

## Welcome to Jiudian Pharmaceutical!



## Background



**Hunan Jiudian Pharmaceutical Co., Ltd.**, founded in 2001 and went to public in 2017 (Stock Code: 300705), is a modern GMP pharmaceutical enterprise specialized in R&D, manufacturing and marketing.

With 2 plants, 400 researchers and total 1,400 Employees, Jiudian produces integrating APIs, excipients, herbal extracts and finished products to global market.





## Company Establishment







- Located in center of Changsha
- Area 10,000 m² R&D Center
- Postdoctoral Research Workstation



#### **Hongyang site**

- Located in Tongguan Circular Economic Industrial Base, Changsha China.
- Area 100,000 m² with 22 workshops
- Produce API and Excipients

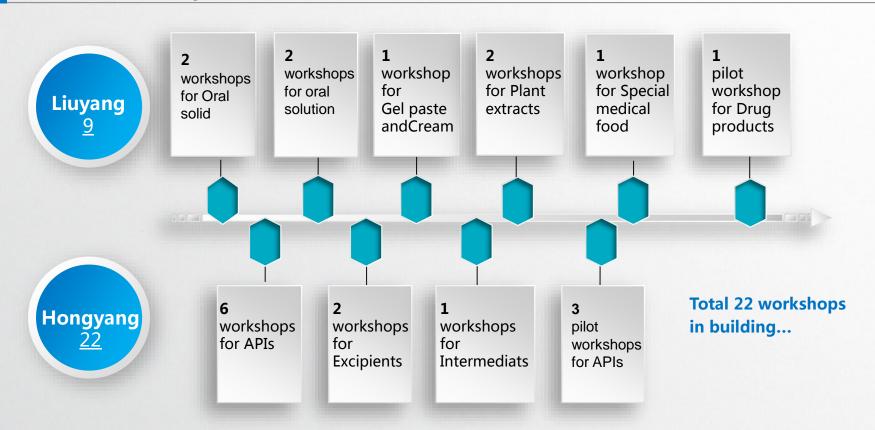


#### **Liuyang Site**

- Located in Liuyang Bio-Pharmaceutical park, Changsha China.
- Area 40,000 m² with 9 workshops
- Produce Finish product and Herbal extract

## Workshops





# Workshops



















- Sewage disposal system: 1,200 ton/day
- Obtained The first Hunan new pollutant discharging license in 2018.









### EHS



 Company is awarded as the National Green Factory by Ministry of Industry and Information Technology.



# Quality





- Comprehensive Quality system with advanced QC instruments
- Experienced quality control team
- Passed GMP inspection by USFDA, Korea MFDS etc.





## Quality





#### Production Lines has all passed national new GMP certification



## Background



With research and development technology as the driving force, company is awarded as the National center for Enterprise technology and Postdoctoral Programme.





## **R&D** Team



400

A high-quality R&D team with pioneering and innovative spirits aims to explore and create the future of Modern Pharmacy

R&D Stall	400	
Returned Overseas Scholars	8	
Provincial Top Talents	2	
Changsha Senior Talents	9	
Doctor	7	
Master	105	

D&D Ctaff





### Research Institutions



#### Dedicate in 'High technology, Innovative products, Patented drugs'

#### Pharmaceutical research institutes

**Pudao Scientific Institute** 

Institute of APIs & Excipients

Institute of Chinese Medicine

Intellectual Property & Information

Clinical research department

Quality department



# A comprehensive industrial platform from lab test to pilot production

- R&D laboratory: more than 10,000 sqm
- Two pilot workshop for drug products
- Three pilot workshops for APIs

### Research Station and Center



#### **Laboratory cooperation with Government and University**



- Hunan engineering technology research center for new gel paste
- Hunan respiratory medicine engineering technology research center







### Advanced instrument



### **QC** instrument

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<b>Instrument name</b>	Quantity
• HPLC	115
• GC	14
• LC-MS	2
• UHPLC	3
<ul> <li>Dissolution apparatus</li> </ul>	21
<ul> <li>Ion Chromatograph</li> </ul>	3
<ul> <li>Laser particle analyzer</li> </ul>	2
<ul> <li>Element Analyzer</li> </ul>	1
• ICPA7000	1
• Constant Temperature H	umidity
Chamber	21
• AAS	2
<ul> <li>UV spectrophotometer</li> </ul>	2
ALPHA FT-IR	2





