - - ZW Heparin Vascular access flush

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

81 J - - BR Test, Heparin Neutralization

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

81 J - - OX Analyzer, Heparin, Automated

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

81 K - - FF Assay, Heparin

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

88 I - - AZ Heparin

Date Published: 09/10/2009

Notes:All heparin products 3/10/2008

**China Resources Sanjiu Medical and Pharmaceutical Co., Ltd.**

**Date Published : 09/03/2014**

No. 1 Guanqing Rd , Guanlan Hi-Tech Park, Longhua District , Shenzhen , Guangdong CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
56 - - - - Antibiotics (Human/Animal) Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
60 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
61 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
62 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
63 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
64 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
65 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
66 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014

**Chongqing Imperial Bio Chem Co**

5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbei Qu, Zhongqingshi CHINA

**Date Published : 09/10/2009**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All APIs 3/16/2009	Date Published: 09/10/2009
56 - - - - Antibiotics (Human/Animal) Notes:All APIs 3/16/2009	Date Published: 09/10/2009
60 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
61 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
62 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
63 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
64 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
65 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
66 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009

**Chongqing Lummy Pharmaceutical Co. Ltd.**

Economic And Technological , NO. 2 the 4th Branch Rd, Huaa??Nan Road , Chongqing, Changshou District CHINA

**Date Published : 04/19/2016**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
63 - - - - Human and Animal Drugs	Date Published: 04/19/2016



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: 04/19/2016  
Date Published: 04/19/2016  
Date Published: 04/19/2016

**Chongqing Paiqiang 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)

Notes:All APIs 3/16/2009

60 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

61 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

62 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

63 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

64 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

65 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

66 - - - - Human and Animal Drugs

Notes:All APIs 3/16/2009

**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: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

**Cixi Zhixin Bird Clean-Care Product Co., Ltd.**

NO. 137 Balilu , Cixi , Ningbo, 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 : 11/22/2016**

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

**Fercy Personal Care Products Co., Ltd**

An'Wen Industrial Zone Pan County , Jinhua, Zhejiang CHINA

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

Notes:All Drug Products

**Date Published : 05/10/2012**

Date Published: 05/10/2012

56 - - - - Antibiotics (Human/Animal) Date Published: 05/10/2012  
Notes:All Drug Products  
60 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products  
61 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products  
62 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products  
63 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products  
64 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products  
65 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products  
66 - - - - Human and Animal Drugs Date Published: 05/10/2012  
Notes:All Drug Products

**Foshan Flying Medical Products Co., Ltd.**

No. 49 Xiangshan 2th Road , Fengtain Industrial District , Foshan, Guangdong CHINA

**Date Published : 05/23/2017**

53 - - - - Cosmetics Date Published: 05/23/2017  
Desc:All Drug and Drug Products  
Notes:For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
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. isopropyl alcohol pads or 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. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
60 - - - - 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. isopropyl 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. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
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. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
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. isopropyl 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. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
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. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
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. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.  
68 - - - - Animal Devices and Diagnostic Products Date Published: 05/23/2017  
Desc:All Drug and Drug Products

Notes:For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

79 L - - RR Kit, First Aid

Date Published: 05/23/2017

Desc:All Drug and Drug Products

Notes:For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

79 N - - AB Gauze/Sponge, Nonresorbable For External Use

Date Published: 05/23/2017

Desc:All Drug and Drug Products

Notes:For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

79 O - - HO First aid kit without drug

Date Published: 05/23/2017

Desc:All Drug and Drug Products

Notes:For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

80 L - - KB Pad, Alcohol

Date Published: 05/23/2017

Desc:All Drug and Drug Products

Notes:For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

### **FriendsUnion(Tianjin) enterprises ltd.**

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

Suites 1808-9 Guohua Building, 857 Dagu- , Nan Road, Hexi , Tianjin,China , tianjin, CN-12 CHINA

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

Date Published: 09/17/2010

Notes:All drug products

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

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

64 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

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

### **Guangdong Pharmaceutical Factory #1**

**Date Published : 09/10/2009**

91 Fangcun Dadao , Guangzhou, CHINA

61 G - - - - A-Bacterial Pt. II (Not Antibiotic)

Date Published: 09/10/2009

Notes:Active Pharmaceutical Ingredients 12/12/1997

61 H - - - - A-Bacterial Pt. III (Not Antibiotic)

Date Published: 09/10/2009

Notes:Active Pharmaceutical Ingredients 12/12/1997

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

**Date Published : 08/21/2017**

NO. 59 Renmin South Road , Zhangjiang, Guangdong CHINA

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

Date Published: 08/21/2017

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 08/21/2017

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

60 - - - - Human and Animal Drugs

Date Published: 08/21/2017

Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices  
61 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices  
62 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices  
63 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices  
64 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices  
65 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drugs and Drug Products; (GMP) Good Manufacturing Practices

**Guangzhou Baiyunshan Pharmaceutical Co., Ltd.**

NO. 52 Xiaogang Damalu , Baiyun , Guangzhou, Guangdong 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  
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.**

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 Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
56 - - - - Antibiotics (Human/Animal) Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
60 - - - - Human and Animal Drugs Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
61 - - - - Human and Animal Drugs Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
62 - - - - Human and Animal Drugs Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
63 - - - - Human and Animal Drugs Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
64 - - - - Human and Animal Drugs Date Published: 03/14/2016  
Notes:All Drug and Drug Products  
65 - - - - Human and Animal Drugs Date Published: 03/14/2016  
Notes:All Drug and Drug Products

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

Date Published: 03/14/2016

**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 : 09/14/2017**

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

**Hebei Yuxing Bio-Engineering Co Ltd**

Xicheng District , Ningjin County , Ningjin, Hebei CHINA

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

Desc:All Drugs and Drug Products

Notes:Problem(s); (GMP) Good Manufacturing Practices;For Product code 54, only drugs and drug products are subject to this Import Alert

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 : 07/08/2016**

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

**Hunan Norchem Pharmaceutical Co. Ltd.**

No. 20 Mengjiangnv Avenue , Economic Development Zone , Jin, Hunan CHINA

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

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

56 - - - - Antibiotics (Human/Animal)

**Date Published : 10/18/2017**

Date Published: 10/18/2017

Date Published: 10/18/2017

Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs	Date Published: 10/18/2017
Notes:Add Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 10/18/2017

**Huzhou Aupower Sanitary Commodity**

339 Jingsan Road , Changxing Dist , Huzhou, Zhejiang CHINA	<b>Date Published : 08/05/2016</b>
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 08/05/2016
Notes:All Drugs; (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 08/05/2016
Notes:All Antibiotics; (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 08/05/2016
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	
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	Date Published: 08/05/2016
Notes:All Drugs; (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 08/05/2016
Notes:All Drugs; (GMP) Good Manufacturing Practices	

