

Your Global Contract Service

partner

Welcome to Shandong Xinhua

保护健康 造福社会 For good health and better life



















Quality management



Manufacturing Sites



Safety Percaution



Company Basic Information

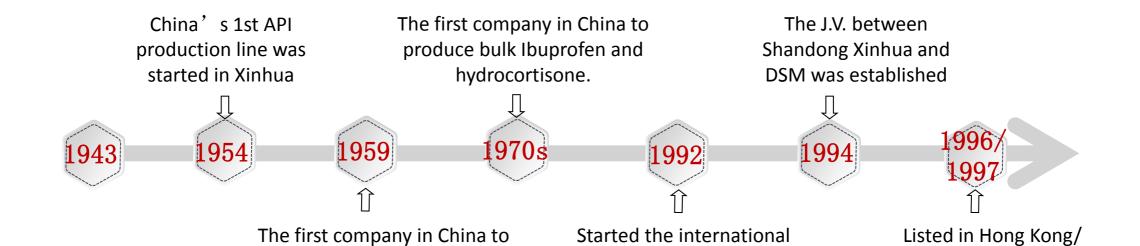


Established in 1943 during the 2nd world war from a medical group of army.



Leading Supplier for the manufacturing of antipyretics and analgesics, also a key manufacturer for anti-infective, cardio-vascular, central nervous system, steroids and anti-parasites drugs.





trading business by ourselves.



produce bulk Aspirin and

Caffeine

Shenzhen stock exchange



Xinhua Pharmaceutical (European) Shouguang Site was **Hutian Site was** GmbH was established in Hamburg, established (for Pharma established (for in 2010 moved to the Netherlands intermediate). innovative APIs). 2009 2007 2008 2003 The J.V. between Xinhua Contract project for Contract project with Xinhua Pharmaceutical **UK Partner for FDF** (U.S.) Co., Ltd. was and Perrigo (U.S.) was finished dosage with established. Bayer Healthcare. triggered. established. **Company History and Milestones**





ISO 10012 was certified in 1998





2000



2009

ISO 14001 was certified in 2000

ISO 22000 was certified in 2009



Qualitation and subsection field

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200,000







ISO management system





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Dongy i Road: 490, 000 m² API and Solid dosage products

Nanding site: 20,000 m²

Solid dosage products

(Cephalosporins and Hormone)



Headquarters:

Administration and R&D

Center: 490, 000 m²

Finished Dosages: 280,000 m²

16km

10km



East site: 360,000 m², APIs: Ibuprofen, Caffeine, Levodopa, etc.

10km

18km



Hutian site: 270,000 m², APIs: Aspirin, Analgin, etc.



Manufacturing Sites

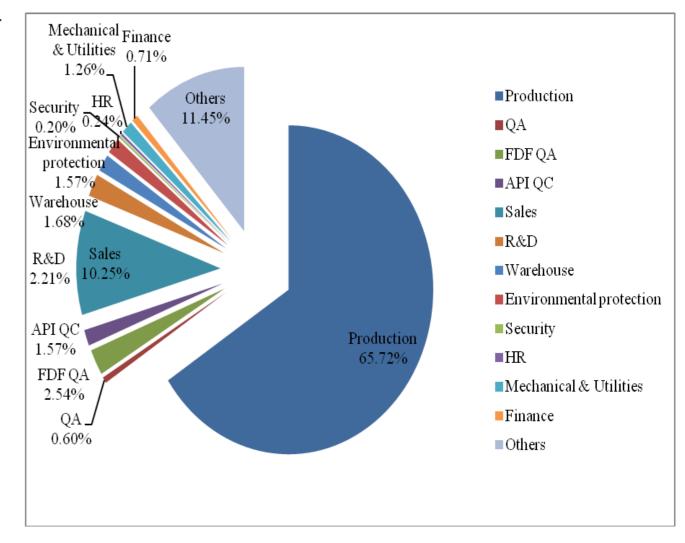


There are 4525 employees by the end of 2017.

