

U.S. Food & Drug Administration

## Import Alert 66-40

1

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**(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:** 07/15/2016

**Type:** DWPE

**Import Alert Name:**

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

### Reason for Alert:

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

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

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

### Guidance:

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

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

### Product Description:

Various drugs (See attachment)

### Charge:

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

OASIS Charge Code: DRUG GMPS

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

### AUSTRALIA

**Radpharm Scientific**  
**57 Oatley Court, Belconnen, AUSTRALIA**

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

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

Notes:Nexavir

Date Published: 09/10/2009

**BELGIUM****Laboratoria Qualiphar NV  
Rijksweg 9 , Bornem, Antwerp BELGIUM****Date Published : 01/18/2011**

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

**BRAZIL****Lima & Pergher Ind. Com. Rep Ltda  
Av Airon Borges Da Silva 740 , Minas Gerais, BRAZIL****Date Published : 07/15/2016**

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

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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: 07/15/2016

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Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

**Lima & Pergher Industria e Comercio S/A  
Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL****Date Published : 07/15/2016**

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

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

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

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

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

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

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

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Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

**CANADA****Aleeda Inc  
7155 Tomken Rd , Mississauga, ON CANADA****Date Published : 05/29/2012**

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

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

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

Date Published: 05/29/2012

66 - - - - Human and Animal Drugs

**Attix Pharmaceuticals Inc.****184 Front St Unit 801 , Toronto, Ontario CANADA**

55 - - - - Pharm Necess &amp; 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

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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 : 04/10/2014****Baxter Healthcare****Unknown Street , Mississauga, ON CANADA**

55 R - - 55 Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent)

Desc:0.9% Sodium Chloride Injection USP

65 R - - 12 Potassic Saline (Injection) (Replenisher)

Desc:0.9% Sodium Chloride Injection USP

Date Published: 04/10/2014

Date Published: 04/10/2014

**CMI Cosmetic Manufacturers Inc.****90 Moyal Court , Concord, On CANADA**

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

Notes:(GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes:(GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

**Date Published : 09/28/2015**

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

**Date Published : 12/10/2015****Gemini Packaging Ltd.****12071 Jacobson Way , Richmond, British Columbia CANADA**

55 - - - - Pharm Necess &amp; 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: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

**Date Published : 03/14/2014****International Laboratories (Canada) Ltd.****63 Skyline Cres NE , Calgary, Alberta CANADA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug Products

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

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

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

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

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

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

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

**Pax-All Manufacturing Inc.  
7115 Tomken Road , Mississauga, ON CANADA**

**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

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

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

**CHINA**

**Attix Pharmaceuticals (Xiamen)  
Xiangyue Road , NO. 7 Xinganlu , Shamen, Fujian CHINA**

**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

Date Published: 05/13/2016

Date Published: 05/13/2016

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)  
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

**BOAI NKY PHARMACEUTICALS LTD.  
Suites 1808-9 Guohua Building, 857 Dagu- , Nan Road, Hexi , Tianjin,China , tianjin, CN-12 CHINA**

**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

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63 - - - - Human and Animal Drugs  
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Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

**Beijing Lunarsun Pharmaceutical Co., Ltd**  
**C1 802 Yangguang Plaza, No. 68 Anli Rd , Chaoyang Dis. , Beijing, CHINA**

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

Date Published: 04/19/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drugs and Drug Products

Date Published: 04/19/2016

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drugs and Drug Products

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

**Beijing Shunxin Meihua Bio-technical Co., Ltd.**  
**No 7 Fuqiandongjie , Shunyi District , Shunyiqiu, Beijingshi CHINA**

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

Date Published: 07/22/2014

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

60 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

61 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

62 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

63 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

64 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

65 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

Date Published: 07/22/2014

66 - - - - Human and Animal Drugs  
Notes:All drug products; Firm refused FDA inspection

**Beijing Taiyang Pharmaceutical Industry Co Ltd**  
**No 1 Shuangqiao (E) Road , Chaoyang, Beijing CHINA**

**Date Published : 04/29/2016**

Date Published: 04/29/2016

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

Date Published: 04/29/2016

56 - - - - Antibiotics (Human/Animal)  
Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 04/29/2016

60 - - - - Human and Animal Drugs  
Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 04/29/2016

61 - - - - Human and Animal Drugs  
Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 04/29/2016

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

Date Published: 04/29/2016

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

Date Published: 04/29/2016

64 - - - - Human and Animal Drugs  
Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 04/29/2016

65 - - - - Human and Animal Drugs  
Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 04/29/2016

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

**Bluetech Chemicals Limited**  
**Rm 703, No. 25, Lane 175 , Shanghai, CN-31 CHINA**

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

Date Published: 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products

Date Published: 09/17/2010

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products

Date Published: 09/17/2010

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

Date Published: 09/17/2010

61 - - - - Human and Animal Drugs  
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Date Published: 09/17/2010

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Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

**Boai NKY Pharmaceuticals Ltd.****Date Published : 05/18/2015****No.1888 Wenhua Road , Boai , Jiaozuo, Henansheng CHINA**

Date Published: 05/18/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug and drug products;(GMP) Good Manufacturing Practices

Date Published: 05/18/2015

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

Date Published: 05/18/2015

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

Date Published: 05/18/2015

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Date Published: 05/18/2015

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

Date Published: 05/18/2015

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

Date Published: 05/18/2015

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

Date Published: 05/18/2015

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

**Boai NKY Pharmaceuticals Ltd.****Date Published : 09/17/2010****No. 9 Zhongshan Road , Boai County , Jiaozuo, Henan CHINA**

Date Published: 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products

Date Published: 09/17/2010

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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Date Published: 09/17/2010

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64 - - - - Human and Animal Drugs  
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Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

**Boai Xinda Food Co., Ltd.****Date Published : 09/17/2010****The North Of Dong Wang He, Xiaojing , Boai, Henansheng CHINA**

Date Published: 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products

Date Published: 09/17/2010

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products

Date Published: 09/17/2010

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Date Published: 09/17/2010

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Notes:All drug products

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

65 - - - - Human and Animal Drugs

Date Published: 09/17/2010

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

**Changshu Huangang Pharmaceuticals Co., Ltd  
Yuxiang Village, Shanghu Town, , Changshu City, Jiangsu Province CHINA**

**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

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

**Changzhou SPL Company, Ltd.  
West Rd. , Hutang Township, Wujin City , Changzhou City, Jiangsusheng CHINA**

**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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)  
Notes:All heparin products 3/10/2008  
55 R - - 99 Pharmaceutic Necessities, N.E.C.  
Notes:All heparin products 3/10/2008  
57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)  
Notes:All heparin products 3/10/2008  
61 L - - 08 Heparin Sodium (Anti-Coagulant)  
Notes:All heparin products 3/10/2008  
61 L - - 22 Anti-Coagulant Heparin Sol  
Notes:All heparin products 3/10/2008  
61 L - - 30 Heparin Calcium (Anti-Coagulant)  
Notes:All heparin products 3/10/2008  
74 L - - 15 Heparin Coating Chemicals,  
Notes:All heparin products 3/10/2008  
80 N - - ZW Heparin Vascular access flush  
Notes:All heparin products 3/10/2008  
81 J - - BR Test, Heparin Neutralization  
Notes:All heparin products 3/10/2008  
81 J - - OX Analyzer, Heparin, Automated  
Notes:All heparin products 3/10/2008  
81 K - - FF Assay, Heparin  
Notes:All heparin products 3/10/2008  
88 I - - AZ Heparin  
Notes:All heparin products 3/10/2008