**Jiangmen Nowadays Daily Goods Co., Ltd.**

Boyukou Liangde Chong , Jiangmen, Guangdong CHINA	<b>Date Published : 06/07/2017</b>
53 - - - - Cosmetics	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.	
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	
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	
62 - - - - Human and Animal Drugs	Date Published: 06/07/2017
Notes:All Drug and Drug Products	

63 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 06/07/2017

64 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 06/07/2017

65 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 06/07/2017

66 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 06/07/2017

80 - - - - General Hospital/Personal Use  
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.  
Date Published: 06/07/2017

95 - - - - Light Emitting Non-Device Products  
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.  
Date Published: 06/07/2017

**Jinan Jinda Pharmaceutical Chemistry Co., Ltd.**

NO. 6121 Longquan Road , Zhangqui City (Jinan), Shandong CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

60 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

61 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

62 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

63 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

64 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

65 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

66 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 11/25/2015

**Kunshan Chemicals & Pharmaceutical Factory**

No 242 Kun Tai Road , Kunshan City , Jiangsu, CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:8/30/2007  
Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)  
Notes:8/30/2007  
Date Published: 09/10/2009

60 - - - - Human and Animal Drugs  
Notes:8/30/2007  
Date Published: 09/10/2009

61 - - - - Human and Animal Drugs  
Notes:8/30/2007  
Date Published: 09/10/2009

62 - - - - Human and Animal Drugs  
Notes:8/30/2007  
Date Published: 09/10/2009

63 - - - - Human and Animal Drugs  
Notes:8/30/2007  
Date Published: 09/10/2009

64 - - - - Human and Animal Drugs  
Notes:8/30/2007  
Date Published: 09/10/2009

65 - - - - Human and Animal Drugs  
Date Published: 09/10/2009

Notes:8/30/2007

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:8/30/2007

**Lumis Global Pharmaceuticals Co. Ltd.**

**Date Published : 02/15/2017**

Huishang Mansion Unit 305 , 2 Wudayuan Rd Donghu Ntdz , Wuhan, Hubei CHINA

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

Date Published: 02/15/2017

Notes:All Drug and Drug Products;For Industry Code 54, only drug and drug products are subject to DWPE under this notice

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

Date Published: 02/15/2017

Notes:All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 02/15/2017

Notes:All Drug and Drug Products

60 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 02/15/2017

Notes:All Drug and Drug Products

**Nanjing Maohai Biotech Co.**

**Date Published : 10/18/2011**

8 Developing Zone , Yaxi Town, Gaochun County , Nanjing Jiangsu Province, CHINA

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)

Date Published: 10/18/2011

Desc:Crude Heparin (Pharmaceutical Necessity)

61 L - - 08 Heparin Sodium (Anti-Coagulant)

Date Published: 10/18/2011

Desc:Heparin Sodium (Anti-Coagulant)

**Nantong Strip Medical Supply Co Ltd**

**Date Published : 03/27/2013**

Building A , 182 Yue Long Nan Road , Nantong, Jiangsu CHINA

50 - - - - Color Additiv Food/Drug/Cosmetic

Date Published: 03/27/2013

Notes:All Drug Products

53 - - - - Cosmetics

Date Published: 03/27/2013

Notes:All Drug Products

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

Date Published: 03/27/2013

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/27/2013

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/27/2013

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/27/2013

Notes:All Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/27/2013

Notes:All Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/27/2013

Notes:All Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/27/2013



Notes:All Drug Products  
66 - - - - Human and Animal Drugs  
Notes:All Drug Products  
80 - - - - General Hospital/Personal Use  
Notes:All Drug Products

Date Published: 03/27/2013

Date Published: 03/27/2013

**Ningbo Smart Pharmaceutical Co., Ltd.**

Sec. C1, Ningbo Eco. & , Tech. Dev. Zone, Beilun District , Ningbo, Zhejiang 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

**Date Published : 04/08/2011**

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

Date Published: 04/08/2011

**Ningbo Unichem Household Products Co Ltd.**

NO. 27 Luotuo Jiedao Jiushu Fangnanlu , Zhenhai , Ningbo, Zhejiang 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

**Date Published : 03/05/2013**

Date Published: 03/05/2013

Date Published: 03/05/2013

Date Published: 03/05/2013

Date Published: 03/05/2013

Date Published: 03/05/2013

Date Published: 03/05/2013

Date Published: 03/05/2013

Date Published: 03/05/2013

**Ningbo Zhixin Bird Clean-Care Product Co. Ltd.**

137 Bali Road , Zhangqi Town , 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

**Date Published : 11/22/2016**

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

Date Published: 11/22/2016

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: 11/22/2016

Date Published: 11/22/2016

**Northeast Pharmaceutical Group Co., Ltd.**

**Date Published : 09/10/2009**

37 Zhonggongbeijie , Tiexi , Chenyang, Liaoning CHINA

45 - - - - Food Additives (Human Use)

Date Published: 08/28/2010

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

46 - - - - Food Additives (Human Use)

Date Published: 08/28/2010

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

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

Date Published: 08/28/2010

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

Date Published: 09/10/2009

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)

Date Published: 09/10/2009

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

60 - - - - Human and Animal Drugs

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

**Qinhuangdao Zizhu Pharmaceutical, Co.** **Date Published : 03/08/2017**  
 No 10, Longhai Road , Economic & Technological Development Zon , Qinhuangdao, Hebei CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

56 - - - - Antibiotics (Human/Animal) Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

60 - - - - Human and Animal Drugs Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

61 - - - - Human and Animal Drugs Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

62 - - - - Human and Animal Drugs Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

63 - - - - Human and Animal Drugs Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

64 - - - - Human and Animal Drugs Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

65 - - - - Human and Animal Drugs Date Published: 03/08/2017  
 Notes:All Drugs and Drug Products

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/22/2017  
 Notes:All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal) Date Published: 08/22/2017  
 Notes:All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs Date Published: 08/22/2017  
 Notes:All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs Date Published: 08/22/2017  
 Notes:All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs Date Published: 08/22/2017  
 Notes:All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs Date Published: 08/22/2017  
 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

Date Published: 08/22/2017

Date Published: 08/22/2017

Date Published: 08/22/2017

**Shanghai Biochemical And Pharmaceutical Co Ltd**

Room A403, No. 494 Zhongxing Road , Shanghai, CHINA

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)

Notes:All heparin products 1/21/2009

55 R - - 99 Pharmaceutic Necessities, N.E.C.

Notes:All heparin products 1/21/2009

57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)