### **R&D** Achievements





#### **Since October 2017**

#### 1. Obtained 11 production approval documents

- Loxoprofen Sodium Cataplasm
- Levocetirizine Dihydrochloride oral solution,
- Nifuratel vaginal tablet
- Clotrimazole vaginal tablet
- Colloidal Bismuth Pectin dry powder suspension
- Ferrous succinate tablet

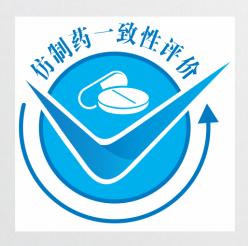
#### 2. Application for 28 new products

Preparation Products: Almagate chewable tablet, Levodropropizine and guaiacol capsule, Utagen granule, Irbesartan tablet, Loxoprofen Sodium tablet, Ferrous succinate tablet, Ketoprofen Cataplasm, Paracetamol dry powder suspension agent, Indometacin Cataplasm etc.

API: Almagate、Lansoprazole、Esomeprazole sodium、Rabeprazole sodium、Ferrous succinate、Azithromycin、 Meloxicam、Omperazole、Clarithromycin、 Imidapril hydrochloride etc.

### **R&D** Achievements





#### 3. Passed the consistency evaluation of generic drugs.

- Levocetirizine Dihydrochloride Tablets and Capsules
- Pantoprazole Sodium Enteric coated-Tablets
- Potassium Sodium Hydrogen Citrate Granuels
- Loxoprofen Sodium Tablets
- Irbesartan Tablets
- Hydrotalcite Chewable Tablets
- Imidapril Hydrochloride Tablets

82 Invention patents have been authorized



# Superior-quality Product



#### **APIs**

#### On market:

- Ornidazole
- Secnidazole
- Dirithromycin
- Levodropropizine
- Levocetirizine dihydrochloride
- Bambuterol hydrochloride
- Liranaftate
- Allantoin
- Cilnidipine
- Docusate Sodium

#### Registered:

- Almagate
- Hydrotalcite
- Simethicone
- Imidapril hydrochloride
- Rivaroxaban
- Rosuvastatin Calcium
- Acotiamide hydrochloride hydrate
- Flurbiprofen
- Pelubiprofen
- Ebastine
- CDCA/UDCA
- •







**Almagate** 

CAS NO. 66827-12-1

**Hydrotalcite** 

CAS NO.12304-65-3

Anti-acid Medicine, API and finished product both available, we can provide different specifications according to customer requirements. The crystal type is consistent with the original. Annual output more than 1000MT with dedicated line.



**Tadalafil** 

CAS NO. 171596-29-5

API and finished product both available, we obtained the registration number and approval from CFDA, Bioequivalence study of Tadalafil Tablets completed.



**Oseltamivir Phosphate** 

CAS NO. 204255-11-8

**Peramivir** 

CAS NO.229614-55-5

Antiviral medicine, source materials produced by our own factory and already built long term business relathionship with many leading forlumation producer. Paramivir is a stable crystal form of peramivir trihydrate.



#### **Tofacitinib Citrate**

CAS NO.540737-29-9

Tofacitinib Citrate and Flurbiprofen, Pelubiprofen, Celecoxib are antipyretic and analgesic drugs series in our company, and rank leading position in China, Tofacitinib Citrate API and finished product both available. We have formed an integrated strategy of APIs to Formulations with competitive price.



Levodropropizine

CAS NO.99291-25-5

API, capsule and tablet sold in commercial order for more than 15 years with perfect process and stable quality, We are the sole manufacturer with GMP certificate in China and registration done in Korea FDA.



**Docusate Sodium** 

CAS NO. 577-11-7

Jiudian is the largest GMP manufacturer of Docusate Sodium in China with good technics and full specification like 99% walex, 85% powder and 50% liquid which is popular selling to US. Annual output more than 1000MT.



Choline Alfoscerate (GPC)

CAS NO. 28319-77-9

GPC is our strength medicine with high purity and large output, the manufacturing process is green and environmental protection, Exported to Korea and enjoying good reputation in international market.