**China Resources Sanjiu Medical and Pharmaceutical Co., Ltd.  
No. 1 Guanqing Rd , Guanlan Hi-Tech Park, Longhua District , Shenzhen , Guangdong CHINA**

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

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

Date Published: 09/03/2014

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

<b>Chongqing Imperial Bio Chem Co</b> <b>5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbei, Chongqing, CHINA</b>	<b>Date Published : 09/10/2009</b>
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
<b>Chongqing Lummy Pharmaceutical C</b> <b>NO. 2 4th Branch Road Hua'Nan Rd , Changshou , Zhongqing, Chongqing CHINA</b>	<b>Date Published : 04/19/2016</b>
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 Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
<b>Chongqing Lummy Pharmaceutical Co. Ltd.</b> <b>Economic And Technological , NO. 2 the 4th Branch Rd, Huaa??Nan Road , Chongqing, Changshou District CHINA</b>	<b>Date Published : 04/19/2016</b>
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 Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
<b>Chongqing Paiquiag Agribyproduct Co., Ltd</b> <b>158 Gonglongpo , Yudong , Chongqing, CHINA</b>	<b>Date Published : 09/10/2009</b>
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



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

**Fercy Personal Care Products Co., Ltd  
An'Wen Industrial Zone Pan County , Jinhua, Zhejiang CHINA**

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

Date Published: 05/10/2012

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug Products

Date Published: 05/10/2012

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug Products

Date Published: 05/10/2012

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

Date Published: 05/10/2012

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

Date Published: 05/10/2012

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

Date Published: 05/10/2012

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

Date Published: 05/10/2012

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

Date Published: 05/10/2012

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

Date Published: 05/10/2012

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

**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**

Date Published: 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products

Date Published: 09/17/2010

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

**Guangdong Pharmaceutical Factory**

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

**91 Fangcun Dadao , Guangzhou, Guangdong CHINA**

Date Published: 09/10/2009

61 G - - - - A-Bacterial Pt. II (Not Antibiotic)  
Notes:Active Pharmaceutical Ingredients 12/12/1997

Date Published: 09/10/2009

61 H - - - - A-Bacterial Pt. III (Not Antibiotic)  
Notes:Active Pharmaceutical Ingredients 12/12/1997

**Guangzhou Haishi Biological Technology Co., Ltd.**

**Date Published : 03/14/2016**

**1/F,2/F, Bldg.1, no.3, Songyuan Rd , New Industrial Zone, No.11 She, Xiamao , Guangdong, Guangzhou CHINA**

Date Published: 03/14/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug and Drug Products

Date Published: 03/14/2016

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug and Drug Products

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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: 03/14/2016

Date Published: 03/14/2016

Date Published: 03/14/2016

**Hebei Yuxing Bio-Engineering Co Ltd**  
**Xicheng District , Ningjin County , Ningjin, Hebei CHINA**

**Date Published : 07/08/2016**

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

Date Published: 07/08/2016

Desc:All Drugs and Drug Products

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

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

Date Published: 07/08/2016

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 07/08/2016

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

60 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

61 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

62 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

63 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

64 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

65 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

66 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

**Jinan Jinda Pharmaceutical Chemistry Co., Ltd.**  
**No.6121 Longquan Road , Zhangqui City (Jinan), Shandong CHINA**

**Date Published : 11/25/2015**

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

Date Published: 11/25/2015

Notes:All Drug and Drug Products

60 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 11/25/2015

Notes:All Drug and Drug Products

**Kunshan Chemicals & Pharmaceutical Factory**  
**No 242 Kun Tai Road , Kunshan City , Jiangsu, CHINA**

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

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

Date Published: 09/10/2009

Notes:8/30/2007

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/10/2009

Notes:8/30/2007

60 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:8/30/2007

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:8/30/2007

62 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:8/30/2007

63 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:8/30/2007

64 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:8/30/2007

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

**Nanjing Maohai Biotech Co.**  
**8 Developing Zone , Yaxi Town, Gaochun County , Nanjing Jiangsu Province, CHINA**

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

Date Published: 10/18/2011

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)  
 Desc:Crude Heparin (Pharmaceutical Necessity)

Date Published: 10/18/2011

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

**Nantong Strip Medical Supply Co Ltd**  
**182 Yue Long Nan Road , Building A , Nantong, Jiangsu CHINA**

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

Date Published: 03/27/2013

50 - - - - Color Additiv Food/Drug/Cosmetic  
 Notes:All Drug Products

Date Published: 03/27/2013

53 - - - - Cosmetics  
 Notes:All Drug Products

Date Published: 03/27/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All Drug Products

Date Published: 03/27/2013

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

Date Published: 03/27/2013

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

Date Published: 03/27/2013

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

Date Published: 03/27/2013

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

Date Published: 03/27/2013

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

Date Published: 03/27/2013

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

Date Published: 03/27/2013

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

Date Published: 03/27/2013

80 - - - - General Hospital/Personal Use  
 Notes:All Drug Products

**Ningbo Smart Pharmaceutical Co., Ltd.**  
**Sec. C1, Ningbo Eco. & , Tech. Dev. Zone, Beilun District , Ningbo, Zhejiang CHINA**

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

Date Published: 04/08/2011

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All Drug Products

Date Published: 04/08/2011

56 - - - - Antibiotics (Human/Animal)  
 Notes:All Drug Products

Date Published: 04/08/2011

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

Date Published: 04/08/2011

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

Date Published: 04/08/2011

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

Date Published: 04/08/2011

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

Date Published: 04/08/2011

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

Date Published: 04/08/2011

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

Date Published: 04/08/2011

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

**Ningbo Unichem Household Products Co Ltd.**  
**NO. 27 Luotuo Jiedao Jiushu Fangnanlu , Zhenhai , Ningbo, Zhejiang CHINA**

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

Date Published: 03/05/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All Drug Products

Date Published: 03/05/2013

56 - - - - Antibiotics (Human/Animal)  
 Notes:All Drug Products

Date Published: 03/05/2013

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

Date Published: 03/05/2013

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

Date Published: 03/05/2013

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

Date Published: 03/05/2013

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

Date Published: 03/05/2013

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

Date Published: 03/05/2013

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

Date Published: 03/05/2013

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

**Northeast Pharmaceutical Group Co., Ltd.**  
**37 Zhonggong Bei Street , Tiexi District , Shenyang, Liaoning CHINA**

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

Date Published: 08/28/2010

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

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

intended for pharmaceutical use are subject to DWPE	
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	

