

## Import Alert 66-40

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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:** 01/05/2017

**Type:** DWPE

**Import Alert Name:**

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

### Reason for Alert:

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

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

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

### Guidance:

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

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

### Product Description:

Various drugs (See attachment)

### Charge:

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

OASIS Charge Code: DRUG GMPS

## 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

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

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

## BRAZIL

### Lima & Pergher Ind. Com. Rep Ltda Av Airton Borges Da Silva 740 , Minas Gerais, BRAZIL

Date Published : 07/15/2016

Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
Date Published: 07/15/2016  
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  
62 - - - - 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  
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

### Lima & Pergher Industria e Comercio S/A Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL

Date Published : 07/15/2016

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

## CANADA

### Aleeda Inc 7115 Tomken Rd , Mississauga, ON CANADA

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

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: 05/29/2012

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

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

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

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

**Baxter Healthcare**  
**Unknown Street , Mississauga, ON CANADA**

**Date Published : 04/10/2014**

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**

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

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

Date Published: 09/28/2015

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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

**Gemini Packaging Ltd.**  
**12071 Jacobson Way , Richmond, British Columbia CANADA**

**Date Published : 12/10/2015**

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

Date Published: 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

**International Laboratories (Canada) Ltd.**  
**63 Skyline Cres NE , Calgary, Alberta CANADA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 03/14/2014
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/14/2014

**Pax-All Manufacturing Inc  
5000 Howard Business Parkway , Windsor, On CANADA**

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

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

**CHINA**

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

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

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

**Ausmetics Daily Chemicals (Guangzhou) Co., Ltd.  
Economic And Technical , NO. 1 Jinxiulu; Huangpu , Guangzhou, Guangdong CHINA**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016
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63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016

**Date Published : 12/20/2016**

64 - - - - Human and Animal Drugs  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
Date Published: 12/20/2016

65 - - - - Human and Animal Drugs  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
Date Published: 12/20/2016

66 - - - - Human and Animal Drugs  
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices  
Date Published: 12/20/2016

**Baoying County Fukang Medical Appliance Co., Ltd.**  
**Trade of , Su Zhongbeilu; Baoyingxian , Yangzhou, Jiangsu CHINA**

**Date Published : 09/20/2016**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All Drug and Drug Products  
Date Published: 09/20/2016

56 - - - - Antibiotics (Human/Animal)  
Notes:All Drug and Drug Products  
Date Published: 09/20/2016

60 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 09/20/2016

61 - - - - Human and Animal Drugs  
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Date Published: 09/20/2016

62 - - - - Human and Animal Drugs  
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63 - - - - Human and Animal Drugs  
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Date Published: 09/20/2016

64 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 09/20/2016

65 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 09/20/2016

66 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products  
Date Published: 09/20/2016

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

**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  
Date Published: 07/22/2014

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

**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

62 - - - - Human and Animal Drugs  
Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices  
Date Published: 04/29/2016

63 - - - - Human and Animal Drugs  
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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  
Date Published: 04/29/2016

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

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Date Published: 09/17/2010



Notes:All drug products	
56 - - - - Antibiotics (Human/Animal)	Date Published: 09/17/2010
Notes:All drug products	
60 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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61 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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63 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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64 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
65 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
66 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	

**Boai NKY Pharmaceuticals Ltd.  
No.1888 Wenhua Road , Boai , Jiaozuo, Henansheng CHINA**

**Date Published : 05/18/2015**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	

**Boai NKY Pharmaceuticals Ltd.  
No. 9 Zhongshan Road , Boai County , Jiaozuo, Henan CHINA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/17/2010
Notes:All drug products	
56 - - - - Antibiotics (Human/Animal)	Date Published: 09/17/2010
Notes:All drug products	
60 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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61 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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63 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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64 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
65 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
66 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	

**Boai Xinda Food Co., Ltd.  
The North Of Dong Wang He, Xiaojing , Boai, Henansheng CHINA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/17/2010
Notes:All drug products	
56 - - - - Antibiotics (Human/Animal)	Date Published: 09/17/2010
Notes:All drug products	
60 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
61 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
62 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
63 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
64 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	

65 - - - - Human and Animal Drugs  
Notes:All drug products  
Date Published: 09/17/2010

66 - - - - Human and Animal Drugs  
Notes:All drug products  
Date Published: 09/17/2010

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

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

50 - - - - Color Additiv Food/Drug/Cosmetic  
Desc:All drug and drug products  
Date Published: 09/30/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drug and drug products  
Date Published: 09/30/2013

56 - - - - Antibiotics (Human/Animal)  
Desc:All drug and drug products  
Date Published: 09/30/2013

60 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
Date Published: 09/30/2013

61 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
Date Published: 09/30/2013

62 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
Date Published: 09/30/2013

63 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
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64 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
Date Published: 09/30/2013

65 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
Date Published: 09/30/2013

66 - - - - Human and Animal Drugs  
Notes:All drug and drug products  
Date Published: 09/30/2013