- •2974 for production
- •27 for QA;
- •115 for FDF QA
- •71 for API QC
- •464 for Sales
- •100 for R&D;
- •76 for Warehouse
- •71 for Environmental protection
- •9 for Security
- •11 for HR
- •57 for Mechanical & Utilities

Among them:

- •902 obtained the B.S degree
- •220 obtained the M.S degree
- •11 obtained the Dr degree
- •95 for licensed pharmacist





Personal Distribution



Quality management



Company Mission

"For Good Health and Better Life"

Company Quality Value

"the product quality effects the company's development, and the drug quality effects the people's life"

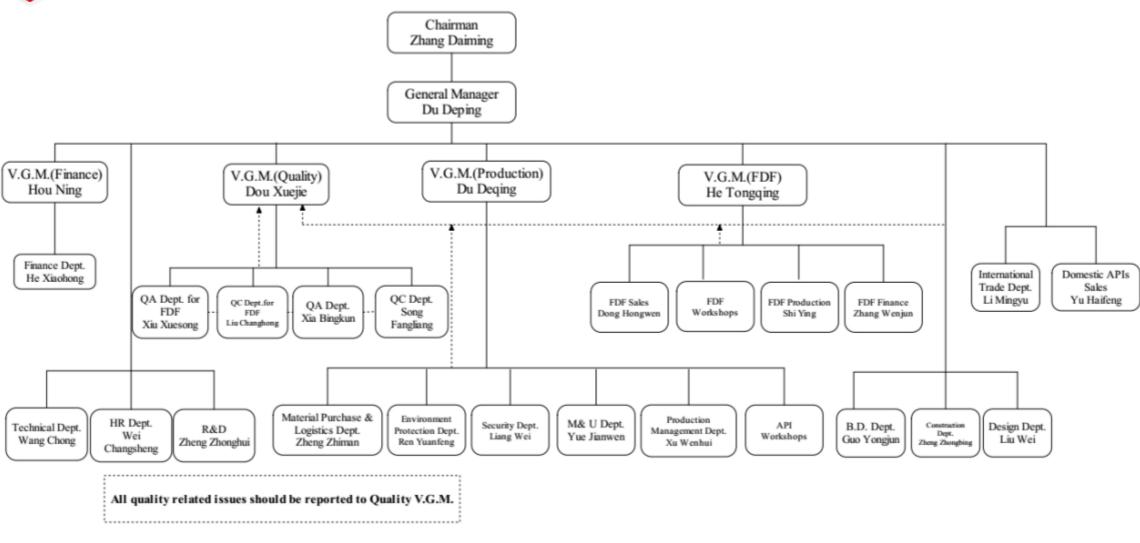
Continuing the dedication to improve the quality system and to meet the demands of the clients.