Notes:All heparin products 1/21/2009

61 L - - 08 Heparin Sodium (Anti-Coagulant)

Notes:All heparin products 1/21/2009

61 L - - 22 Anti-Coagulant Heparin Sol

Notes:All heparin products 1/21/2009

61 L - - 30 Heparin Calcium (Anti-Coagulant)

Notes:All heparin products 1/21/2009

74 L - - IS Heparin Coating Chemicals,

Notes:All heparin products 1/21/2009

80 N - - ZW Heparin Vascular access flush

Notes:All heparin products 1/21/2009

81 J - - BR Test, Heparin Neutralization

Notes:All heparin products 1/21/2009

81 J - - OX Analyzer, Heparin, Automated

Notes:All heparin products 1/21/2009

81 K - - FF Assay, Heparin

Notes:All heparin products 1/21/2009

88 I - - AZ Heparin

Notes:All heparin products 1/21/2009

**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: 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

**Shanghai Huhui Daily Use Chemical Products Co., Ltd.**

Pudong District , NO 8 Ludalu , Shanghai, Shanghai CHINA

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

**Date Published : 04/03/2013**

Date Published: 04/03/2013

Date Published: 04/03/2013

Date Published: 04/03/2013

Date Published: 04/03/2013

Date Published: 04/03/2013

Date Published: 04/03/2013

Date Published: 04/03/2013

Date Published: 04/03/2013

**Shanghai Life-Beauty Cosmetics Co., Ltd.**

No 2000 Fengxiang Rd , Baoshan District , Shanghai, CHINA

53 E - - 06 Shampoos (Hair Preparations, Non-coloring)

Desc:Dandruff Shampoo

Notes:(GMP) Good Manufacturing Practices

53 F - - 04 Hair Shampoos (Coloring) (Hair Coloring Preparations)

Desc:Dandruff Shampoo

Notes:(GMP) Good Manufacturing Practices

53 J - - 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C.

**Date Published : 03/28/2014**

Date Published: 03/28/2014

Date Published: 03/28/2014

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 60 - - - - Human and Animal Drugs	Date Published: 03/28/2014
Notes:All Drugs;(GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs	Date Published: 03/28/2014
Notes:All Drugs;(GMP) Good Manufacturing Practices 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

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.**

**Date Published : 09/10/2009**

387 Shangqiulu , Shanghai, Shanghai CHINA 55 R - - 75 Crude Heparin (Pharmaceutic Necessity) Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
55 R - - 99 Pharmaceutic Necessities, N.E.C. Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives) Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
61 L - - 08 Heparin Sodium (Anti-Coagulant) Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
61 L - - 22 Anti-Coagulant Heparin Sol Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
61 L - - 30 Heparin Calcium (Anti-Coagulant) Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
74 L - - /S Heparin Coating Chemicals, Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
80 N - - ZW Heparin Vascular access flush Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
81 J - - BR Test, Heparin Neutralization Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
81 J - - OX Analyzer, Heparin, Automated Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
81 K - - FF Assay, Heparin Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009
88 I - - AZ Heparin Notes:All Heparin Products 1/21/2009	Date Published: 09/10/2009

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.**

**Date Published : 09/10/2009**

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)

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.

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 to DWPE for heparin products only.

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.

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 to DWPE for heparin products 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 to DWPE for heparin products only.

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 to DWPE for heparin products only.

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 to DWPE for heparin products only.

66 - - - - 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.

### **Shanghai Weierya Daily Chemicals Factory**

**Date Published : 09/14/2017**

No. 1072 Dongsheng Lu , Shanghai, Shanghai CHINA

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

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

60 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

61 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

62 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

63 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

64 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

65 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

66 - - - - Human and Animal Drugs

Date Published: 09/14/2017

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

**Sichuan Pharmaceutical Co., Ltd.**

189 Hua Long Road , Pengzhou, Sichuan Province 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

**Date Published : 05/08/2012**

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

Date Published: 05/08/2012

**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

**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: 07/10/2014

**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

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

**Date Published : 10/17/2016**

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

Date Published: 10/17/2016

**Taizhou Kanglin Health Protection Products Co., Ltd.**

The West of Qiliqiao , Economic Development Zone , Taizhou, Jiangsu Province CHINA

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

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

80 L - - KB Pad, Alcohol

**Date Published : 01/15/2013**

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

Date Published: 01/15/2013

**Tianjin Boai NKY International Ltd.**

Suites 1808-9 Guohua Building , Dagu-Nan Road, Hexi District , 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

**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: 09/17/2010

Date Published: 09/17/2010

**Tianjin Boai Pharmaceutical Co. Ltd**

NO. 4 Ronghua Road , Xiqing , Tianjin, Tianjin 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

**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: 09/17/2010



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

Date Published: 09/17/2010

**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

**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: 09/17/2010

Date Published: 09/17/2010

**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

**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: 02/11/2016

**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

**Date Published : 10/19/2017**

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Date Published: 10/19/2017

Notes:All Drug and Drug Products  
62 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
63 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
64 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
65 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
66 - - - - Human and Animal Drugs Date Published: 10/19/2017  
Notes:All Drug and Drug Products  
89 / - - - - Portion of device code Date Published: 10/19/2017  
Desc:All Drug and Drug Products  
Notes:For industry code 89I; only products found to be drug products are subject to DWPE under this listing

**Xiamen Origin Biotech Co. Ltd.**

NO. 7 Xiang Yue Road , Xiamen Torch , Xiamen, Fujian CHINA

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/13/2016  
Desc:All Drugs and Drug Products  
Notes:(GMP) Good Manufacturing Practices  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
56 - - - - Antibiotics (Human/Animal) Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
60 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
61 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
62 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
63 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
64 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
65 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs Date Published: 05/13/2016  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices

**Xinxiang Pharmaceutical Co. Ltd.**

NO. 30 Jianshe West Road , Beigandao , 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.