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

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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

55 R - - 99 Pharmaceutic Necessities, N.E.C.  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

61 L - - 08 Heparin Sodium (Anti-Coagulant)  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

61 L - - 22 Anti-Coagulant Heparin Sol  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

61 L - - 30 Heparin Calcium (Anti-Coagulant)  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

74 L - - IS Heparin Coating Chemicals,  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

80 N - - ZW Heparin Vascular access flush  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

81 J - - BR Test, Heparin Neutralization  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

81 J - - OX Analyzer, Heparin, Automated  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

81 K - - FF Assay, Heparin  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

88 I - - AZ Heparin  
Notes:All heparin products 3/10/2008  
Date Published: 09/10/2009

**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**

55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

56 - - - - Antibiotics (Human/Animal)  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

60 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

61 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

62 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

63 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

64 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

65 - - - - Human and Animal Drugs  
Notes:(GMP) Good Manufacturing Practices  
Date Published: 09/03/2014

66 - - - - Human and Animal Drugs  
Date Published: 09/03/2014

Notes:(GMP) Good Manufacturing Practices

<b>Chongqing Imperial Bio Chem Co</b> <b>5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbei, Zhongqingshi 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 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 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 Paiquiang 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
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

**Cixi Zhixin Bird Clean-Care Product Co., Ltd.**  
**NO. 137 Balilu , Cixi , Ningbo, Zhejiang CHINA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016

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

**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	Date Published: 05/10/2012

**FriendsUnion(Tianjin) enterprises ltd.**  
**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	Date Published: 09/17/2010

Notes:All drug products

**Guangdong Pharmaceutical Factory #1  
91 Fangcun Dadao , Guangzhou, CHINA**

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

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

Date Published: 09/10/2009

Date Published: 09/10/2009

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

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

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

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

Date Published: 03/14/2016

Notes:All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 03/14/2016

Notes:All Drug and Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

**Hebei Yuxing Bio-Engineering Co Ltd**

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

**Xicheng District , Ningjin County , Ningjin, Hebei CHINA**

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

Date Published: 07/08/2016

Desc:All Drugs and Drug Products

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

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

Date Published: 07/08/2016

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 07/08/2016

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

60 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

61 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

62 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

63 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

64 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

65 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

66 - - - - Human and Animal Drugs

Date Published: 07/08/2016

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

**Huzhou Aupower Sanitary Commodity**

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

**339 Jingsan Road , Changxing Dist , Huzhou, Zhejiang CHINA**

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

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Date Published: 08/05/2016

Notes:All Antibiotics; (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Date Published: 08/05/2016

Notes:All Drugs; (GMP) Good Manufacturing Practices



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

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

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

Date Published: 04/08/2011

Notes:All Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 04/08/2011

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 04/08/2011

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 04/08/2011

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 04/08/2011

Notes:All Drug Products

63 - - - - Human and Animal Drugs

Date Published: 04/08/2011

Notes:All Drug Products

64 - - - - Human and Animal Drugs

Date Published: 04/08/2011

Notes:All Drug Products

65 - - - - Human and Animal Drugs

Date Published: 04/08/2011

Notes:All Drug Products

66 - - - - Human and Animal Drugs

Date Published: 04/08/2011

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**

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

Date Published: 03/05/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 03/05/2013

60 - - - - Human and Animal Drugs

Date Published: 03/05/2013

61 - - - - Human and Animal Drugs

Date Published: 03/05/2013

62 - - - - Human and Animal Drugs

Date Published: 03/05/2013

63 - - - - Human and Animal Drugs

Date Published: 03/05/2013

64 - - - - Human and Animal Drugs

Date Published: 03/05/2013

65 - - - - Human and Animal Drugs

Date Published: 03/05/2013

66 - - - - Human and Animal Drugs

Date Published: 03/05/2013

**Ningbo Zhixin Bird Clean-Care Product Co. Ltd.**  
**137 Bali Road , Zhangqi Town , Zhejng, CHINA**

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

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

Date Published: 11/22/2016

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 11/22/2016

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

60 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

61 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

62 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

63 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

64 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

65 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

66 - - - - Human and Animal Drugs

Date Published: 11/22/2016

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

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

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

45 - - - - Food Additives (Human Use)

Date Published: 08/28/2010

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

46 - - - - Food Additives (Human Use)

Date Published: 08/28/2010

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

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

Date Published: 08/28/2010

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

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

Date Published: 09/10/2009

Notes:10/30/2007;All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products;NOTE: Food additives/vitamins for food use are

not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

- 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009  
Notes:10/30/2007 All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 60 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007 All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: PRODUCT CODE 60S[ ] [ ] 26 FOR PRODUCT SUCRALFATE IS EXEMPT FROM THIS ALERT. NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 61 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 62 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 63 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 64 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 65 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 66 - - - - Human and Animal Drugs Date Published: 09/10/2009  
Notes:10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

