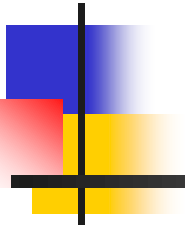


WELCOME TO

WANLONG PHARMA



**西安万隆制药股份有限公司**  
**Xi'an Wanlong Pharmaceutical Co.,ltd**

# Company Overview



**Xi'an Wanlong Pharmaceutical Co., Ltd is comprehensive modern pharmaceutical enterprise. All the workshops are compliant with cGMP requirements.**



# Company introduction

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- Established in 1995
- Specialized in Finished products, API and intermediates
- 20 experienced production management peoples, 8 senior professional registration specialist and 100 R&D staffs
- New factory 200,000 square meters,
- 4 API GMP workshops, 2 GMP solid forms plants, 1 GMP injection workshop

# Certification

## API GMP

### 中华人民共和国 药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS  
PEOPLE'S REPUBLIC OF CHINA

证书编号: SN20160214  
Certificate No.:

西安万隆制药股份有限公司

企业名称: Xi' an wanlong Pharmaceutical Co., Ltd

Manufacturer: 杨凌农业高新技术产业示范区永安路2号

地址: No.2 Yong an Road, Yangling agricultural hi-tech Industrial  
Address: Demonstrative zone

认证范围: 原料药(混合核苷)

Scope of Inspection: Active Pharmaceutical Ingredient (API) (Mixed Nucleoside)

经审查,符合中华人民共和国《药品生产质量管理规范》要求。  
特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2021 年 11 月 13 日

This certificate remains valid until

13/11/2021

发证机关:  
Issued By

14/11/2016

Date for Issuing



2016 年 11 月 14 日

国家食品药品监督管理总局制  
CHINA FOOD AND DRUG ADMINISTRATION

## Drugs GMP

### 中华人民共和国 药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS  
PEOPLE'S REPUBLIC OF CHINA

证书编号: SN20130044  
Certificate No.:

西安万隆制药股份有限公司

企业名称: Xi' an wanlong Pharmaceutical Co., Ltd

Manufacturer: 西安市高新区新型工业园创新路5号

地址: No.5 Chuang xin Road, Xi' an High and New Technology Industry Development  
Address:

认证范围: 片剂、胶囊剂、散剂

Scope of Inspection: Tablets, Capsules, Powders

经审查,符合中华人民共和国《药品生产质量管理规范》要求。  
特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2018 年 11 月 13 日

This certificate remains valid until

13/11/2018

发证机关:  
Issued By

14/11/2013

Date for Issuing



2013 年 11 月 14 日

国家食品药品监督管理局制  
PRINTED BY STATE FOOD AND DRUG ADMINISTRATION

## ISO



### 质量管理体系认证证书

证书编号: 00110Q26039R0M/6100

兹证明

西安万隆制药有限责任公司

中国陕西省西安市高新区新型工业园创新路5号

建立的质量管理体系符合标准:

ISO9001:2008

GB/T 19001-2008

通过认证范围如下:

散剂、片剂、胶囊剂、大容量注射剂的生产和服务

首次发证日期: 2010年7月9日 本次发证日期: 2010年7月9日 有效期至: 2013年7月8日

在一个年度内,本证书由获证企业自愿接受监督审核并合格方可有效,否则证书将按自动暂停处理。CQC-004-001



Signed by Wang Kajiao

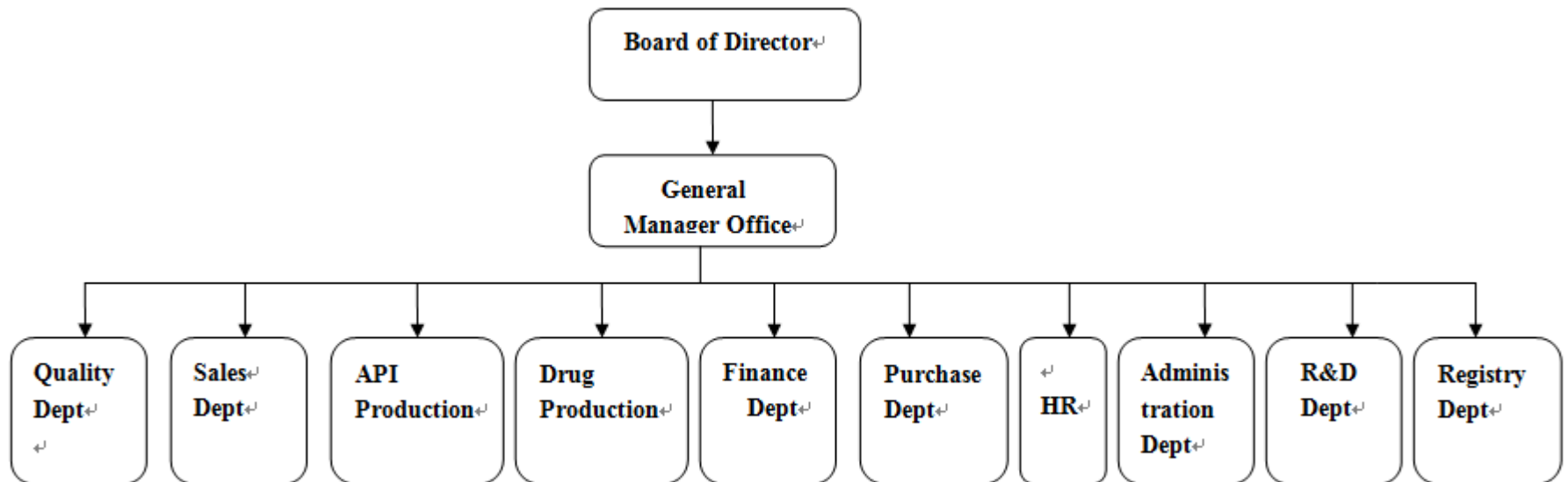


中国质量认证中心

中国·北京·南四环西路188号9区 100070

http://www.cqc.com.cn

# Organization Chart



# Drug products manufacturing area



# API manufacturing area



# Warehouse



Drugs warehouse



API warehouse



# Company Honor





# R&D

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- Over 5 million CNY worth of instruments
- 100 research scientists, including over 20 master's degree holders
- Government Certified Shaanxi R&D center
- Instruments: NMR spectrometer, LC – MS/MS, GC-MS, LC – MS, Dissolution Tester, HPLC

# Atomic Spectrophotometer



# Gas Chromatography



仪器使用完请及时填写使用记录



仪器名称：高效液相色谱仪  
仪器型号：岛津 2010C-HT  
仪器编号：9号  
仪器责任人：孙路  
出厂编号：C21255110860LP

HPLC

# Dissolution tester



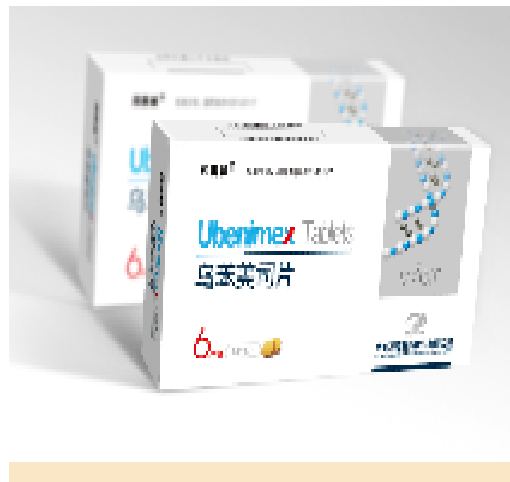
# Drug products

Injection: 25  
Tablet: 11

Capsule: 7  
Granules: 3



Ornidazole injection



Ubenimex Tablet



Alanyl glutamine Injection



# API product list (Commercial)

## API IN COMMERCIAL

Item	PRODUCTS	CAS NO	SPECIFICATION	GMP	DMF
1	Dextran 40	9004-54-0	JP17 USP40	√	PLAN
2	Dextran 70	9004-54-0	JP17 USP40		
3	Dextran 20	9004-54-0	USP40		
4	Epalrestat	82159-09-9	ChP2015 JP17		√
5	Tirofiban HCL	150915-40-5	In-Home Standard	√	√
6	Ubenimex	58970-76-6	ChP2015 JP17	√	PLAN
7	Alanyl Glutamine	39537-23-0	EP9.0		
8	L(-)-Malic acid	97-67-6	In-Home Standard		PLAN
9	Mixed nucleoside		In-Home Standard	√	
10	Moxonidine	75438-57-2	ChP2015 EP9.0		