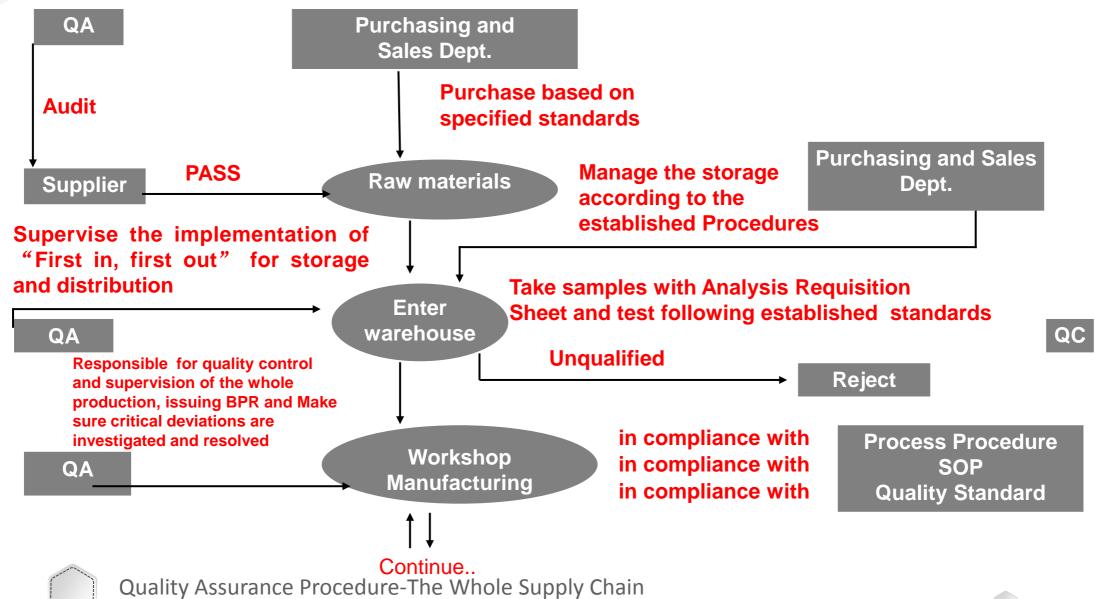
Quality Policy

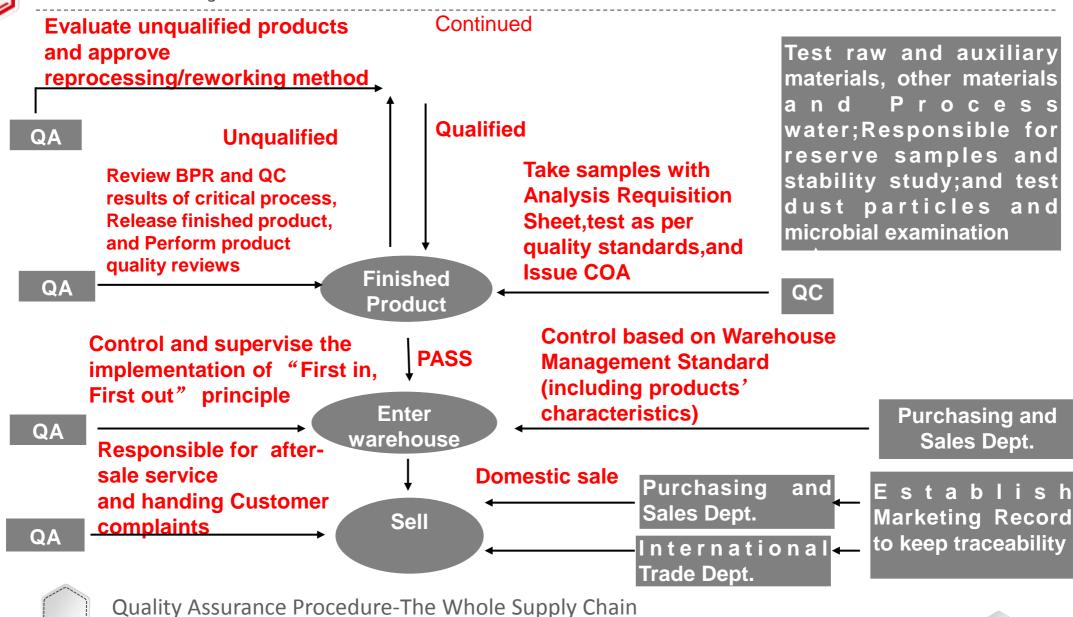
Organization Chart of Shandong Xinhua Pharma. Co., LTD













No.	DMF No.	Submitted Date	Product
1	4633	28-Jul-1982	THEOPHYLLINE
2	10730	20-Jan-1994	ASPIRIN
3	11606	27-Jul-1995	HYDROCORTISONE BASE
4	13092	10-Jul-1998	CAFFEINE ANHYDROUS
5	13144	18-Aug-1998	TRIMETHOPRIM
6	15511	3-Jul-2001	IBUPROFEN
7	17263	15-Mar-2004	HYDROCORTISONE ACETATE
8	22598	5–Mar-2009	LEVODOPA
9	24476	8-Dec-2010	MELOXICAM
10	26132	25-May-2012	AMLODIPINE BESYLATE
11	26844	18-Jan-2013	ASPIRIN REFINED
12	27430	23-Jul-2013	CARBIDOPA
13	27827	1-Dec-2013	PHENOBARBITAL
14	28403	10-Jun-2014	IBUPROFEN SODIUM
15	29184	2-Feb-2015	OMEGA-3-ACID-ETHYL ESTERS
16	29793	12-Oct-2015	Aspirin DC-90
17	31035	19-Oct-2016	DIPYRONE (Metamizole Sodium Monohydrate)



No.	Product	CEP No.	Certified Date
1	Metamizole Sodium	CEP 2001-356	2004-04
2	Phenazone	CEP 2002-093	2003-11
3	Caffeine Anhydrous	CEP 2003-027	2003-09
4	Acetylsalicylic Acid	CEP 2001-210	2002-04
5	Ibuprofen	CEP 2004-023	2005-12
6	Trimethoprim	CEP 2003-195	2004-19
7	Theophylline Anhydrous	CEP 1998-004	1999-07
8	Propyphenazone	CEP 2003-059	2004-05
9	Levodopa	CEP 2009-174	2011-04
10	Carbidopa	CEP 2016-052	2017-04