**Shanghai Biochemical And Pharmaceutical Co Ltd  
Room A403, No. 494 Zhongxing Road , Shanghai, 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

**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
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 & 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	Date Published: 03/28/2014

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.  
1317 Jianchuanlu , Minhang District , Shanghai, Shanghai CHINA**

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

55 - - - - Pharm Necess & 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 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
66 - - - - 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

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.  
387 Shangqiulu , Shanghai, Shanghai CHINA**

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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)	Date Published: 09/10/2009
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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	
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

**Suzhou Pharmaceutical Technology Co.,Ltd**  
**Tongjing Commercial Plaza Room 920 # 3 , Jiefang Rd , Suzhou, Jiangsu CHINA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 10/17/2016
Notes:All Drug and Drug Products	
56 - - - - Antibiotics (Human/Animal)	Date Published: 10/17/2016
Notes:All Drug and Drug Products	
60 - - - - Human and Animal Drugs	Date Published: 10/17/2016
Notes:All Drug and Drug Products	
61 - - - - Human and Animal Drugs	Date Published: 10/17/2016
Notes:All Drug and Drug Products	
62 - - - - Human and Animal Drugs	Date Published: 10/17/2016
Notes:All Drug and Drug Products	
63 - - - - Human and Animal Drugs	Date Published: 10/17/2016
Notes:All Drug and Drug Products	
64 - - - - Human and Animal Drugs	Date Published: 10/17/2016
Notes:All Drug and Drug Products	

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

Date Published: 10/17/2016

Date Published: 10/17/2016

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

**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

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

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

**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

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

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

**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  
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65 - - - - Human and Animal Drugs  
66 - - - - Human and Animal Drugs  
80 L - - KB Pad, Alcohol

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

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

**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

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

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

**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

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

**Tianjin Boai NKY International Ltd.  
Suites 1808-9 Guohua Building , Dagu-Nan Road, Hexi District , 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  
Date Published: 09/17/2010

**Tianjin Boai Pharmaceutical Co. Ltd  
NO. 4 Ronghua Road , Xiqing , Tianjin, Tianjin 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  
Date Published: 09/17/2010

**Tianjin Boai Pharmaceutical Ltd. co. 6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin ,  
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  
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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  
Date Published: 09/17/2010

**Tianjin Zhongan Pharmaceutical Co., Ltd.**  
**Xiqing , 188 Fukang Road , Tianjin, Tianjin CHINA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
56 - - - - Antibiotics (Human/Animal) Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
60 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
61 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
62 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
63 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
64 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
65 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
66 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016

**Xiamen Origin Biotech Co. Ltd.**  
**NO. 7 Xiang Yue Road , Xiamen Torch , Xiamen, Fujian CHINA**

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

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

**Xinxiang Pharmaceutical Co. Ltd.**  
**No. 30 Jianshe West Road , Beigandao , Xinxiang, Henan, CHINA**

**Date Published : 04/06/2016**

53 - - - - Cosmetics 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.	Date Published: 04/06/2016
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) 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.	Date Published: 04/06/2016
55 - - - - Pharm Necess & Ctnr For Drug/Bio 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.	Date Published: 04/06/2016
56 - - - - Antibiotics (Human/Animal) 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.	Date Published: 04/06/2016
60 - - - - Human and Animal Drugs 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.	Date Published: 04/06/2016
61 - - - - Human and Animal Drugs 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.	Date Published: 04/06/2016
62 - - - - Human and Animal Drugs 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.	Date Published: 04/06/2016
63 - - - - Human and Animal Drugs 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.	Date Published: 04/06/2016
64 - - - - Human and Animal Drugs	Date Published: 04/06/2016



Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

65 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

66 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

**Xinxiang Tuoxin Biochemical Co. Ltd**

**Date Published : 04/06/2016**

**Muye And Deyuan Road Cross Street , Xinxiang City, Henan CHINA**

53 - - - - Cosmetics Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

56 - - - - Antibiotics (Human/Animal) Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

60 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

61 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

62 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

63 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

64 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

65 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

66 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

**Yangzhou Hengyuan Daily Chemical Plastic Co Ltd**

**Date Published : 08/12/2016**

**7 Sitong Road , Hanjiang District, Hangji Town , Yangzhou, Jiangsu CHINA**

53 I - - 01 Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products)

Desc:All Drug and Drug Products Date Published: 08/12/2016

Notes:For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

53 J - - 02 Deodorants (underarm)(Not Antiperspirant) (Personal Cleanliness) Date Published: 08/12/2016

Desc:All Drug and Drug Products

Notes:For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/12/2016

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

56 - - - - Antibiotics (Human/Animal) Date Published: 08/12/2016

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

60 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

61 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

62 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

63 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

64 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

65 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

66 - - - - Human and Animal Drugs Date Published: 08/12/2016

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

**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 Bangli Medical Products Co., Ltd**  
**Huachuan Block , 118 South of Yuegui Road , Yongkang City, Zhejiang CHINA**