# API product list (R&D)

## API UNDER RESEARCH

1	Iopromide	73334-07-3	USP40	Lab
2	Moxifloxacin HCL	186826-86-8	USP 40	Pilot
3	Gadodiamide	131410-48-5	EP9.0 USP40	Pilot
4	Topiroxostat	577778-58-6	USP40	Lab
5	Vonoprazan fumarate	1260141-27-2	In-Home Standard	Lab
6	Cefotiam hydrochloride	66309-69-1	In-Home Standard	Lab
7	Cefotiam hexetil HCL	95789-30-3	In-Home Standard	Lab
8	Satranidazole	56302-13-7	In-Home Standard	Pilot
9	Tofogliflozin	1201913-82-7	In-Home Standard	Lab



# Finished product list

No	Product name	Dosage Form	Strength	Indication
1	Ornidazole and Sodium Chloride Injection	Injection	100ml:Ornidazole 0.5g& Sodium Chloride0.9g	Antibiotics Drug
2	Ornidazole and Sodium Chloride Injection	Injection	100ml:Ornidazole 0.25g& Sodium Chloride0.9g	Antibiotics Drug
3	Gatifloxacin and Sodium Chloride Injection	Injection	100ml: Gatifloxacin 0.2g& Sodium Chloride0.9g	Antibiotics Drug
4	Alanyl Glutamine Injection	Injection	50ml:10g	Amino acid nutritious drug
5	Alanyl Glutamine Injection	Injection	100ml:20g	Amino acid nutritious drug
6	Compound Dextran 40 Injection	Injection	250ml	Plasma volume expander
7	Tirofiban hydrochloride and Sodium Chloride injection	Injection	100ml: 5mg	Antiplatelet
8	Ornidazole Capsule	Capsule	0.1g	Antibiotics Drug
9	Ornidazole Capsule	Capsule	0.25g	Antibiotics Drug





# Finished product list

10	Gatifloxacin Tablet	Tablet	0.1g	Antibiotics Drug
11	Ubenimex Tablet	Tablet	30mg	Immunomodulator
12	Fexofenadine Hydrochloride Tablet	Tablet	60mg	Antiallergic drug
13	Mixed Nucleoside Tablet	Tablet	20mg	Tumor drugs
14	Ornidazole Vaginal Effervescent Tablet	Tablet	0.5g	Gynecological drug
15	Gucixiaotong Capsule	Capsule	0.3g/pellet	Traditional Chinese medicine
16	Xiaokeling Capsule	Capsule	0.3g/pellet	Traditional Chinese medicine
17	Zaorenanshen <u>Granule</u>	Granule	5g/bag	Traditional Chinese medicine
18	Gujingmaisih Tablets	Tablets	0.2g/tablet	Traditional Chinese medicine
19	Wulongshan Powder	Powder	4g/bag	Traditional Chinese medicine



# Factory Capacity

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<b>NO</b>	<b>Item</b>	<b>Product Line</b>	<b>Capacity/Year</b>
<b>1</b>	<b>Soft bag infusion (100/250/500ml)</b>	<b>4</b>	<b>1.3 billion</b>
<b>2</b>	<b>Solid dosage forms</b>	<b>4</b>	<b>3 billion</b>
<b>3</b>	<b>Cephalosporins preparation</b>	<b>4</b>	<b>1 billion</b>
<b>4</b>	<b>freeze-dried powder injection</b>	<b>1</b>	<b>20 million</b>
<b>5</b>	<b>Small volume injections</b>	<b>1</b>	<b>60 million</b>
<b>6</b>	<b>API</b>	<b>4</b>	<b>100ton</b>



THANK YOU