**Shanghai Huhui Daily Use Chemical Products Co., Ltd.  
Pudong District , NO 8 Ludalu , Shanghai, Shanghai CHINA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 04/03/2013
60 - - - - Human and Animal Drugs	Date Published: 04/03/2013
61 - - - - Human and Animal Drugs	Date Published: 04/03/2013
62 - - - - Human and Animal Drugs	Date Published: 04/03/2013
63 - - - - Human and Animal Drugs	Date Published: 04/03/2013
64 - - - - Human and Animal Drugs	Date Published: 04/03/2013
65 - - - - Human and Animal Drugs	Date Published: 04/03/2013
66 - - - - Human and Animal Drugs	Date Published: 04/03/2013

**Shanghai Life-Beauty Cosmetics Co., Ltd.  
No 2000 Fengxiang Rd , Baoshan District , Shanghai, CHINA**

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

53 E - - 06 Shampoos (Hair Preparations, Non-coloring) Desc:Dandruff Shampoo Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
53 F - - 04 Hair Shampoos (Coloring) (Hair Coloring Preparations) Desc:Dandruff Shampoo Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
53 J - - 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C. Desc:Hand Sanitizers Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014

Date Published: 03/28/2014

53 J - - - Personal Cleanliness

Desc:Antiperspirants

Notes:(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

53 L - - 03 Face,Body,and Hand (excluding Shaving Preparations) (Skin Care Preparations)

Desc:Hand Sanitizers

Notes:(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

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

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

60 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

61 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

62 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

63 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

64 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

65 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

66 - - - - Human and Animal Drugs

Notes:All Drugs;(GMP) Good Manufacturing Practices

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.  
387 Shangqiulu , Shonghaish , Shonghaish CHINA****Date Published : 09/10/2009**

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 - - IS 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.  
1317 Jianchuanlu , Minhang District , Shanghai, Shanghai CHINA****Date Published : 09/10/2009**

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

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.

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)

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.

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs

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.

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs

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.

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs

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.

Date Published: 09/10/2009

63 - - - - Human and Animal Drugs

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.

Date Published: 09/10/2009

64 - - - - Human and Animal Drugs

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.

Date Published: 09/10/2009

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.

**Shanhgai No.1 Biochem & Pharma Co., Ltd.  
494 Zhongxing Road , Room A-403 , Shanhgai, CHINA**

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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

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

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

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

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

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

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

61 L - - 22 Anti-Coagulant Heparin Sol

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

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

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

74 L - - IS Heparin Coating Chemicals,

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

80 N - - ZW Heparin Vascular access flush

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

81 J - - BR Test, Heparin Neutralization

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

81 J - - OX Analyzer, Heparin, Automated

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

81 K - - FF Assay, Heparin

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

88 I - - AZ Heparin

Date Published: 09/10/2009

Notes:All heparin products 1/21/2009

**Sichuan Pharmaceutical Co., Ltd.  
189 Hua Long Road , Pengzhou, Sichuan Province CHINA**

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

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

Date Published: 05/08/2012

Notes:All drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 05/08/2012

Notes:All drug products

60 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

61 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

62 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

63 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

64 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

65 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

66 - - - - Human and Animal Drugs

Date Published: 05/08/2012

Notes:All drug products

**Suzhou No. 4 Pharmaceutical Factory  
171 Baiyanglu , Suzhou City, Jiangsusheng CHINA**

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

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

Date Published: 07/10/2014

56 - - - - Antibiotics (Human/Animal)

Date Published: 07/10/2014

60 - - - - Human and Animal Drugs

Date Published: 07/10/2014

61 - - - - Human and Animal Drugs

Date Published: 07/10/2014

62 - - - - Human and Animal Drugs

Date Published: 07/10/2014

63 - - - - Human and Animal Drugs

Date Published: 07/10/2014

64 - - - - Human and Animal Drugs

Date Published: 07/10/2014

65 - - - - Human and Animal Drugs

Date Published: 07/10/2014

66 - - - - Human and Animal Drugs

Date Published: 07/10/2014

**Taizhou Kanglin Health Protection Prods Co  
No 1 Yaocheng Ave Room 1754 Bldg 1 , Taizhou, CHINA**

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

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

Date Published: 01/15/2013

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

Date Published: 01/15/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 01/15/2013

60 - - - - Human and Animal Drugs

Date Published: 01/15/2013

61 - - - - Human and Animal Drugs

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

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

**Taizhou Kanglin Health Protection Products Co Ltd.  
 8 Dongjinlu , Hailing , Taizhou, Jiangsu CHINA**

**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  
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 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

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

**Taizhou Kanglin Health Protection Products Co., Ltd.  
 The West of Qiliqiao , Economic Development Zone , Taizhou, Jiangsu Province CHINA**

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

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

**Taizhou Kanglin Health Protection Products Co.,Ltd.  
 No.1 East 1 Rd. Economical Dev. , Taizhou, Jiangsu, CHINA**

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

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

**Tianjin Boai NKY International Ltd.  
 Suites 1808-9 Guohua Building , Dagu-Nan Road, Hexi District , Tianjin, CN-12 CHINA**

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

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

**Tianjin Boai Pharmaceutical Co. Ltd  
 No.4, Ronghua Road, Xiqing District , Yong Hong Industry Zone, Nan He Town , Tianjin, Tianlushi CHINA**

**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

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products

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

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

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

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

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

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

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

**Tianjin Boai Pharmaceutical Ltd. co.**

**6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin, CN-12 CHINA**

**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

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug products

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug products

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

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

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

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

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

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

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

**Tianjin Zhongan Pharmaceutical Co., Ltd.**

**188 Fukang Road , Xiqing District , Tianjin, CHINA**

**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

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

**Xiamen Origin Biotech Co. Ltd.**

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

**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

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)  
Desc:All Drugs and Drug Products  
Notes:(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





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.

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

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

**No. 3 Platform Jinding Tech Zone , Kunming, Yunnan CHINA**

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

Date Published: 05/20/2016

Notes:All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 05/20/2016

Notes:All Drug and Drug Products

60 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 05/20/2016

Notes:All Drug and Drug Products

**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 Waisha Branch Rd , Jiaojiang , Taizhou City, Zhejiang Province 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 Hisun Pharmaceutical Co., Ltd.**

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

**46 Waisha Road , Jiaojiang District , Taizhou City, Zhejiang CHINA**

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

Date Published: 09/09/2015

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

56 H - S 25 Daunorubicin Hydrochloride (Antitumor), Active Pharm Ingred/Chems for Further Manuf

Date Published: 02/18/2016

Desc:Daunorubicin Hydrochloride

Notes:

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/09/2015

Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe: Bleomycin 56H[ ]S10; Capreomycin 56F[ ]S15;Doxorubicin Hydrochloride 56H[ ]S24;Mitomycin 56H[ ]S45;Tazobactam 56Y[ ]S99;CDER has recommended Sulbactam Sodium, 56M[ ]02, be excluded from dwpe under this firm listing;

60 - - - - Human and Animal Drugs

Date Published: 09/09/2015

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

61 - - - - Human and Animal Drugs

Date Published: 09/09/2015

Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe:Granisetron 61T[ ]S24; CDER has recommended Mesna, 61R[ ]22, be excluded from dwpe under this firm listing.