**Date Published : 09/09/2016**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	

**Zhejiang Casing Animal By-Products Co.,Ltd.**  
**369 Dong Xing Road , Tonglu Economic Developing District , Hangzhou, Zhejiang Province CN-33 CHINA**

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

61 L - - 08 Heparin Sodium (Anti-Coagulant)	Date Published: 10/18/2011
Desc:Heparin Sodium (Anti-coagulant)	

**Zhejiang Hisoar Pharmaceutical Co. Ltd.**  
**NO. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA**

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

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

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

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:	

56 - - - - Antibiotics (Human/Animal)	; Problem(s); (GMP) Good Manufacturing Practices	Date Published: 09/09/2015
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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[S02, be excluded from dwpe under this firm listing;

60 - - - - Human and Animal Drugs Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/09/2015
61 - - - - Human and Animal Drugs Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe:Granisetron 61T[S24; CDER has recommended Mesna, 61R[S22, be excluded from dwpe under this firm listing.	Date Published: 09/09/2015
62 - - - - Human and Animal Drugs Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Cladribine 62I[S74; Cyclophosphamide 62I[S15 finished form and API; Cytarabine 62I[S16;Floxuridine 62V[S06; Fludarabine 62I[S79;Ivermectin 62L[S47	Date Published: 09/09/2015
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**

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

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

## DENMARK

**Leo Pharma A/S  
Industriparken 55 , Ballerup, DENMARK**

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

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

**Leo Pharmaceutical Products  
A 8 , Copenhagen, DENMARK**

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

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

**Leo Pharmaceutical Products  
Park Alle 26 , Vejle, DENMARK**

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

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

## FRANCE

**CISBIO BIOASSAYS**

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

**1 route du Parc Marcel Boiteux , Codolet, Gard FRANCE**

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	Date Published: 09/10/2009

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

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

**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

**Ligne St. Barth SAS  
Lorient , route de Saline , St Barthelemy, Guadeloupe FRANCE**

**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

**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

**Heel Gmbh , Biologische Heilmittel  
Ruhrstr, 14 , 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 from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

Date Published: 09/10/2009

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

Date Published: 09/10/2009

- 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

**HONG KONG**

**CBSCHEM LIMITED  
13th Floor , Nan Fung Industrial City , 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  
Desc:All drugs and drug products  
88 - - - - Pathology  
Desc:All drugs and drug products

Date Published: 08/31/2013

Date Published: 08/31/2013

**Chan Yat Hing Medicine Factory**  
**Flat 3, 9/F, Fuk Keung Industrial Bldg. , 66-68 Tong Mei Road , Mongkok, Kowloon, HONG KONG**

**Date Published : 12/03/2015**

53 - - - - Cosmetics

Date Published: 01/07/2016

Desc:All drug products declared as Cosmetic Products

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

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

Date Published: 12/03/2015

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 12/03/2015

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

60 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

61 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

62 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

63 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

64 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

65 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

66 - - - - Human and Animal Drugs

Date Published: 12/03/2015

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

**Luen Yick Pharmaceutical Co. Ltd.**

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

**Unit B, 7F, Phase 1 Leader Industry Ctr. , 188-202 Texaco Rd, Tsuen Wan , Kowloon, HK-NA HONG KONG**

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

Date Published: 03/04/2014

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

**Peking Medicine Manufactory**

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

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

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

Date Published: 03/04/2014

Notes:All Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/04/2014

Notes:All Drug Products

**Seedings**

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

**18 Tin Hau Rd. , Room 3, 13/F, Tower 4 , Hong Kong, Hong Kong HONG KONG**

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

Date Published: 08/31/2013

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

## HUNGARY

### **Teva Pharmaceutical Works Private Limited Company**

**Date Published : 05/27/2016**

#### **Tancsics Mihaly ut 82 , Godollo, Pest HUNGARY**

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

## INDIA

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

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

#### **A/7 Badrinath Apartment , Simpoli Road; Borivali West , Mumbai, Maharashtra INDIA**

56 C - - 66 Ceftazidime (Cephalosporins)	Date Published: 05/05/2014
Desc:Ceftazimide for Injection USP (Sterile)	

### **Aarti Drugs Limited**

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

#### **Plot No. E-22, M.I.D.C., Tarapur , Palghar, Maharashtra INDIA**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 03/23/2015
Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 03/23/2015

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

**Aarti Drugs Ltd**

**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	Date Published: 03/23/2015

**Akorn India PVT**

**5/2 5/3 Khasra 5/1 , Paonta Sahib, 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	Date Published: 08/21/2015

**Amsal Chem Pvt. Ltd.**

**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	Date Published: 04/11/2013

**Badrivishal Chemicals & Pharmaceuticals**

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

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
66 - - - - Human and Animal Drugs	Date Published: 12/19/2016

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

**Canton Laboratories Pvt. Ltd.**

**110 A & B Gidc Estate , Makarpura Road; 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 ;	Date Published: 04/10/2014