**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 I - - 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

Notes:All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE 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 DWPE 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 DWPE 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  
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: 08/11/2017

Date Published: 08/11/2017

Date Published: 08/11/2017

Date Published: 08/11/2017

Date Published: 08/11/2017

**Yunnan Hande Bio-Tech. Co. Ltd.**

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

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

**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

Date Published: 05/20/2016

Date Published: 05/20/2016

Date Published: 05/20/2016

**Zhejiang Bangli Medical Products Co., Ltd**

Huachuan Block , 118 South of Yuegui Road , Yongkang City, 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 : 09/09/2016**

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

Date Published: 09/09/2016

**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

61 L - - 08 Heparin Sodium (Anti-Coagulant)

Date Published: 10/18/2011

Desc:Heparin Sodium (Anti-coagulant)

**Zhejiang Hisoar Pharmaceutical Co. Ltd.**

**Date Published : 01/20/2016**

NO. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA

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

Date Published: 01/20/2016

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 01/20/2016

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

60 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

61 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

62 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

63 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

64 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

65 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

66 - - - - Human and Animal Drugs

Date Published: 01/20/2016

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

**Zhejiang Qianfei Enterprise Co. Ltd.**

**Date Published : 11/24/2015**

NO 173 Wulian Road , Yiting Town , Yiwu, Zhejiang CHINA

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

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Date Published: 11/24/2015

Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

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**DENMARK**

**Leo Pharma A/S**

**Date Published : 03/01/2011**

Industriparken 55 , Ballerup, DENMARK

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)

Date Published: 03/01/2011

Desc:Tinzaparin Sodium (Innohep); Anti-coagulant; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.

Date Published: 03/01/2011

Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

**Leo Pharmaceutical Products**

A 8 , Copenhagen, 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.

**Date Published : 03/01/2011**

Date Published: 03/01/2011

Date Published: 03/01/2011

**Leo Pharmaceutical Products**

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.

**Date Published : 03/01/2011**

Date Published: 03/01/2011

Date Published: 03/01/2011

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**FRANCE**

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**CISBIO BIOASSAYS**

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

**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: 09/10/2009

Date Published: 09/10/2009

**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

**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

65 - - - - Human and Animal Drugs  
Notes:Selenomethionine 75 Injection  
66 - - - - Human and Animal Drugs  
Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

Date Published: 09/10/2009

**Ligne St. Barth SAS**

Lorient , route de Saline , St Barthelemy, Guadeloupe FRANCE

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

Date Published: 07/08/2013

60 - - - - Human and Animal Drugs

Date Published: 07/08/2013

61 - - - - Human and Animal Drugs

Date Published: 07/08/2013

62 - - - - Human and Animal Drugs

Date Published: 07/08/2013

63 - - - - Human and Animal Drugs

Date Published: 07/08/2013

64 - - - - Human and Animal Drugs

Date Published: 07/08/2013

65 - - - - Human and Animal Drugs

Date Published: 07/08/2013

66 - - - - Human and Animal Drugs

Date Published: 07/08/2013

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

**Societe Chimique Grevis**

Avenue De La Paix , Limay, FRANCE

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

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

60 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

62 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

63 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

64 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

65 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

**Date Published : 09/10/2009**

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**GERMANY**

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**SANUM-Kehlbeck GmbH & Co. KG**

Hasseler Steinweg, 9-12 , and Bahnhofstrasse 2-4 , Hoya, Niedersachsen GERMANY

50 - - - - Color Additiv Food/Drug/Cosmetic

Date Published: 07/08/2013

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

Date Published: 07/08/2013

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

Date Published: 07/08/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 07/08/2013

60 - - - - Human and Animal Drugs

Date Published: 07/08/2013

61 - - - - Human and Animal Drugs

Date Published: 07/08/2013

62 - - - - Human and Animal Drugs

Date Published: 07/08/2013

63 - - - - Human and Animal Drugs

Date Published: 07/08/2013

64 - - - - Human and Animal Drugs

Date Published: 07/08/2013

65 - - - - Human and Animal Drugs

Date Published: 07/08/2013

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



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**GREECE**


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**CHIA GH LTD.**

Ag. Mina 144 , Chios, GREECE

55 - - - - Pharm Necess &amp; 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

**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

Date Published: 05/06/2013

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**HONG KONG**


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**CBSCHEM LIMITED**

13th Floor , Nan Fung Industrial City , Tuen Mun, New Territories HONG KONG

35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling

Desc:All drugs and drug products

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

Desc:All drugs and drug products

55 - - - - Pharm Necess &amp; 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

78 - - - - Gastroenterological &amp; Urological

Desc:All drugs and drug products

88 - - - - Pathology

Desc:All drugs and drug products

**Date Published : 08/31/2013**

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

**Chan Yat Hing Medicine Factory****Date Published : 12/03/2015**

Flat 3, 9/F , Fuk Keung Industrial Bldg. , Mong Kok, Kowloon HONG KONG

53 - - - - Cosmetics

Date Published: 01/07/2016

Desc:All drug products declared as Cosmetic Products

Notes:The firm has a history of importing some of the following drug products under product code 53: Arthritis Pain Relieving Cream, Pain Relieving Balm, Wok Lok Pain Relieving Oil, Shuang Long Pain Relieving Oil, and Red Flower Oil, Pain Relieving Herbal Oil, Pain Relieving Chi Len Oil, Pain Relieving Po Tong Oil, and Back Pain Relieving Oil. This is not an inclusive list; therefore it is recommended that any products offered for import under product code 53 be thoroughly reviewed to determine if said products are drug products and thus subject to DWPE under this listing.

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

Date Published: 12/03/2015

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 12/03/2015

Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

61 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

62 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

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

Date Published: 12/03/2015

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

65 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

66 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

**Luen Yick Pharmaceutical Co. Ltd.**

**Date Published : 03/04/2014**

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

Date Published: 03/04/2014

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

**Peking Medicine Manufactory**

**Date Published : 03/04/2014**

Unit B, 7/F, Phase 1 , Leader Industry Centre , Tsuen Wan, New Territories HONG KONG

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

Date Published: 03/04/2014

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products	
62 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
63 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
64 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
65 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
66 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	

**Seedings**

18 Tin Hau Rd. , Room 3, 13/F, Tower 4 , Hong Kong, Hong Kong HONG KONG	<b>Date Published : 08/31/2013</b>
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
Notes:All drugs and drug products	
62 - - - - Human and Animal Drugs	Date Published: 08/31/2013
Notes:All drugs and drug products	
63 - - - - Human and Animal Drugs	Date Published: 08/31/2013
Notes:All drugs and drug products	
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	
88 - - - - Pathology	Date Published: 08/31/2013
Notes:All drugs and drug products	

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**HUNGARY**

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<b>Teva Pharmaceutical Works Private Limited Company</b>	<b>Date Published : 05/27/2016</b>
Tancsics Mihaly ut 82 , Godollo, Pest HUNGARY	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 05/27/2016
Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe:	
Amikacin/56D[ ]06; Bleomycin / 56H[ ]10	
60 - - - - Human and Animal Drugs	Date Published: 05/27/2016

Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs	Date Published: 05/27/2016
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	

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## INDIA

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### **Aadivighnesh Chem PVT. LTD.**