62 - - - - Human and Animal Drugs

Date Published: 09/09/2015

Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Cladribine 62I[ ]S74;

Cyclophosphamide 62I[[]]15 finished form and API; Cytarabine 62I[[]]S16;Floxuridine 62V[[]]S06; Fludarabine 62I[[]]S79;Ivermectin 62L[[]]S47

63 - - - - Human and Animal Drugs Notes:All Drugs;These products are excluded from dwpe:Adenosine 63E[[]]S18	Date Published: 09/09/2015
64 - - - - Human and Animal Drugs Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/09/2015
65 - - - - Human and Animal Drugs Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/09/2015
66 - - - - Human and Animal Drugs Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/09/2015

### Zhejiang Qianfei Enterprise Co Ltd

#### No. 173, Wulian Road, Yiting Town, Yiwu , Zhejiang, CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
63 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
64 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
65 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015
66 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices	Date Published: 11/24/2015

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

### Zhejiang Zonebanner Jiuzhou

#### Waisha Road 99 Jia , Taizhou, CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 03/18/2014
56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 03/18/2014
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/18/2014

**Date Published : 03/18/2014**

## DENMARK

### Leo Pharma A/S

#### Industriparken 55 , Ballerup, DENMARK

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant) Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.	Date Published: 03/01/2011
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**

### Leo Pharmaceutical Products

#### A 8 , Copenhagen, DENMARK

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant) Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.	Date Published: 03/01/2011
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**

### Leo Pharmaceutical Products

#### Park Alle 26 , Vejen, DENMARK

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant) Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.	Date Published: 03/01/2011
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**

### Plum A/S

**Date Published : 05/13/2015**

**Frederik Plums Vej 2 , Assens, DENMARK**

65 F - - 06 Water, Purified (Eyewash)  
 Desc:Plum Emergency Eyewash (Sterile)

Date Published: 05/13/2015

**FRANCE****Compagnie Oris Industrie Lpib  
B.P. #2 91 Gif-Sur-Yvette , Saclay, FRANCE****Date Published : 09/10/2009**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

63 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

64 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

**Compagnie Oris Industrie, S.A.  
Centre D'Etudes Nucleaires De Marcoule , BP 171f , Bagnols, FRANCE****Date Published : 09/10/2009**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

63 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

64 - - - - Human and Animal Drugs  
 Notes:Selenomethionine 75 injection

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

**Societe Chimique Grevis  
Avenue De La Paix , Limay, FRANCE****Date Published : 09/10/2009**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)  
 Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs  
 Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs  
 Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs  
 Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

63 - - - - Human and Animal Drugs  
 Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

**GERMANY****Biologische Heilmittel Heel Gmbh  
P O Box 729 , Ruhrstrasse 14 , Baden-Baden, GERMANY****Date Published : 09/10/2009**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs  
 Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported

Date Published: 09/10/2009

from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

62 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

63 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

64 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

65 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

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

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

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

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

66 - - - - Human and Animal Drugs

Date Published: 07/08/2013

## **GREECE**

### **CHIA GH LTD.**

**Ag. Mina 144 , Chios, GREECE**

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

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

## **GUADELOUPE**

### **Ligne St. Barth SAS**

**Route De Saline , Lorient , Saint Barthelemy, GUADELOUPE**

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

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

## **HONG KONG**

### **CBSCHEM LIMITED**

**13Floor, Nan Fung Ind. City , No. 18 Tin Hau Road , TUEN MUN, NEW TERRITORIES HONG KONG**

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

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

Date Published: 08/31/2013

Desc:All drugs and drug products

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

Date Published: 08/31/2013

Desc:All drugs and drug products

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

Date Published: 08/31/2013

Notes:All drugs and drug products	
56 - - - - Antibiotics (Human/Animal)	Date Published: 08/31/2013
Desc:All drugs and drug products	
60 - - - - Human and Animal Drugs	Date Published: 08/31/2013
Notes:All drugs and drug products	
61 - - - - Human and Animal Drugs	Date Published: 08/31/2013
Notes:All drugs and drug products	
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
Desc:All drugs and drug products	
88 - - - - Pathology	Date Published: 08/31/2013
Desc:All drugs and drug products	

**Chan Yat Hing Medicine Factory** **Date Published : 12/03/2015**  
**Flat 3, 9/F, Fuk Keung Industrial Bldg. , 66-68 Tong Mei Road , Mongkok, 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, 188-202 Texaco Road , Tsuen Wan, Kowloon, 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 Notes:All Drug Products	Date Published: 03/04/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014

**Seedings****18 Tin Hau Rd. , Room 3, 13/F, Tower 4 , Hong Kong, Hong Kong HONG KONG****Date Published : 08/31/2013**

35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling Notes:All drugs and drug products	Date Published: 08/31/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Notes:All drugs and drug products	Date Published: 08/31/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 08/31/2013
56 - - - - Antibiotics (Human/Animal) Notes:All drugs and drug products	Date Published: 08/31/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
78 - - - - Gastroenterological & Urological Notes:All drugs and drug products	Date Published: 08/31/2013
88 - - - - Pathology Notes:All drugs and drug products	Date Published: 08/31/2013

**HUNGARY****Teva Pharmaceutical Works Private Limited Company****Tancsics Mihaly ut 82 , Godollo, Pest HUNGARY****Date Published : 05/27/2016**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe: Amikacin/56D[[]]06; Bleomycin / 56H[[]]10	Date Published: 05/27/2016
60 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
61 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
62 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
63 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
64 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
65 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
66 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016

**INDIA****Aadivighnesh Chem PVT. LTD.****A/7 Badrinath Apartment , Simpoli Road, Borivali (West) , Mumbai , Maharashtra INDIA****Date Published : 05/05/2014**

56 C - - 66 Cefazidime (Cephalosporins) Desc:Ceftazimide for Injection USP (Sterile)	Date Published: 05/05/2014
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**Aarti Drugs Limited****Plot No. E-22, M.I.D.C., Tarapur , Palghar, Maharashtra INDIA****Date Published : 03/23/2015**

Date Published: 03/23/2015

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

Date Published: 03/23/2015

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

**Aarti Drugs Ltd****Date Published : 03/23/2015****G-60 Boisar MIDC Tarapur , Tal. Palghar, District Thane , Tarapur, Maharashtra INDIA**

Date Published: 03/23/2015

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

Date Published: 03/23/2015

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

Date Published: 03/23/2015

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

**Akorn India PVT****Date Published : 08/21/2015****Khasra 5/1, 5/2, 5/3 Village , Nihalgarth Tehsil , Paonta Sahib, Simour, Himachal Pradesh INDIA**

Date Published: 08/21/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

60 - - - - Human and Animal Drugs  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

61 - - - - Human and Animal Drugs  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

62 - - - - Human and Animal Drugs  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

63 - - - - Human and Animal Drugs  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

64 - - - - Human and Animal Drugs  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

65 - - - - Human and Animal Drugs  
Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015

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

**Amsal Chem Pvt. Ltd.****Date Published : 04/11/2013****A-1/401-402-403, GIDC , Ankleshwar, Gujarat, INDIA**

Date Published: 04/11/2013

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

Date Published: 04/11/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 04/11/2013