**Emcure Pharmaceuticals Limited**

**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	Date Published: 07/13/2015
62 - - - - Human and Animal Drugs 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	Date Published: 07/13/2015
63 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
64 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
65 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
66 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Haloperidol inj, Antipsychotic / 66M[[]]98	Date Published: 07/13/2015

**Fleming Laboratories Limited**

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

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

56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 04/11/2011
73 - - - - Anesthesiology Notes:All Drug Products	Date Published: 04/11/2011
74 - - - - Cardiovascular Notes:All Drug Products	Date Published: 04/11/2011
76 - - - - Dental Notes:All Drug Products	Date Published: 04/11/2011
77 - - - - Ear,Nose And Throat Notes:All Drug Products	Date Published: 04/11/2011
78 - - - - Gastroenterological & Urological Notes:All Drug Products	Date Published: 04/11/2011
79 - - - - General & Plastic Surgery Notes:All Drug Products	Date Published: 04/11/2011
80 - - - - General Hospital/Personal Use Notes:All Drug Products	Date Published: 04/11/2011
84 - - - - Neurological Notes:All Drug Products	Date Published: 04/11/2011
85 - - - - Obstetrical & Gynecological Notes:All Drug Products	Date Published: 04/11/2011
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 270, Navabpet Village , Medak, 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

**Ipcalaboratories 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	
63 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 03/24/2015
Notes:All Drugs;(GMP) Good Manufacturing Practices	

**Ipcalaboratories Limited**  
**Village Sejavta , Ratlam, Madhya Pradesh INDIA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 01/22/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices;	
56 - - - - Antibiotics (Human/Animal)	Date Published: 01/22/2015
Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 01/22/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 01/22/2015
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	
62 - - - - Human and Animal Drugs	Date Published: 01/22/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Hydroxychloroquine Sulfate/62L[[]]29	
63 - - - - Human and Animal Drugs	Date Published: 01/22/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices:These products are excluded from dwpe: Propranolol Hydrochloride/63E[[]]13	
64 - - - - Human and Animal Drugs	Date Published: 01/22/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from DWPE: Furosemide/64BQS24	
65 - - - - Human and Animal Drugs	Date Published: 01/22/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 01/22/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	

**Ipcalaboratories Limited**  
**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	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 These products are excluded from dwpe: Hydroxychloroquine Sulfate/62L[[]]29	



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: 03/24/2015

**Kamud Drugs Pvt. Ltd.**

**N-6 & 8 MIDC, Kupwad , Taluka Miraj , Sangli, Maharashtra 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	Date Published: 07/10/2013

**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 Desc:All drug and drug products	Date Published: 07/10/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc: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) Desc: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	Date Published: 07/10/2013

**Marck Biosciences Ltd.**

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

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 03/12/2014
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
65 - - - - Human and Animal Drugs	Date Published: 03/12/2014

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

Date Published: 03/12/2014

**Megafine Pharma (P) Limited**  
**48 - 51/201 Plot No 31 - 35 , Lakhamapur, Maharashtra INDIA**

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

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

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

Date Published: 10/14/2015

**Micro Labs Limited**  
**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**  
**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.**  
**A - 14 Maharashtra , M i d C; Andheri East , Mumbai, Maharashtra 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

Date Published: 11/23/2011

Notes:Chlorpheniramine maleate	
61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic)	Date Published: 11/23/2011
Desc:Chlorpheniramine maleate	
61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)	Date Published: 11/23/2011
Desc:Ppyrilamine maleate Ppyrilamine maleate USP	
61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)	Date Published: 11/23/2011
Desc:Chlorpheniramine maleate	
61 X - - 99 Anti-Histaminic N.E.C.	Date Published: 11/23/2011
Desc:Ppyrilamine maleate Ppyrilamine maleate USP	
61 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate	
62 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate	
63 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate	
64 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate	
65 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate	
66 - - - - Human and Animal Drugs	Date Published: 11/23/2011
Notes:Chlorpheniramine maleate	

**Pan Drugs Limited**

**192 G I D C Makarpura Industrial Estate , M I Estate , Vadodara, Gujarat INDIA**

**Date Published : 12/08/2015**

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

**Pan Drugs Ltd.**

**167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA**

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

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

**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)	Date Published: 09/11/2015
Desc:All Drugs	
Notes:Problem(s): (GMP) Good Manufacturing Practices	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/11/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 09/11/2015
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 09/11/2015

Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices  
62 - - - - Human and Animal Drugs Date Published: 09/11/2015  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices  
63 - - - - Human and Animal Drugs Date Published: 09/11/2015  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices  
64 - - - - Human and Animal Drugs Date Published: 09/11/2015  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices  
65 - - - - Human and Animal Drugs Date Published: 09/11/2015  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices  
66 - - - - Human and Animal Drugs Date Published: 09/11/2015  
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices

**RPG Life Sciences Limited**  
**25, M.I.D.C. Land, Thane-Belapur Road , Thane, Maharashtra INDIA**

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

50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/10/2013  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/10/2013  
56 - - - - Antibiotics (Human/Animal) Date Published: 06/10/2013  
60 - - - - Human and Animal Drugs Date Published: 06/10/2013  
61 - - - - Human and Animal Drugs Date Published: 06/10/2013  
62 - - - - Human and Animal Drugs Date Published: 06/10/2013  
63 - - - - Human and Animal Drugs Date Published: 06/10/2013  
64 - - - - Human and Animal Drugs Date Published: 06/10/2013  
65 - - - - Human and Animal Drugs Date Published: 06/10/2013  
66 - - - - Human and Animal Drugs Date Published: 06/10/2013

**RPG Life Sciences Limited**  
**3102/A G.I.D.C. Estate , 393002 , Ankleshwar, Gujarat INDIA**

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

50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/11/2013  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/11/2013  
56 - - - - Antibiotics (Human/Animal) Date Published: 06/11/2013  
60 - - - - Human and Animal Drugs Date Published: 06/11/2013  
61 - - - - Human and Animal Drugs Date Published: 06/11/2013  
62 - - - - Human and Animal Drugs Date Published: 06/11/2013  
63 - - - - Human and Animal Drugs Date Published: 06/11/2013  
64 - - - - Human and Animal Drugs Date Published: 06/11/2013  
65 - - - - Human and Animal Drugs Date Published: 06/11/2013  
66 - - - - Human and Animal Drugs Date Published: 06/11/2013

**Sentiss Pharma Pvt. Ltd.**  
**Village Khera Nihla , Tehsil Nalargarh , District Solan, Himachal Pradesh INDIA**

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

50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/20/2013  
55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/20/2013  
56 - - - - Antibiotics (Human/Animal) Date Published: 06/20/2013  
60 - - - - Human and Animal Drugs Date Published: 06/20/2013  
61 - - - - Human and Animal Drugs Date Published: 06/20/2013  
62 - - - - Human and Animal Drugs Date Published: 06/20/2013  
63 - - - - Human and Animal Drugs Date Published: 06/20/2013  
64 - - - - Human and Animal Drugs Date Published: 06/20/2013  
65 - - - - Human and Animal Drugs Date Published: 06/20/2013  
66 - - - - Human and Animal Drugs Date Published: 06/20/2013  
86 - - - - Ophthalmic Date Published: 06/20/2013

**Smruthi Organics Limited**  
**Plot No. A-27, MIDC, Chincholi , Solapur District, Maharashtra, INDIA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/03/2013  
60 - - - - Human and Animal Drugs Date Published: 06/03/2013  
61 - - - - Human and Animal Drugs Date Published: 06/03/2013  
62 - - - - Human and Animal Drugs Date Published: 06/03/2013  
63 - - - - Human and Animal Drugs Date Published: 06/03/2013  
64 - - - - Human and Animal Drugs Date Published: 06/03/2013  
65 - - - - Human and Animal Drugs Date Published: 06/03/2013  
66 - - - - Human and Animal Drugs Date Published: 06/03/2013

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

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/13/2015  
Notes:All Drugs  
60 - - - - Human and Animal Drugs Date Published: 08/13/2015  
Notes:All Drugs  
61 - - - - Human and Animal Drugs Date Published: 08/13/2015  
Notes:All Drugs  
62 - - - - Human and Animal Drugs Date Published: 08/13/2015

Notes:All Drugs	
63 - - - - Human and Animal Drugs	Date Published: 08/13/2015
Notes:All Drugs	
64 - - - - Human and Animal Drugs	Date Published: 08/13/2015
Notes:All Drugs	
65 - - - - Human and Animal Drugs	Date Published: 08/13/2015
Notes:All Drugs;This product is excluded from dwpe: Sodium Phenylbutyrate granules/65C[[[09	
66 - - - - Human and Animal Drugs	Date Published: 08/13/2015
Notes:All Drugs	

**Srikem Laboratories Pvt. Ltd.**

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

**Plot No. 17/24, MIDC Talaja , Navi Mumbai, INDIA**

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

**Stericon Pharma Pvt. Ltd.**

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

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

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

**Sun Pharmaceutical Industries (prev. Ranbaxy)**

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

**Industrial Area No. 3 , Madhya Pradesh , Dewas, Madhya Pradesh INDIA**

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



Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

**Sun Pharmaceutical Industries (prev. Ranbaxy)**

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

**Village Ganguwala , Tehsil, Paonta Sahib , Simour District, Himachal Pradesh INDIA**

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

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

60 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

62 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

63 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

64 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

65 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

**Sun Pharmaceutical Industries Limited - Karkhadi**

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

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

60 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

**Sun Pharmaceutical Industries, Inc**

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

**SEZ Unit 1, Plot No. A-41 , Industrial Area Phase VIII-A, SAS Nagar , Mohali, Punjab INDIA**

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

Date Published: 09/13/2013

Desc:All drugs and drug products

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

Date Published: 09/13/2013

Desc:All drug and drug products

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

Date Published: 09/13/2013

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/13/2013

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

61 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

62 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

63 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

64 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

65 - - - - Human and Animal Drugs

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

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

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

**Unique Chemicals**

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

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

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**

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

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

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

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

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

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

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

Date Published: 09/28/2016

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

Date Published: 11/26/2013

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

Date Published: 09/28/2016

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

Date Published: 11/26/2013

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

Date Published: 11/26/2013

62 - - - - Human and Animal Drugs  
Notes:All Drug and Drug Products; \* Notes: These products are excluded from DWPE: Enalapril Maleate (Antihypertensive - part II)  
(62OCA28, 62OCS28)