A/7 Badrinath Apartment , Simpoli Road; Borivali West , Mumbai, Maharashtra INDIA  
56 C - - 66 Ceftazidime (Cephalosporins)  
Desc:Ceftazimide for Injection USP (Sterile)

**Date Published : 05/05/2014**

Date Published: 05/05/2014

### **Aarti Drugs Limited**

Plot No. E-22, M.I.D.C., Tarapur , Palghar, Maharashtra INDIA  
55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
60 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
61 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
62 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
63 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
64 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
65 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
66 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices

**Date Published : 03/23/2015**

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

### **Aarti Drugs Ltd**

G-60 Boisar MIDC Tarapur , Tal. Palghar, District Thane , Tarapur, Maharashtra INDIA  
55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
60 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices  
61 - - - - Human and Animal Drugs

**Date Published : 03/23/2015**

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

Date Published: 03/23/2015

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

Date Published: 03/23/2015  
Date Published: 03/23/2015  
Date Published: 03/23/2015  
Date Published: 03/23/2015  
Date Published: 03/23/2015

#### **Akorn India PVT**

5/2 5/3 Khasra 5/1 , Paonta Sahib, Himachal Pradesh INDIA

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

**Date Published : 08/21/2015**

Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015  
Date Published: 08/21/2015

#### **Amsal Chem Pvt. Ltd.**

A-1/401-402-403, GIDC , Ankleshwar, Gujarat, INDIA

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

**Date Published : 04/11/2013**

Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013  
Date Published: 04/11/2013

#### **Badrivishal Chemicals & Pharmaceuticals**

Gat No. 29, Village Jambwade (Induri) , Post Sudumbre, Taluka Maval , Dist. Pune, Maharashtra INDIA

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

**Date Published : 12/19/2016**

Date Published: 12/19/2016  
Date Published: 12/19/2016  
Date Published: 12/19/2016  
Date Published: 12/19/2016  
Date Published: 12/19/2016  
Date Published: 12/19/2016

Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices  
63 - - - - Human and Animal Drugs Date Published: 12/19/2016  
Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices  
64 - - - - Human and Animal Drugs Date Published: 12/19/2016  
Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices  
65 - - - - Human and Animal Drugs Date Published: 12/19/2016  
Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs Date Published: 12/19/2016  
Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices

**Canton Laboratories Pvt. Ltd.**

110 A & B Gidc Estate , Makarpura Road , Vadodara, Gujarat INDIA

54 B - - - - Mineral

Desc:All Drugs and Drug Products

Notes: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 ;

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 : 04/10/2014**

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

**Divi's Laboratories Ltd. (Unit II)**

Chippada Village, Annavaram , Bheemunipatnam Mandal , Visakhapatnam District, Andhra Pradesh 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;The following drugs are excluded from DWPE: Levetiracetam - 61M[]42;Gabapentin -

61N[]69;Lamotrigine ◆ 61M[]38

62 - - - - Human and Animal Drugs

Notes:All Drug and Drug Products;The following drugs are excluded from DWPE:Capecitabine - 62I[]72;Naproxen - 62G[]

[]49;Raltegravir potassium - 62V[]61;Atovaquone ◆ 62L[]44;Levodopa - 62J[]09;Bosentan API ◆ 62C[]66; Naproxen Sodium ◆ 62G[]50

63 - - - - Human and Animal Drugs

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Notes:All Drug and Drug Products The following drugs are excluded from DWPE: Carbidopa - 64U[]03

65 - - - - Human and Animal Drugs

Notes:All Drug and Drug Products

**Date Published : 03/20/2017**

Date Published: 03/20/2017

Date Published: 03/20/2017

Date Published: 03/20/2017

Date Published: 03/20/2017

Date Published: 03/20/2017

Date Published: 03/20/2017

Date Published: 03/20/2017

Date Published: 03/20/2017

66 - - - - Human and Animal Drugs Date Published: 03/20/2017  
Notes:All Drug and Drug Products;The following drugs are excluded from DWPE: Intermediate 26U90 (chloropurine) - 66V[]99;BOC core succinate - 66V[]99;2,4-wing active ester - 66V[]99; Ethyl-7-chloro-2-oxo-heptanoate (CKE) - 66V[]99;(+) -2,2-Dimethylcyclopropyl-carboxamide (DCAM) - 66V[]99; L-moc valine - 66V[]99; Oky Ksalt - 66V[]99; Methyl 3-benzyloxy-1-[(uRS)-2,3-dihydroxypropyl]- 4-oxo-1,4-dihydropyridine-2-carboxylate (DHPM) - 66V[]99 ; 1-(2,2-Dimethoxyethyl)- 5-methoxy-6-(methoxycarbonyl)- 4-oxo-1,4-dihydropyridine-3-carboxylic acid (DHPA) - 66V[]99; (3R)-3-Amino-1-butanol (RABO) - 66V[]99 ; 2,3-dimethyl-2H-indazol-6-amine (GW776944B) - 66V[]99; 5-amino-2-methyl-benzenesulfonamide (GW700143X) - 66V[]99

**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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/13/2015

Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal) Date Published: 07/13/2015

Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe:

Amikacin inj, antibiotic / 56D[]06

60 - - - - Human and Animal Drugs Date Published: 07/13/2015

Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

61 - - - - 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:

Ondansetron inj. Antiemetic (for nausea/vomiting)/61T[]26 Prochlorperazine inj, Antiemetic (for nausea/vomiting)/ 61T[]

[]14 Metoclopramide inj, used for GERD and antiemetic / 61T[]12

62 - - - - 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:

Zoledronic Acid inj, treats/prevents osteoporosis / 62A[]05 Cidofovir inj, treats eye infection in HIV patients / 62V[]21

Carmustine inj, cancer / 62I[]12 Efavirenz / 62V[]24

63 - - - - Human and Animal Drugs Date Published: 07/13/2015

Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs Date Published: 07/13/2015

Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs Date Published: 07/13/2015

Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

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

**Fleming Laboratories Limited**

**Date Published : 04/11/2011**

48 Temple Rock Enclave , Tarbund Road; Plot No; Bhowanpalli , Secunderabad, Telangana INDIA

56 - - - - Antibiotics (Human/Animal) Date Published: 04/11/2011

Notes:All Drug Products

73 - - - - Anesthesiology Date Published: 04/11/2011

Notes:All Drug Products

74 - - - - Cardiovascular Date Published: 04/11/2011

Notes:All Drug Products

76 - - - - Dental Date Published: 04/11/2011

Notes:All Drug Products

77 - - - - Ear,Nose And Throat Date Published: 04/11/2011

Notes:All Drug Products

78 - - - - Gastroenterological & Urological Date Published: 04/11/2011

Notes:All Drug Products

79 - - - - General & Plastic Surgery Date Published: 04/11/2011

Notes:All Drug Products

80 - - - - General Hospital/Personal Use Date Published: 04/11/2011

Notes:All Drug Products	
84 - - - - Neurological	Date Published: 04/11/2011
Notes:All Drug Products	
85 - - - - Obstetrical & Gynecological	Date Published: 04/11/2011
Notes:All Drug Products	
86 - - - - Ophthalmic	Date Published: 04/11/2011
Notes:All Drug Products	
87 - - - - Orthopedic	Date Published: 04/11/2011
Notes:All Drug Products	
89 - - - - Physical Medicine	Date Published: 04/11/2011
Notes:All Drug Products	
90 - - - - Radiological	Date Published: 04/11/2011
Notes:All Drug Products	

**Fleming Laboratories Ltd.**

**Date Published : 10/20/2017**

Survey No. 270, Kanukunta Road , Nawabpet Village, Medak District , Hyderabad, Telangana Pradesh INDIA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
56 - - - - Antibiotics (Human/Animal)	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
60 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
61 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
62 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
63 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
64 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
65 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	
66 - - - - Human and Animal Drugs	Date Published: 10/20/2017
Notes:All Drug and Drug Products	

**Ipca Laboratories LTd**

**Date Published : 03/24/2015**

1 Pharma Zone , Pithampur, Madhya Pradesh INDIA	
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
Notes:All Drugs;(GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	



**Ipca Laboratories Limited**

Village Sejavta , Ratlam, Madhya Pradesh INDIA

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

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

56 - - - - Antibiotics (Human/Animal)

Notes:All Antibiotics;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;This product is excluded from DWPE: Chloroquine

Phosphate API/61A0006

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; These products are excluded from DWPE:

Furosemide/64BQS24

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

**Date Published : 01/22/2015**

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

Date Published: 01/22/2015

**Ipca Laboratories Limited**

Plot No. 65 and 99, Danudyog , Ind. Estate, Piparia , Silvasa (D and NH), INDIA

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

Notes:All Drugs;(GMP) Good Manufacturing Practices;

60 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices;

64 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

**Date Published : 03/24/2015**

Date Published: 03/24/2015

Date Published: 03/24/2015

Date Published: 03/24/2015

Date Published: 03/24/2015

Date Published: 03/24/2015

Date Published: 03/24/2015

Date Published: 03/24/2015

Date Published: 03/24/2015

**Kamud Drugs Pvt. Ltd.**

N-6 &amp; 8 MIDC, Kupwad , Taluka Miraj , Sangli, Maharashtra INDIA

50 - - - - Color Additiv Food/Drug/Cosmetic

Notes:All drug and drug products

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

Notes:All drug and drug products

55 - - - - Pharm Necess &amp; 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

**Date Published : 07/10/2013**

Date Published: 07/10/2013

Date Published: 07/10/2013

Date Published: 07/10/2013

Date Published: 07/10/2013

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  
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  
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 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  
Notes:For Industry Code 53; only drug and drug products (i.e. petroleum jelly; etc.) are subject to DWPE under this notice.  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
56 - - - - Antibiotics (Human/Animal) Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
60 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
61 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
62 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
63 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
64 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
65 - - - - Human and Animal Drugs Date Published: 08/21/2017  
Notes:All Drug and Drug Products  
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 State, INDIA

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  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/10/2013  
Notes:All drug and drug products  
56 - - - - Antibiotics (Human/Animal) Date Published: 07/10/2013  
Desc:All drug and drug products  
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  
62 - - - - Human and Animal Drugs Date Published: 07/10/2013

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

Date Published: 07/10/2013  
Date Published: 07/10/2013  
Date Published: 07/10/2013  
Date Published: 07/10/2013

#### **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

**Date Published : 08/25/2017**

Date Published: 08/25/2017  
Date Published: 08/25/2017  
Date Published: 08/25/2017  
Date Published: 08/25/2017  
Date Published: 08/25/2017  
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Date Published: 08/25/2017  
Date Published: 08/25/2017  
Date Published: 08/25/2017  
Date Published: 08/25/2017  
Date Published: 08/25/2017

#### **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  
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 : 03/12/2014**

Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014  
Date Published: 03/12/2014

#### **Megafine Pharma (P) Limited**

48 - 51/201 Plot No 31 - 35 , Lakhmapur, Maharashtra INDIA  
55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug and Drug Products

**Date Published : 10/14/2015**

Date Published: 10/14/2015

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

Date Published: 10/14/2015  
Date Published: 10/14/2015  
Date Published: 10/14/2015  
Date Published: 10/14/2015  
Date Published: 10/14/2015  
Date Published: 10/14/2015  
Date Published: 10/14/2015

#### **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 Ppyrilamine Maleate (Anti-Histaminic)

Desc:Chlorpheniramine maleate

61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)

Desc:Ppyrilamine maleate Ppyrilamine maleate USP

61 X - - 99 Anti-Histaminic N.E.C.

Desc:Ppyrilamine maleate Ppyrilamine 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

**Date Published : 11/23/2011**

Date Published: 11/23/2011  
Date Published: 11/23/2011  
Date Published: 11/23/2011  
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Date Published: 11/23/2011  
Date Published: 11/23/2011

#### **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 Ppyrilamine Maleate (Anti-Histaminic)

Desc:Ppyrilamine maleate Ppyrilamine maleate USP

61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)

**Date Published : 11/23/2011**

Date Published: 11/23/2011  
Date Published: 11/23/2011  
Date Published: 11/23/2011  
Date Published: 11/23/2011  
Date Published: 11/23/2011  
Date Published: 11/23/2011

Desc:Chlorpheniramine maleate 61 X - - 99 Anti-Histaminic N.E.C.	Date Published: 11/23/2011
Desc:Pyrilamine maleate Pyrilamine maleate USP 61 - - - - 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 63 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate 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**

192 G I D C Makarpura Industrial Estate , M I Estate , Vadodara, Gujarat INDIA	<b>Date Published : 12/08/2015</b>
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	
61 - - - - Human and Animal Drugs	Date Published: 12/08/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
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	
64 - - - - 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	
66 - - - - Human and Animal Drugs	Date Published: 12/08/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	

**Pan Drugs Ltd.**

167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA	<b>Date Published : 05/05/2015</b>
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/05/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 05/05/2015
Notes:All Antibiotics;(GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 05/05/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 05/05/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 05/05/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 05/05/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 05/05/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	

65 - - - - Human and Animal Drugs  
Notes:All Drugs;(GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs  
Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 05/05/2015