60 - - - - Human and Animal Drugs

Date Published: 04/11/2013

61 - - - - Human and Animal Drugs

Date Published: 04/11/2013

62 - - - - Human and Animal Drugs

Date Published: 04/11/2013

63 - - - - Human and Animal Drugs

Date Published: 04/11/2013

64 - - - - Human and Animal Drugs

Date Published: 04/11/2013

65 - - - - Human and Animal Drugs

Date Published: 04/11/2013

66 - - - - Human and Animal Drugs

**Apotex Pharmachem India Pvt Ltd.****Date Published : 04/01/2014****Plot No.: 1A, Bommasandra , Industrial Area, 4th Phase , Bangalore, INDIA**



Date Published: 04/01/2014

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

56 - - - - Antibiotics (Human/Animal)  
Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

60 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

61 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

62 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices This product is excluded from DWPE: Riluzole tablets 62J[[]]16;

Date Published: 04/01/2014

63 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

64 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

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

Date Published: 04/01/2014

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

**Apotex Research Private Limited****Date Published : 09/22/2014****Plot 1/2, Site #2 Bommasandra Ind. Area , 4th Phase, Jigani Link Rd., Jigani Hobli , Bangalore, Karnataka State INDIA**

Date Published: 09/22/2014

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:Good Manufacturing Practices (GMP);

Date Published: 09/22/2014

56 - - - - Antibiotics (Human/Animal)  
Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

60 - - - - Human and Animal Drugs  
Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

61 - - - - Human and Animal Drugs  
Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

62 - - - - Human and Animal Drugs  
Notes:Good Manufacturing Practices (GMP); These products are excluded from DWPE Riluzole tablets (62J[[]]16) and Abacavir tablets (62V[[]]17).

Date Published: 09/22/2014

63 - - - - Human and Animal Drugs  
Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

64 - - - - Human and Animal Drugs  
Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

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

Date Published: 09/22/2014

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

**Canton Laboratories Pvt. Ltd.****Date Published : 04/10/2014****110 A & B Gidc Estate , Makarpura Road; M I Estate , Vadodara, Gujarat INDIA**

Date Published: 04/10/2014

54 B - - - - Mineral

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

Date Published: 04/10/2014

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

**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**

Date Published: 07/13/2015

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

Date Published: 07/13/2015

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Amikacin inj, antibiotic / 56D[[]]06

Date Published: 07/13/2015

60 - - - - Human and Animal Drugs  
Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

Date Published: 07/13/2015

61 - - - - Human and Animal Drugs  
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**  
**Plot No. 48, Temple Rock Enclave , Tarbund X Road , Secunderabad, INDIA**

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

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.**  
**Survey No 270 (Old no.: 364/1), , Kanukuta Road, , Shivampet Mandal, Medak District, Andhra Pradesh INDIA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 04/08/2011
56 - - - - Antibiotics (Human/Animal)	Date Published: 04/08/2011
60 - - - - Human and Animal Drugs	Date Published: 04/08/2011
61 - - - - Human and Animal Drugs	Date Published: 04/08/2011
62 - - - - Human and Animal Drugs	Date Published: 04/08/2011
63 - - - - Human and Animal Drugs	Date Published: 04/08/2011
64 - - - - Human and Animal Drugs	Date Published: 04/08/2011
65 - - - - Human and Animal Drugs	Date Published: 04/08/2011
66 - - - - Human and Animal Drugs	Date Published: 04/08/2011

**Ipca Laboratories LTD**  
**1 Pharma Zone , Pithampur, Madhya Pradesh INDIA**

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

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 This product is excluded from dwpe: Hydroxychloroquine Sulfate/62L[]29	Date Published: 03/24/2015
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	

Date Published: 03/24/2015

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

Date Published: 03/24/2015

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

**Ipca Laboratories Limited****Date Published : 03/24/2015****Plot No. 65 and 99, Danudyog , Ind. Estate, Piparia , Silvasa (D and NH), INDIA**

Date Published: 03/24/2015

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

Date Published: 03/24/2015

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

Date Published: 03/24/2015

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

Date Published: 03/24/2015

62 - - - - Human and Animal Drugs  
Notes:All Drugs;(GMP) Good Manufacturing Practices These products are excluded from dwpe: Hydroxychloroquine Sulfate/62L[]29

Date Published: 03/24/2015

63 - - - - Human and Animal Drugs  
Notes:All Drugs;(GMP) Good Manufacturing Practices; These products are excluded from dwpe: Propranolol Hydrochloride/63E[]13

Date Published: 03/24/2015

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

Date Published: 03/24/2015

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

Date Published: 03/24/2015

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

**Date Published : 01/22/2015****Ipca Laboratories Limited****Village Sejavta , Ratlam, Madhya Pradesh INDIA**

Date Published: 01/22/2015

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

Date Published: 01/22/2015

56 - - - - Antibiotics (Human/Animal)  
Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 01/22/2015

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

Date Published: 01/22/2015

61 - - - - Human and Animal Drugs  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe:Sulfamethoxazole/ 61G[]  
[]57 Trimethoprim/61H[]03 Ondansetron/61T[]26, 61T[]27, 61T[]28;This product is excluded from DWPE: Chloroquine  
Phosphate API/61A[]06

Date Published: 01/22/2015

62 - - - - Human and Animal Drugs  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Hydroxychloroquine  
Sulfate/62L[]29

Date Published: 01/22/2015

63 - - - - Human and Animal Drugs  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices:These products are excluded from dwpe: Propranolol  
Hydrochloride/63E[]13

Date Published: 01/22/2015

64 - - - - Human and Animal Drugs  
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from DWPE: Furosemide/64BQS24

Date Published: 01/22/2015

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

Date Published: 01/22/2015

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

**Date Published : 07/10/2013****Kamud Drugs Pvt. Ltd.****N-608, MIDC, Kupwad , Sangli, M.S., INDIA**

Date Published: 07/10/2013

50 - - - - Color Additiv Food/Drug/Cosmetic  
Notes:All drug and drug products

Date Published: 07/10/2013

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)  
Notes:All drug and drug products

Date Published: 07/10/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug and drug products

Date Published: 07/10/2013

56 - - - - Antibiotics (Human/Animal)  
Notes:All drug and drug products

Date Published: 07/10/2013

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

Date Published: 07/10/2013

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

Date Published: 07/10/2013

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

Date Published: 07/10/2013

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

Date Published: 07/10/2013

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

Date Published: 07/10/2013

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

Date Published: 07/10/2013

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

**Konduskar Laboratories Pvt Ltd, T-47 Kagel Hatkanangale Five Star, MIDC , Talandage (Village), Tal: Kagal, , Maharashtra State, INDIA**

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

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

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

**Marck Biosciences Ltd.**

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

**Plot No. 876, N.H. - 8 , Vill: Hariyala, Tal: Matar , Kheda, Gujarat INDIA**

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

Date Published: 03/12/2014

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Notes:All Drug Products

**Megafine Pharma (P) Limited**

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

**48 - 51/201 Plot No 31 - 35 , Lakhamapur, Maharashtra INDIA**

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

Date Published: 10/14/2015

Notes:All Drug and Drug Products

60 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 10/14/2015

Notes:All Drug and Drug Products

**Micro Labs Limited**

**Date Published : 08/21/2013**

**Plot No. 113-116 4th Phase KIADB , Bommasandra Industrial Area,Anekal Taluk , Bangalore, INDIA**

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

Date Published: 08/21/2013

Desc:All drugs and drug products

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

Date Published: 08/21/2013

Notes:Desc -- All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 08/21/2013