Date Published: 11/26/2013

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

Date Published: 11/26/2013

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

Date Published: 11/26/2013

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

Date Published: 11/26/2013

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

Date Published: 11/26/2013

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

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

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

Date Published: 05/22/2013

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

Date Published: 05/22/2013

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

Date Published: 05/22/2013

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

Date Published: 05/22/2013

62 - - - - Human and Animal Drugs  
Notes:All Drugs and drug products Except -- Enalapril Maleate (62O[[[28)

Date Published: 05/22/2013

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

Date Published: 05/22/2013

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

Date Published: 05/22/2013

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

Date Published: 05/22/2013

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

Date Published: 05/22/2013

**Wockhardt, Ltd.**  
**Plot 138 GIDC Industrial , Bulk Drug Division, Dist. Bharuch , Ankleshwar, INDIA**

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products	Date Published: 08/05/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drug and Drug Products;The following drug is excluded from DWPE; Ceftriaxone Sodium / 56C[[[]70 ;	Date Published: 08/05/2016
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016
63 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016
64 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016
65 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016
66 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 08/05/2016

**Yag Mag Labs Private Limited**  
**Survey No. 10, Gaddapotharam Village , Jinnaram Mandal , Medak District, Telangana INDIA**

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

60 L - - 69 Tramadol HCl (Analgesic) Desc:Tramadol HCl (Analgesic)	Date Published: 09/13/2011
60 L - - 99 Analgesic, N.E.C. Desc:Tramadol HCl (Analgesic)	Date Published: 09/13/2011
64 H - - 02 Guaifenesin (Expectorant) Desc:Guaifensein (Expectorant)	Date Published: 09/13/2011

## ITALY

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

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

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
56 - - - - Antibiotics (Human/Animal) Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
60 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
61 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
62 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
63 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
64 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
65 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	Date Published: 09/10/2009
66 - - - - Human and Animal Drugs Notes:All bulk drugs 8/4/1992	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	Date Published: 08/29/2012
60 - - - - Human and Animal Drugs	Date Published: 08/29/2012
61 - - - - Human and Animal Drugs	Date Published: 08/29/2012
62 - - - - Human and Animal Drugs	Date Published: 08/29/2012
63 - - - - Human and Animal Drugs	Date Published: 08/29/2012
64 - - - - Human and Animal Drugs	Date Published: 08/29/2012
65 - - - - Human and Animal Drugs	Date Published: 08/29/2012
66 - - - - Human and Animal Drugs	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	Date Published: 02/13/2013
60 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013
61 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013

62 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013
63 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013
64 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013
65 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013
66 - - - - Human and Animal Drugs Notes:All Drugs Products	Date Published: 02/13/2013

**Kanebo Cosmetics Inc.**

**Odawara-shi Kanagawa 28 , Kotobuki-Cho , Odawara, Kanagawa JAPAN**

**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

**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	Date Published: 09/04/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drugs and drug products	Date Published: 09/04/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 09/04/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 09/04/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 09/04/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 09/04/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	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.**

**Calle Monzon (Juarez) No. 184 , Iztapalapa, Col. CERRO DE LA ESTRELLA , Mexico, 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  
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: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012  
Date Published: 05/17/2012

**Farma Quimia S.A. de C.V.**

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

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

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.**

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

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

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  
Notes:Problems: (GMP) Good Manufacturing Practices

Date Published: 06/17/2015

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

Date Published: 06/17/2015

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

Date Published: 06/17/2015

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

Date Published: 06/17/2015

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

Date Published: 06/17/2015

**NEW ZEALAND**

**Jaychem Industries Ltd**

**Date Published : 12/22/2014**

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

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**

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

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

- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014
- Date Published: 03/28/2014

## SOUTH AFRICA

**Clover Production**

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

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

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

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

## SPAIN

**Dysers S.A.L.**

**Depositos 12 , Segovia, SPAIN**

- 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

**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

**Jabones Pardo S.A.**

**Calle Sierra Nevada 1 , Fuenlabrada, Madrid SPAIN**

- 53 - - - - Cosmetics  
Desc:All drugs and drug products
- 55 - - - - Pharm Necess & Ctnr For Drug/Bio  
Notes:All drugs and drug products
- 56 - - - - Antibiotics (Human/Animal)  
Desc:All drugs and drug products