Rivaroxaban

CAS NO. 366789-02-8

API and finished product both available, with competitive price and good qualtity, Jiudian keep long term business relationship with several well-known company.



Simethicone

CAS NO. 8050-81-5

We are the largest GMP manufacturer of Simethicone in China, API and finished product both available which selling to US, Korea and European countries.



Imidapril Hydrochloride

CAS NO. 89371-37-9

API and finished product both aavailable, Imidapril Hydrochloride Tablets get approval of Drug consistency evaluation as the first company in China. API exported to Korea, Vietnam etc.



**Dexketoprofen Trometamol** 

CAS NO. 156604-79-4

API and finished product both available, we have complete the process validation and DMF in processing, it's wildely used in Europea market.



Ornidazole

CAS NO. 3366-95-8

Secnidazole

CAS NO.16773-42-5

We are the GMP manufacturer for 20 years in big output with impurity less than 0.1%, API officially registered in Russian, India, Brazil, Turkey etc.

# Superior-quality Product



#### **Pharmaceutical excipients:**

- Microcrystaline Cellulose
- Glycerol
- Mannitol
- Calcium Stearate
- Stearic Acid
- Sodium Lauryl Sulfate
- White Vaselin
- Yellow Vaselin
- Dimethyl Sulfoxide
- Dibasic Sodium Phosphate Monobasic Sodium Phosphate
- .....

#### **Extracts:**

- Bangpoongtongsungsan Dry Extract (4.6→1)
- 95% Ethanol Soft Extract (20→1) of Artemisia Argyi Folium
- Siwu Extract
- Rhizoma Picrorhizae Extract
- Banggihwanggitang Dried Extract
- Daesihotang Dried Extract
- Hydrogenated protein......







## Pharmaceutical excipients



#### **Sodium lauryl sulfate**

Jiudian have sell Sodium lauryl sulfate to many dosage companies in pharmaceutical grade with high quality, we can provide Dangerous goods transport packing and certificate.

#### Sucrose(Injection grade)

We have normal and Injection grade of Sucrose in good quality, Jiudian keep long term business relationship with Merck, Astrazeneca and other well-known company.

### International certification



# Regulatory affair team is professional and stable, DMF and GMP 11 information provided. A series of APIs and plant extract products have passed the international certification

Appendix 2-6 KFDA Certificate

#### Appendix 2-4 USFDA EIR page U.S. FOOD & DRUG Center for Drug Evaluation and Research Office of Pharmaceutical Quality Office of Surveillance Division of Quality Surveillance Assessment 10903 New Hampshire Avenue Building 51, Room 4316 Silver Spring, MD 20993 TELEPHONE: (301) 796-3254 FAX: (301) 847-8742 Mr. Xiahui Zheng, General Manager Hunan Jiudian Pharmaceutical Co., Ltd. Hunan Liuyang Bio-Pharmaceutical Park 1 Jiang Kang Avenue Changsha, Hunan, China 410011 Reference: Inspection Date(s): 05/22/2017 - 05/25/2017 Location: Hunan Jiudian Pharmaceutical Co., Ltd. Hunan Liuyang Bio-Pharmaceutical Park 1 Jiang kang Avenue Changsha, Hunan, China 410011 Dear Mr. Xiahui Zheng: We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA. If there is any question about the released information, feel free to contact me at 301-796-0611. For more information on the U.S. FDA, please visit our website at www.fda.gov. FEI: 3007684055 Enclosure: Establishment Inspection Report (EIR) U.S. Food and Drug Administration www.fda.gov

		0 .:5 .		
		Certificate		
			Registration No.	20140173092
	Drug Substance	Manufacture	Registra	
	Sanitary Aid	Import	Certific	ate
	Name of Importer	Twowinpharma Co., Ltd.	Registration No.	5600
	Address of Importer	168-23. Osongsaen	gmyeong 4-ro, Os	ong-eup.
Applicant		Heungdeok-gu, Cheoungju-si.Chungcheongbuk-do,Korea		oren
applicalle	Name of	Chot Jin		591026-***
	Representative	600	No.	***
Product Name		Twowin Artemisia Herb (20→1)	95% Ethanol So	ft Extract
Source Quantity	of Raw Materials and	Attached	101	
Appearance		Dark brown soft extract, have special smell and bitter		
Manufactu	ring Process	Attached		
Efficacy		Attached		
Uses	1 20 1	Attached		
Warnings		Attached		
Packing	Unit	Manufacturer's packing six	ze.	
Storage Condition and Shelf Life		Storage Condition: tight container, preserve in room temperature (1-30°C). Shelf Life: 24 months from manufacture date		
Specifications and Testing Methods		Attached		
	rer (imported)	Attached	/XX/	
Acceptabl	e Report		1	
Other R	emark	Classification No. 07190	Store	nge tion
as above	under the provisions	substance is registered of Article 31 and Article 39 of Enforcement Rule of 2015, 05, 18	42 of Pharmace	eutical Affairs