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs

Date Published: 08/21/2013

Notes:Desc -- All drugs and drug products

Date Published: 08/21/2013

61 - - - - Human and Animal Drugs  
Notes:Desc -- All drugs and drug products

Date Published: 08/21/2013

62 - - - - Human and Animal Drugs  
Notes:Desc -- All drugs and drug products

Date Published: 08/21/2013

63 - - - - Human and Animal Drugs  
Notes:Desc -- All drugs and drug products

Date Published: 08/21/2013

64 - - - - Human and Animal Drugs  
Notes:Desc -- All drugs and drug products

Date Published: 08/21/2013

65 - - - - Human and Animal Drugs  
Notes:Desc -- All drugs and drug products

Date Published: 08/21/2013

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

**Micro Labs Limited****Date Published : 09/19/2014****S - 155 Plot No , Verna Industrial Estate , Vasco Da Gama, Goa INDIA**

Date Published: 09/19/2014

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drugs and drug products (GMP) Good Manufacturing Practices

Date Published: 09/19/2014

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

Date Published: 09/19/2014

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

Date Published: 09/19/2014

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

Date Published: 09/19/2014

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

Date Published: 09/19/2014

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

Date Published: 09/19/2014

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

Date Published: 09/19/2014

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

Date Published: 09/19/2014

**Nivedita Chemicals P ITd****Date Published : 11/23/2011****A14 MIDC Andheri East , Mumbai, IN-MH INDIA**

Date Published: 11/23/2011

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

60 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic)  
Desc:Chlorpheniramine maleate

Date Published: 11/23/2011

61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)  
Desc:Chlorpheniramine maleate

Date Published: 11/23/2011

61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)  
Desc:Ppyrilamine maleate Ppyrilamine maleate USP

Date Published: 11/23/2011

61 X - - 99 Anti-Histaminic N.E.C.  
Desc:Ppyrilamine maleate Ppyrilamine maleate USP

Date Published: 11/23/2011

61 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

62 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

63 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

64 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

65 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

66 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

**Nivedita Chemicals Pvt. Ltd.****Date Published : 11/23/2011****A-14 M.I.D.C. Andheri (East) , Maharashtra, MS INDIA**

Date Published: 11/23/2011

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

60 - - - - Human and Animal Drugs  
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic)  
Desc:Chlorpheniramine maleate

Date Published: 11/23/2011

61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)  
Desc:Ppyrilamine maleate Ppyrilamine maleate USP

Date Published: 11/23/2011

61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)  
Desc:Chlorpheniramine maleate

Date Published: 11/23/2011

61 X - - 99 Anti-Histaminic N.E.C.  
Desc:Ppyrilamine maleate Ppyrilamine maleate USP

Date Published: 11/23/2011

61 - - - - Human and Animal Drugs

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

**Pan Drugs Limited****192 G I D C Makarpura Industrial Estate , M I Estate , Vadodara, Gujarat INDIA****Date Published : 12/08/2015**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Antibiotics;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
60 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
61 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
62 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
63 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
65 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
66 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015

**Pan Drugs Ltd.****167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA****Date Published : 05/05/2015**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Antibiotics;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
60 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
61 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
62 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
63 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
65 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
66 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015

**Polydrug Laboratories Pvt. Ltd.****Plot N37, Ambernath Industrial Area , Anand Nagar MIDC , Mumbai, Maharashtra INDIA****Date Published : 09/11/2015**

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All Drugs Notes:Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
60 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
61 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
62 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
63 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
65 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
66 - - - - Human and Animal Drugs	Date Published: 09/11/2015

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

**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

**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

**Ranbaxy Laboratories Limited  
Phase III Industrial Area SAS Nagar , Mohali, Punjab, 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 : 09/13/2013**

Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
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 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013

**Sentiss Pharma Pvt. Ltd.  
Village Khera Nihla, , Tehsil Nalargarh , 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  
 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, INDIA**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 60 - - - - Human and Animal Drugs  
 61 - - - - 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

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

**Sri Krishna Pharmaceuticals Ltd. - Unit II  
 A-35, IDA, Nacharam , Hyderabad, Andhra Pradesh, INDIA**

**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  
 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

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  
 Notes:All Drugs  
 63 - - - - Human and Animal Drugs  
 Notes:All Drugs  
 64 - - - - Human and Animal Drugs  
 Notes:All Drugs  
 65 - - - - Human and Animal Drugs  
 Notes:All Drugs;This product is excluded from dwpe: Sodium Phenylbutyrate granules/65C[[[]]09  
 66 - - - - Human and Animal Drugs  
 Notes:All Drugs

**Srikem Laboratories Pvt. Ltd.  
 Plot No. 17/24, MIDC Talaja , Navi Mumbai, INDIA**

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

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

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

**Stericon Pharma Pvt. Ltd.  
 No. 9, Sub Layout Of Plot 9 , 1st Phase Bommasandra Ind. Area , Bangalore, Karnataka INDIA**

**Date Published : 01/13/2011**

Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011  
 Date Published: 01/13/2011

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

**Sun Pharmaceutical Industries (prev. Ranbaxy)  
 SEZ Unit 1, Plot No. A-41 , Industrial Area Phase VIII-A, SAS Nagar , Mohali, Punjab INDIA**

**Date Published : 09/13/2013**

Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013  
 Date Published: 09/13/2013

50 - - - - Color Additiv Food/Drug/Cosmetic  
 Desc:All drugs and drug products  
 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)  
 Desc:All drug and drug products  
 55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All drugs and drug products  
 56 - - - - Antibiotics (Human/Animal)





**Sun Pharmaceutical Industries Limited - Karkhadi**  
**Plot No. 817/A, Village - Karkhadi , Taluka - Padra District , Vadodara, Gujarat, INDIA**

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

60 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014
61 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014
62 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014
63 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014
64 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014
65 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014
66 - - - - Human and Animal Drugs Desc:All Human Drug Products	Date Published: 03/12/2014

**Unique Chemicals**

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

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

50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drugs and drug products	Date Published: 06/28/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 06/28/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013

**Vignesh Life Science Pvt Ltd**

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

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

50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drugs and drug products	Date Published: 06/28/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 06/28/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013

**Vignesh Life Sciences Pvt., Ltd.**

**93 & 94 P Mundargi Industrial Estate , Bellary Karnataka, INDIA**

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

50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drugs and drug products	Date Published: 06/28/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio 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

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

**Wockhardt Limited****Plot H-14/2, Biotech Park , M.I.D.C. Area Waluj , Aurangabad, Maharashtra INDIA**

55 - - - - Pharm Necess &amp; 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

66 - - - - 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

Date Published: 05/22/2013

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

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

Desc:Drugs and Drug products

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

56 - - - - Antibiotics (Human/Animal)

Desc:Drugs and Drug products

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

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

63 - - - - Human and Animal Drugs

64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

**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

Date Published: 11/26/2013

Date Published: 11/26/2013

Date Published: 11/26/2013

**Yag Mag Labs Private Limited****Survey No. 10, Gaddapotharam Village, , Jinnatam Mandel , Medak District, AP, 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