**Date Published : 10/01/2013**

- Date Published: 10/01/2013
- Date Published: 10/01/2013
- Date Published: 10/01/2013

60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 10/01/2013

**Natura Bisse International S.A.**

**Parque Tecnológico del Valles , Artesans , , 12 Cerdanyola, Barcelona SPAIN**

**Date Published : 10/28/2016**

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

**TAIWAN**

**Beanne Chemical Co.**

**No. 28, Lane 456, Fongihou Road , Shengang District , Taichung City, TAIWAN**

**Date Published : 09/28/2012**

50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drug and drug products	Date Published: 09/28/2012
53 - - - - Cosmetics Desc:All drug and drug products	Date Published: 09/28/2012
56 - - - - Antibiotics (Human/Animal) Desc:All drug and drug products	Date Published: 09/28/2012

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

**3 Jingzhong Rd. , Tainan City, TAIWAN**

**Date Published : 09/04/2012**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/04/2012
60 - - - - Human and Animal Drugs	Date Published: 09/04/2012
61 - - - - Human and Animal Drugs	Date Published: 09/04/2012
62 - - - - Human and Animal Drugs	Date Published: 09/04/2012
63 - - - - Human and Animal Drugs	Date Published: 09/04/2012
64 - - - - Human and Animal Drugs	Date Published: 09/04/2012
65 - - - - Human and Animal Drugs	Date Published: 09/04/2012
66 - - - - Human and Animal Drugs	Date Published: 09/04/2012

**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**

53 - - - - Cosmetics Notes:All Drug and Drug Products	Date Published: 03/10/2015
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products	Date Published: 03/10/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Drug and Drug Products	Date Published: 03/10/2015
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 03/10/2015
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 03/10/2015
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 03/10/2015
63 - - - - Human and Animal Drugs	Date Published: 03/10/2015

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

Date Published: 03/10/2015

Date Published: 03/10/2015

**PCIC Co., Ltd.**

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

**Date Published : 03/10/2015**

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

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

## TUNISIA

**Unite de Fabrication de Medicaments SA**

**Zone Industrielle , Kalaa El Kebira , Sousse, Sousse TUNISIA**

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

Date Published: 02/03/2015

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

## TURKEY

**Ansa**

**UNKNOWN , Izmit, TURKEY**

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

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)

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

**Cobancesme Mah. , Sanayi Cad. , Bahcelievler, Istanbul TURKEY**

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

Date Published: 04/16/2013

Date Published: 04/16/2013

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

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**

**Digdaga , Airport Road , Ra's al Khaymah, UNITED ARAB EMIRATES**

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

Date Published: 01/31/2012

Date Published: 01/31/2012

Date Published: 01/31/2012

Date Published: 01/31/2012

Date Published: 01/31/2012

Date Published: 01/31/2012

Date Published: 01/31/2012

Date Published: 01/31/2012

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

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

Date Published: 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  
56 - - - - Antibiotics (Human/Animal)  
Notes:All finished pharmaceutical products  
60 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products  
61 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products  
62 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products  
63 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products  
64 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products  
65 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products  
66 - - - - Human and Animal Drugs  
Notes:All finished pharmaceutical products

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

### **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  
60 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf  
Notes:All bulk pharmaceuticals 1/26/1996  
61 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf  
Notes:All bulk pharmaceuticals 1/26/1996  
62 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf  
Notes:All bulk pharmaceuticals 1/26/1996  
63 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf  
Notes:All bulk pharmaceuticals 1/26/1996  
64 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf  
Notes:All bulk pharmaceuticals 1/26/1996  
65 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf  
Notes:All bulk pharmaceuticals 1/26/1996  
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

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

## 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  
73 - - - - Anesthesiology  
Notes:All Drug Products  
74 - - - - Cardiovascular  
Notes:All Drug Products  
76 - - - - Dental  
Notes:All Drug Products  
77 - - - - Ear,Nose And Throat  
Notes:All Drug Products  
78 - - - - Gastroenterological & Urological  
Notes:All Drug Products  
79 - - - - General & Plastic Surgery  
Notes:All Drug Products  
80 - - - - General Hospital/Personal Use  
Notes:All Drug Products  
84 - - - - Neurological  
Notes:All Drug Products  
85 - - - - Obstetrical & Gynecological  
Notes:All Drug Products  
86 - - - - Ophthalmic  
Notes:All Drug Products  
87 - - - - Orthopedic  
Notes:All Drug Products  
89 - - - - Physical Medicine  
Notes:All Drug Products

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010



90 - - - - Radiological  
Notes:All Drug Products

Date Published: 05/14/2010

**Laboratorios L.O. Oftalmi, C.A.**  
**Zona Industrial de La Urbina , Calle 6, Centro Empresarial R.S. , 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

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

Date Published: 05/14/2010

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

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4. <http://www.fda.gov/ForIndustry/ImportProgram/default.htm>

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U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)  
[Email FDA](#)

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