Daejeon Regional Food & Drug Administration



ФС 000292-201211.

Реестровая запись № ФС-000292

К решению о включении фармацевтической субстанции в государственный реестр лекарственных средств для медицинского применения придагается нормативная документация в 1 экз.:

почения в реестр 20.12.2011

A В.И. Скворнова

# APIs registration



Region	Product		
US FDA	Allantoin		
Russia	Ornidazole		
Belarus	Ornidazole, Sumatriptan Succinate		
Turkey	Dirithromycin, Ornidazole, Secnidazole, Levocetirizine Dihydrochloride, Levodropropizine		
Korea MFDS	Levocetirizine Dihydrochloride, Levodropropizine, Bangpoongtongsungsan Dry Extract (4.6→1) 95% Ethanol Soft Extract (20→1) of Artemisia Argyi Folium		
Ukraine	Ornidazole, Levocetirizine Dihydrochloride, Allantoin		
Poland	Dibasic Sodium Phosphate, Monobasic Sodium Phosphate, Allantoin		
Taiwan	Dibasic Sodium Phosphate, Monobasic Sodium Phosphate, Allantoin		
India	Ornidazole, Secnidazole		

### Sales Network





#### **Domestic:**

Sales network covers 34 provinces, cities and town.

#### **International:**

Export to more than 30 countries and regions, including America, Russia, Turkey, Poland, Korea and India, etc.,



## Formulation Development



 The product lines include Digestive system, cardiovascular and cerebrovascular medication, anti-inflammatory and analgesic, anti-allergy, nutritions etc.



## Equipment and facilities





Tablet press in solid preparation workshop



Automatic Packer for Solid Preparation Workshop



Packing machine for Liquid preparation

## Equipment and facilities





Automatic inspection machine for Oral liquids



Washing-drying-closing line for Oral liquids



Automatic label &packing production line



#### Anti Allergy

## **Levocetirizine Dihydrochloride Tablet, Capsule, Oral solution**

Δ Drug action: Allergic rhinitis, chronic urticaria





#### Digestive

## Pantoprazole Sodium enteric coated tablet

Δ Drug action: Active peptic ulcer (gastric and duodenal ulcer)





#### **Urinary**

## Potassium Sodium Hydrogen Citrate Granuels

 $\Delta$  Drug action: Dissolve uric acid stone, prevent the recurrence of uric acid stone





#### **Anti-inflammatory**

#### **Loxoprofen Sodium Tablets**

Δ Drug action: Anti-inflammatory and analgesic





#### Digestive

#### **Hydrotalcite Chewable Tablets**

Δ Drug action: Acute or chronic gastritis



## Popular Formulation



#### Gel paste products

#### **Loxoprofen Sodium Cataplasm**

Δ Drug action: Anti-inflammatory and analgesic



## Chinese Drug Formulation



#### **Nutritions**

#### **Shibawei Bushen Yiqi oral solution**

Δ Drug action: Nourish the kidney and strengthen body



#### **Fufang Nanwujia oral solution**

Δ Drug action: Nourish the heart and body





## CMO/CDMO partner



Jiudian Pharmaceutical provide Contract Development and Manufacturing Services to pharma companies looking for outsource to increased efficiency.

#### Service Offerings:

- Co-development
- Custom Synthesis
- Dossier development services



## CMO/CDMO partner











## CMO/CDMO partner





# A platform from lab test to pilot and industrial production.

- R&D laboratory: more than 10,000 sqm
- Two pilot workshops for Formulation
- Three pilot workshops for APIs