**ITALY****Topchem SRL****Viale Andrea Doria 17 , Milano, MI ITALY**

55 - - - - Pharm Necess &amp; 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

**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

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

## JAMAICA

### **P.A. Benjamin Manufacturing Co., Ltd. 95-97 East Street , Kingston, JAMAICA**

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

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

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

## JAPAN

### **Asada Milling Co., Ltd. 253 Obata Kanra-machi , Kanra-gun, Gunma-ken JAPAN**

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

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

### **Kanebo Cosmetics Inc. 3-28, Kotobuki-Cho 5-Chome , Odawara-shi Kanagawa, Kanagawa-ken JAPAN**

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

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: 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

## KOREA, REPUBLIC OF (SOUTH)

### **K J I Industrial Co., Ltd. 29 Gyeseok-ro, Dong-myeon , Yangsan-si, Gyeongsangnam-do, KOREA, REPUBLIC OF (SOUTH)**

**Date Published : 09/04/2013**

53 - - - - Cosmetics  
 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  
 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

Date Published: 09/04/2013  
 Date Published: 09/04/2013  
 Date Published: 09/04/2013  
 Date Published: 09/04/2013  
 Date Published: 09/04/2013  
 Date Published: 09/04/2013  
 Date Published: 09/04/2013

64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 09/04/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 09/04/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 09/04/2013
80 - - - - General Hospital/Personal Use Desc:All Drugs and Drug Products	Date Published: 09/06/2013
81 - - - - Hematology Desc:All drugs and drug products	Date Published: 09/04/2013
89 - - - - Physical Medicine Desc:All drugs and drug products	Date Published: 09/04/2013

**LG Life Sciences****129 Seokam-ro , Iksan Plant , Iksan-si, Jeollabuk-do, KOREA, REPUBLIC OF (SOUTH)****Date Published : 05/06/2013**

50 - - - - Color Additiv Food/Drug/Cosmetic	Date Published: 05/06/2013
53 - - - - Cosmetics	Date Published: 05/06/2013
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
80 - - - - General Hospital/Personal Use	Date Published: 05/06/2013

**MEXICO****Compania Internacional de Comercio, S.A. P.I. de C.V.****Monzon No. 184 , Cerro de la Estrella, Iztapalapa , Mexico City , , Distrito Federal MEXICO****Date Published : 05/17/2012**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/17/2012
56 - - - - Antibiotics (Human/Animal)	Date Published: 05/17/2012
60 - - - - Human and Animal Drugs	Date Published: 05/17/2012
61 - - - - Human and Animal Drugs	Date Published: 05/17/2012
62 - - - - Human and Animal Drugs	Date Published: 05/17/2012
63 - - - - Human and Animal Drugs	Date Published: 05/17/2012
64 - - - - Human and Animal Drugs	Date Published: 05/17/2012
65 - - - - Human and Animal Drugs	Date Published: 05/17/2012
66 - - - - Human and Animal Drugs	Date Published: 05/17/2012

**Farma Quimica S.A. de C.V.****Av Andre Marie Ampere No 11 , Parque Industrial Cuamatla , Cuautitlan Izcalli, Mex MEXICO****Date Published : 02/23/2012**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 02/23/2012
56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 02/23/2012
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 02/23/2012

**Prosintesis S.A. de C.V.****Avenida Educacion s/n , Pueblo Santa Maria Mazatlan , Jilotzingo, Mexico MEXICO****Date Published : 06/17/2015**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:Problems: (GMP) Good Manufacturing Practices	Date Published: 06/17/2015
56 - - - - Antibiotics (Human/Animal) Notes:Problems: (GMP) Good Manufacturing Practices	Date Published: 06/17/2015
60 - - - - Human and Animal Drugs Notes:Problems: (GMP) Good Manufacturing Practices	Date Published: 06/17/2015
61 - - - - Human and Animal Drugs Notes:Problems: (GMP) Good Manufacturing Practices	Date Published: 06/17/2015
62 - - - - Human and Animal Drugs	Date Published: 06/17/2015

Notes:Problems: (GMP) Good Manufacturing Practices  
 63 - - - - Human and Animal Drugs  
 Notes:Problems: (GMP) Good Manufacturing Practices  
 64 - - - - Human and Animal Drugs  
 Notes:Problems: (GMP) Good Manufacturing Practices  
 65 - - - - Human and Animal Drugs  
 Notes:Problems: (GMP) Good Manufacturing Practices  
 66 - - - - Human and Animal Drugs  
 Notes:Problems: (GMP) Good Manufacturing Practices

Date Published: 06/17/2015

Date Published: 06/17/2015

Date Published: 06/17/2015

Date Published: 06/17/2015

## NEW ZEALAND

### Jaychem Industries Ltd

#### 3 Kordel Place , East Tamaki , Auckland, NEW ZEALAND

Date Published : 12/22/2014

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All Drug and Drug Products

Date Published: 12/22/2014

56 - - - - Antibiotics (Human/Animal)  
 Notes:All Drug and Drug Products

Date Published: 12/22/2014

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

Date Published: 12/22/2014

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

Date Published: 12/22/2014

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

Date Published: 12/22/2014

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

Date Published: 12/22/2014

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

Date Published: 12/22/2014

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

Date Published: 12/22/2014

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

Date Published: 12/22/2014

## SINGAPORE

### Licht Far East (S) Pte Ltd

#### 2 Woodlands Sector 1 , #05-04 , Singapore, SINGAPORE

Date Published : 03/28/2014

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

Date Published: 03/28/2014

56 - - - - Antibiotics (Human/Animal)  
 Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices

Date Published: 03/28/2014

60 - - - - Human and Animal Drugs  
 Notes:All Drugs; Problem: (GMP) Good Manufacturing Practices

Date Published: 03/28/2014

61 - - - - Human and Animal Drugs  
 Notes:All Drugs; Problem: (GMP) Good Manufacturing Practices

Date Published: 03/28/2014

62 - - - - Human and Animal Drugs  
 Notes:All Drugs; Problem: (GMP) Good Manufacturing Practices

Date Published: 03/28/2014

63 - - - - Human and Animal Drugs  
 Notes:All Drugs; Problem: (GMP) Good Manufacturing Practices

Date Published: 03/28/2014

64 - - - - Human and Animal Drugs  
 Notes:All Drugs; Problem: (GMP) Good Manufacturing Practices

Date Published: 03/28/2014

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

Date Published: 03/28/2014

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

Date Published: 03/28/2014

## SOUTH AFRICA

### Clover Production

#### 200 Constantia Drive , Weltevreden Park , johannesburg, ZA-GT SOUTH AFRICA

Date Published : 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All sterile drug products