Date Published: 05/05/2015

**Polydrug Laboratories Pvt. Ltd.**

Plot N37, Ambarnath Industrial Area , Anand Nagar MIDC , Mumbai, Maharashtra INDIA

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

Desc:All Drugs

Notes:Problem(s): (GMP) Good Manufacturing Practices

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

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

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

**Date Published : 09/11/2015**

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

Date Published: 09/11/2015

**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

**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: 06/10/2013

**RPG Life Sciences Limited**

3102/A G.I.D.C. Estate , 393002 , Ankleshwar, Gujarat 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

**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: 06/11/2013

**Sal Pharma**

**Date Published : 02/15/2017**

1-7-176 Bakaram , Hyderabad, Andhra Pradesh INDIA

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: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

Date Published: 02/15/2017

#### **Sentiss Pharma Pvt. Ltd.**

Village Khera Nihla , Tehsil Nalagarh , District Solan, Himachal Pradesh 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

86 - - - - Ophthalmic

**Date Published : 06/20/2013**

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

Date Published: 06/20/2013

#### **Smruthi Organics Limited**

Plot No. A-27, MIDC, Chincholi , Solapur District, Maharashtra, Maharashtra State INDIA

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

**Date Published : 06/03/2013**

Date Published: 06/03/2013

Date Published: 06/03/2013

Date Published: 06/03/2013

Date Published: 06/03/2013

Date Published: 06/03/2013

Date Published: 06/03/2013

Date Published: 06/03/2013

Date Published: 06/03/2013

#### **Sri Krishna Pharmaceuticals Ltd. - Unit II**

A-35, IDA, Nacharam , Hyderabad, Andhra Pradesh, INDIA

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

Notes:All Drugs

60 - - - - Human and Animal Drugs

Notes:All Drugs

61 - - - - Human and Animal Drugs

Notes:All Drugs

62 - - - - Human and Animal Drugs

**Date Published : 08/13/2015**

Date Published: 08/13/2015

Date Published: 08/13/2015

Date Published: 08/13/2015

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/65C09  
66 - - - - Human and Animal Drugs Date Published: 08/13/2015  
Notes:All Drugs

**Srikem Laboratories Pvt. Ltd.**

Plot No. 17/24, MIDC Taloja , Navi Mumbai, Maharashtra INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
56 - - - - Antibiotics (Human/Animal) Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
60 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
61 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
62 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
63 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
64 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
65 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs Date Published: 07/06/2016  
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices

**Date Published : 07/06/2016**

**Stericon Pharma Pvt. Ltd.**

No. 9, Sub Layout Of Plot 9 , 1st Phase Bommasandra Ind. Area , Bangalore, Karnataka INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/13/2011  
Notes:All Drug Products  
60 - - - - Human and Animal Drugs Date Published: 01/13/2011  
Notes:All Drug Products  
61 - - - - Human and Animal Drugs Date Published: 01/13/2011  
Notes:All Drug Products  
62 - - - - Human and Animal Drugs Date Published: 01/13/2011  
Notes:All Drug Products  
63 - - - - Human and Animal Drugs Date Published: 01/13/2011  
Notes:All Drug Products  
64 - - - - Human and Animal Drugs Date Published: 01/13/2011  
Notes:All Drug Products  
65 - - - - Human and Animal Drugs Date Published: 01/13/2011  
Notes:All Drug Products  
66 - - - - Human and Animal Drugs Date Published: 01/13/2011  
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

**Date Published : 09/10/2009**





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 Ganciclovir API.

Districts should contact 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

Date Published: 03/12/2014

Desc:All Human Drug Products

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

Date Published: 03/12/2014

Desc:All Human Drug Products

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

66 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

**Unique Chemicals**

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

Shiv Mahape Gansoli , Thane Belapur Road , Navi Mumbai, Maharashtra INDIA

50 - - - - Color Additiv Food/Drug/Cosmetic

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 06/28/2013

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

61 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

62 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

63 - - - - Human and Animal Drugs

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

**Vignesh Life Science Pvt Ltd**

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

202 Sarada Residency , H - 26 , Madhura Nagar Ameerpet , Hyderabad, Tamil Nadu INDIA

50 - - - - Color Additiv Food/Drug/Cosmetic

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 06/28/2013

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

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

**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  
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

**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  
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

**Vikshara Trading & Investments Ltd.**

Odhav Road , Ahmedabad, Gujarat INDIA

53 - - - - Cosmetics  
Notes:All Drug and Drug Products;For Industry Code 53, only drug and drug products are subject to DWPE under this notice.  
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;

**Date Published : 02/08/2017**

Date Published: 02/08/2017  
Date Published: 02/08/2017  
Date Published: 02/08/2017  
Date Published: 02/08/2017  
Date Published: 02/08/2017

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;

Date Published: 02/08/2017

Date Published: 02/08/2017

Date Published: 02/08/2017

Date Published: 02/08/2017

Date Published: 02/08/2017

#### **Wockhardt Limited**

L-1, MIDC Area, Jalgaon Road 43 , Chikalthana , Aurangabad, Maharashtra INDIA

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; \* Notes: These products are excluded from DWPE: Enalapril Maleate (Antihypertensive - part II) (62OCA28, 62OCS28)

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

**Date Published : 11/26/2013**

Date Published: 09/28/2016

Date Published: 11/26/2013

Date Published: 09/28/2016

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

#### **Wockhardt Limited**

H-14/2 Plot , Biotech Park , Aurangabad, Maharashtra INDIA

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 Except -- Enalapril Maleate (62O[ ]28)

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

**Date Published : 05/22/2013**

Date Published: 05/22/2013

Date Published: 05/22/2013

Date Published: 05/22/2013

Date Published: 05/22/2013

Date Published: 05/22/2013

Date Published: 05/22/2013

Date Published: 05/22/2013

Date Published: 05/22/2013

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

Date Published: 05/22/2013

**Wockhardt, Ltd.**

Plot 138 GIDC Industrial , Bulk Drug Division, Dist. Bharuch , Ankleshwar, 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

**Date Published : 08/05/2016**

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

**Yag Mag Labs Private Limited**

Survey No. 10, Gaddapotharam Village , Jinnaram Mandal , Medak District, Telangana INDIA

60 L - - 69 Tramadol HCl (Analgesic)

Desc:Tramadol HCl (Analgesic)

60 L - - 99 Analgesic, N.E.C.

Desc:Tramadol HCl (Analgesic)

64 H - - 02 Guaifenesin (Expectorant)

Desc:Guaifensein (Expectorant)