Date Published: 09/17/2010

56 - - - - Antibiotics (Human/Animal)  
 Notes:All sterile drug products

Date Published: 09/17/2010

60 - - - - Human and Animal Drugs  
 Notes:All sterile drug products

Date Published: 09/17/2010

61 - - - - Human and Animal Drugs  
 Notes:All sterile drug products

Date Published: 09/17/2010

62 - - - - Human and Animal Drugs  
 Notes:All sterile drug products

Date Published: 09/17/2010

63 - - - - Human and Animal Drugs  
 Notes:All sterile drug products

Date Published: 09/17/2010

64 - - - - Human and Animal Drugs  
 Notes:All sterile drug products

Date Published: 09/17/2010

65 - - - - Human and Animal Drugs  
 Notes:All sterile drug products

Date Published: 09/17/2010

Date Published: 09/17/2010

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

**SPAIN****Dysers S.A.L.****Depositos 12 , Segovia, SPAIN****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

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:Non-sterile bulk drug products 5/1/1992

56 - - - - Antibiotics (Human/Animal)  
Notes:Non-sterile bulk drug products 5/1/1992

60 - - - - Human and Animal Drugs  
Notes:Non-sterile bulk drug products 5/1/1992

61 - - - - Human and Animal Drugs  
Notes:Non-sterile bulk drug products 5/1/1992

62 - - - - Human and Animal Drugs  
Notes:Non-sterile bulk drug products 5/1/1992

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

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

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

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

**Jabones Pardo S.A.****Calle Sierra Nevada, 1 , Fuenlabrada, Madrid SPAIN****Date Published : 10/01/2013**

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

53 - - - - Cosmetics  
Desc:All drugs and drug products

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)  
Desc:All drugs and drug products

60 - - - - Human and Animal Drugs  
Notes:All drugs and drug products

61 - - - - Human and Animal Drugs  
Notes:All drugs and drug products

62 - - - - Human and Animal Drugs  
Notes:All drugs and drug products

63 - - - - Human and Animal Drugs  
Notes:All drugs and drug products

64 - - - - Human and Animal Drugs  
Notes:All drugs and drug products

65 - - - - Human and Animal Drugs  
Notes:All drugs and drug products

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

**TAIWAN****Beanne Chemical Co.****No. 28, Lane 456, Fongihou Road , Shengang District , Taichung City, TAIWAN****Date Published : 09/28/2012**

Date Published: 09/28/2012

Date Published: 09/28/2012

Date Published: 09/28/2012

50 - - - - Color Additiv Food/Drug/Cosmetic  
Desc:All drug and drug products

53 - - - - Cosmetics  
Desc:All drug and drug products

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

**Taiwan Three Mast Pharmaceutical Co., Ltd.****3 Jingzhong Rd. , Tainan City, TAIWAN****Date Published : 09/04/2012**

Date Published: 09/04/2012

Date Published: 09/04/2012

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Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

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

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

**THAILAND****PAN RAJDHEVEE GROUP PUBLIC COMPANY LIMITED****50/234-275 MOO 3, LAT SA WAI, LAM LUK KA , Lam Luk Ka, Pathum Thani THAILAND****Date Published : 03/10/2015**

Date Published: 03/10/2015

53 - - - - Cosmetics

Notes:All Drug and Drug Products  
 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: 03/10/2015  
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 Date Published: 03/10/2015  
 Date Published: 03/10/2015

**PCIC Co., Ltd.****73 Moo 12, Pracharaduthid Rd., , Lam Luk Ka , Bang Phli, Samut Prakan THAILAND**

53 - - - - Cosmetics  
 Notes:All Drug and Drug Products  
 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 : 03/10/2015**

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 Date Published: 03/10/2015

**TUNISIA****Unite De Fabrication De Medicaments****Zone Industrielle Kalaa El Kebira , Sousse, Sousse TUNISIA**

65 F - - 06 Water, Purified (Eyewash)  
 Desc:Cederroth Emergency Eye Wash

**Date Published : 02/03/2015**

Date Published: 02/03/2015

**TURKEY****Ansa****UNKNOWN , Izmit, TURKEY**

56 - - - - Antibiotics (Human/Animal)

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

Date Published: 09/10/2009

**Mustafa Nevzat Ilac Sanayii, A.S.****Cobancesme Mah. , Sanayi Cad. , Bahcelievler, Istanbul TURKEY**

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

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

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Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

**UNITED ARAB EMIRATES****Julphar Gulf Pharmaceutical Industries****Airport Road, Digdaga , Ras Al-Khaimah, UNITED ARAB EMIRATES**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
 Notes:All Drug Products  
 56 - - - - Antibiotics (Human/Animal)

**Date Published : 01/31/2012**

Date Published: 01/31/2012

Date Published: 01/31/2012



Notes:All Drug Products 60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 01/31/2012

## UNITED KINGDOM

### Fresenius Kabi Oncology Plc

#### Lion Court Farnham Road , Bordon, Hampshire UNITED KINGDOM

Date Published : 09/10/2009

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

### Hampshire Chemicals, Ltd.

#### Seal Sands Road , Middlesborough, Cleveland UNITED KINGDOM

Date Published : 09/10/2009

56 - - S -- Antibiotics (Human/Animal), Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
60 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
61 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
62 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
63 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
64 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
65 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
66 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009

## VENEZUELA

### LABORATORIOS LO OFTALMI CA

#### CTO. EMPRESARIAL "RS", CALLE 6 , ZONA INDUSTRIAL LA URBINA , Caracas, VE-NOTA VENEZUELA

Date Published : 05/14/2010

56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 05/14/2010
73 - - - - Anesthesiology Notes:All Drug Products	Date Published: 05/14/2010
74 - - - - Cardiovascular Notes:All Drug Products	Date Published: 05/14/2010
76 - - - - Dental Notes:All Drug Products	Date Published: 05/14/2010
77 - - - - Ear,Nose And Throat Notes:All Drug Products	Date Published: 05/14/2010
78 - - - - Gastroenterological & Urological Notes:All Drug Products	Date Published: 05/14/2010
79 - - - - General & Plastic Surgery Notes:All Drug Products	Date Published: 05/14/2010

80 - - - - General Hospital/Personal Use Notes:All Drug Products	Date Published: 05/14/2010
84 - - - - Neurological Notes:All Drug Products	Date Published: 05/14/2010
85 - - - - Obstetrical & Gynecological Notes:All Drug Products	Date Published: 05/14/2010
86 - - - - Ophthalmic Notes:All Drug Products	Date Published: 05/14/2010
87 - - - - Orthopedic Notes:All Drug Products	Date Published: 05/14/2010
89 - - - - Physical Medicine Notes:All Drug Products	Date Published: 05/14/2010
90 - - - - Radiological Notes:All Drug Products	Date Published: 05/14/2010

**Laboratorios L.O. Oftalmi, C.A.****Calle 6, Centro Empresarial R.S. , Zona Industrial de La Urbina , Caracas, VENEZUELA****Date Published : 05/14/2010**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 05/14/2010
56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 05/14/2010
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
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64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010

**VIETNAM****Rohto-Mentholatum (Vietnam) Company, Ltd.****16 VSIP Street 5 , Vietnam-Singapore Industrial Park , Thuan An Town, Binh Duong Province VIETNAM****Date Published : 08/26/2013**

50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drug and drug products	Date Published: 08/26/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug and drug products	Date Published: 08/26/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drug and drug products	Date Published: 08/26/2013
60 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
61 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
62 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
63 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
64 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
65 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
66 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013

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U.S. Food and Drug Administration  
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Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Email FDA](#)

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