**Date Published : 09/13/2011**

Date Published: 09/13/2011

Date Published: 09/13/2011

Date Published: 09/13/2011

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**ITALY**

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**Topchem SRL**

Viale Andrea Doria 17 , Milano, MI ITALY

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

Notes:All bulk drugs 8/4/1992

56 - - - - Antibiotics (Human/Animal)

Notes:All bulk drugs 8/4/1992

60 - - - - Human and Animal Drugs

Notes:All bulk drugs 8/4/1992

61 - - - - Human and Animal Drugs

Notes:All bulk drugs 8/4/1992

62 - - - - Human and Animal Drugs

Notes:All bulk drugs 8/4/1992

63 - - - - Human and Animal Drugs

Notes:All bulk drugs 8/4/1992

64 - - - - Human and Animal Drugs

Notes:All bulk drugs 8/4/1992

**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: 09/10/2009

65 - - - - Human and Animal Drugs  
Notes:All bulk drugs 8/4/1992  
66 - - - - Human and Animal Drugs  
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

Date Published: 09/10/2009

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## JAMAICA

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### **P.A. Benjamin Manufacturing Company Limited**

95-97 East Street , Kingston, JM-01 JAMAICA

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

**Date Published : 08/29/2012**

Date Published: 08/29/2012

Date Published: 08/29/2012

Date Published: 08/29/2012

Date Published: 08/29/2012

Date Published: 08/29/2012

Date Published: 08/29/2012

Date Published: 08/29/2012

Date Published: 08/29/2012

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## JAPAN

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### **Asada Milling Co., Ltd.**

253 Obata Kanra-machi , Kanra-gun, Gunma-ken JAPAN

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

Notes:All Drugs Products

60 - - - - Human and Animal Drugs

Notes:All Drugs Products

61 - - - - Human and Animal Drugs

Notes:All Drugs Products

62 - - - - Human and Animal Drugs

Notes:All Drugs Products

63 - - - - Human and Animal Drugs

Notes:All Drugs Products

64 - - - - Human and Animal Drugs

Notes:All Drugs Products

65 - - - - Human and Animal Drugs

Notes:All Drugs Products

66 - - - - Human and Animal Drugs

Notes:All Drugs Products

**Date Published : 02/13/2013**

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

### **Daito Kasei Kogyo Co Ltd**

441 , Kidani , Bizen, Okayama JAPAN

53 - - - - Cosmetics

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

Notes:Cosmetics;Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

**Date Published : 10/25/2017**

Date Published: 10/25/2017

Date Published: 10/25/2017

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

**Kanebo Cosmetics Inc.**

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
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	Date Published: 05/06/2013
64 - - - - Human and Animal Drugs	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

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**KOREA, REPUBLIC OF (SOUTH)**

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**Amaros Co., Ltd**

Jungwon-gu , 560 Dunchon-daero , Seongnam-si, KOREA, REPUBLIC OF (SOUTH)

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	
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	
63 - - - - Human and Animal Drugs	Date Published: 08/23/2017
Notes:All Drug and Drug Products	
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  
Notes:All Drug and Drug Products

Date Published: 08/23/2017

**Firson Co., Ltd.**

**Date Published : 05/11/2017**

Seobuk-Gu , 47 Handeul 1-ro , Seobuk-gu, Cheonan-si, Chungcheongnam-do KOREA, REPUBLIC OF (SOUTH)

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.

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

61 - - - - Human and Animal Drugs

Date Published: 05/11/2017

Notes:All Drug and Drug Products

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

Date Published: 05/11/2017

Notes:All Drug and Drug Products

77 - - - - Ear,Nose And Throat

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.

**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

55 - - - - 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

Notes:All drugs and drug products

64 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

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

80 - - - - General Hospital/Personal Use

Date Published: 09/06/2013



Desc:All Drugs and Drug Products

81 - - - - Hematology

Desc:All drugs and drug products

89 - - - - Physical Medicine

Desc:All drugs and drug products

Date Published: 09/04/2013

Date Published: 09/04/2013

**LG Chem, Ltd.**

129 Seogam-Ro , Igsan-Si, Jeonrabug-do KOREA, REPUBLIC OF (SOUTH)

50 - - - - Color Additiv Food/Drug/Cosmetic

53 - - - - Cosmetics

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

80 - - - - General Hospital/Personal Use

**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

Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013

**Seindni Co., Ltd.**

Seongbuk-gu , 610-304 16, Gireum-ro , Seoul, KOREA, REPUBLIC OF (SOUTH)

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 : 08/23/2017**

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

Date Published: 08/23/2017

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**MEXICO**

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**Compania Internacional de Comercio, S.A. P.I. de C.V.**

Calle Monzon (Juarez) No. 184 , Iztapalapa, Col. CERRO DE LA ESTRELLA , Mexico, Distrito Federal MEXICO

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

**Date Published : 05/17/2012**

Date Published: 05/17/2012

Date Published: 05/17/2012

Date Published: 05/17/2012

Date Published: 05/17/2012

Date Published: 05/17/2012

63 - - - - Human and Animal Drugs  
64 - - - - Human and Animal Drugs  
65 - - - - Human and Animal Drugs  
66 - - - - Human and Animal Drugs

Date Published: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012

**Farma Quimía S.A. de C.V.**

**Date Published : 02/23/2012**

Av Andre Marie Ampere No 11 , Parque Industrial Cuamatla , Cuautitlan Izcalli, Mex MEXICO

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

Date Published: 02/23/2012

Notes:All Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 02/23/2012

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 02/23/2012

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 02/23/2012

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 02/23/2012

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

**PROSANA DISTRIBUCIONES SA DE CV**

**Date Published : 07/12/2017**

Calle Oriente 225 97-1 , Iztacalco, Col. AGRICOLA ORIENTAL , Mexico, Distrito Federal MEXICO

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

Date Published: 07/12/2017

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 07/12/2017

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

60 - - - - Human and Animal Drugs

Date Published: 07/12/2017

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

61 - - - - Human and Animal Drugs

Date Published: 07/12/2017

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

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

Date Published: 07/12/2017

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

64 - - - - Human and Animal Drugs

Date Published: 07/12/2017

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

65 - - - - Human and Animal Drugs

Date Published: 07/12/2017

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

66 - - - - Human and Animal Drugs

Date Published: 07/12/2017

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

**Prosintesis S.A. de C.V.**

**Date Published : 06/17/2015**

Avenida Educacion s/n , Pueblo Santa Maria Mazatlan , Jilotzingo, Mexico MEXICO

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

Date Published: 06/17/2015

Notes:Problems: (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Date Published: 06/17/2015

Notes:Problems: (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Date Published: 06/17/2015