10 Products COS certified



Date	Investigator	Products	Result	Manufacturing Site	
May 2002	Mr. Regina T. Brown, Mr. S Nasir Ali	Hydrocortisone	483:9 Pass	Dongyi Road site	
Apr. 2007	Mr. Michael Taylor Mr. George Pyramides	Ibuprofen Hydrocortisone Trimtheoprim	483:4 (4 Pass	DEPARTMENT FREE LITE THUMAN SERVICES Public Health Services Food and Drug Administration Dongyi Road site	ENTER FOR DRUG EVALUATION AND RESEARCH Office of Manufacturing and Product Quality Division International Drug Quality
July 2010	Ms. Charisse Green	Levodopa/Ibuprofen Trimtheoprim	483:0 Pass	East site Dongyi Road site	International Complexion Branch 1090; New Hampshire Avenue Bulking #51, Room 4212 Silver Spring, MD 20993 TELEPHONE: (301) 976-3816 FAX: (301) 647-8742
		Acetylsalicylic Acid; Phenazone;	483:6	Mr. Du Deping General Manager Hutian Site Sindong Xinhua Pharmacented Company Limited Intian Chemical Industrial Zone	
March 24- April 4, 2014	Mr. Joel Hustedt	Ibuprofen; Levodopa; Trimtheoprim; Caffeine; Theophylline; CPC;	483:6 Xw	China Reference: FEI 3004254526 Dear Mr. Du: We have completed our review of the Establishment Inspection Reported the manufacturing facility in 7ths. China by Investigator foel D. He	vations was issued at the conclusion of the 014 with supportive documentation. Based g your facility as acceptable. This letter is
		Hydrocortisone; Hydrocortisone acetate;		through April 4, 2014. An FDA-483, Notice of Inspectional Observa inspection. Me have also rejected your company's response dates April 24, 2010 at the profile carbon being high Road Gin, Si La Cassifying at intended as an endorsement or certification of the facility. It remiscompliance with current good manufacturing practice (CGMP).	
		Acetylsalicylic Acid; Phenazone;ASA, Refined Aspirin	483:0	rease be advised that all manufacturers must register annually as request to register is available at	



No.	Date	Authority	Products	Result	Manufacturing Site	
1	Jan. 2013	K-FDA	Meloxicam	Pass	Ease site	
2	Mar. 2013	EDQM	Levodopa Trimethoprim artification of Substances Division celluprofenty Levodopa Company of Substances Division celluprofenty	Pass	Ease site	
3	May 2014	Germany 1 A	ame of the substance: CETYLSALICYL PROPYPHENAZONE ame of hodge: HANDONG XINHUA PHARMACEUTICAL CO., LTD. P Dongy Road ASPIRIN Janagdian District Jina-255 005 Zibo, Shandong Province	Pass	Hutian site Accordance to the control of the contr	3 CHUTZ ar entre:
4	April 2015	TGA 11 2 2 3 13 5	And Do production: HANDONG XINHUA PHARMACEUTICAL CO., LTD. I Dongyl Road Langdian District. Inna-255 005 Zibo, Shandong Prov. Spirin HANDONG XINHUA PHARMACEUTICAL CO., LTD.	Pass	HUTIAN SITE AND GENERAL SECURITY CONTROL SECURITY CONTROL CONT	P COMPLANCE OF A CTUPER RT Mon in assendance with 08149/BC F GEFANNY sontage 5
5	May 2015	KFDA 16 17	ina-255 075 Zibo, Shandong Province Hydrogortisone R1-CEP 2001-210-REV 02	Pass	Der Horender Mandeng Kinhus Pleamassendind Cin., Ltd. Dongstir Road site Die Jamie Verlander Standard Site 202075 Zien, Shandard Ziene 202075 Ziene 202	oestical Co., Ltd.
6	Nov 2015	PMDA 23 129 PMDA 23 121 PMDA 23 124 PMDA	occesses (including purification) for this substance on the site(s) of production mentioned as e certify that the quality of the substance is suitably controlled by the current version of orongraph Acetysalicylic acid no. 309 of the European Pharmacopoeia, current ed duding supplements. In the last steps of the synthesis sector and or success the success of the test for loss on drying described in the monograph, with a limit of not more than 0.5%.	the bion Pass	§ 64 Abs. 1 Activativity easity transposed in the following ran	emulacturer that has but tool tradict; adonal legislation; easts (Derovan Brug Lav d stelling the inspection; of which was conducted at that it complies with s
7	Dec 2016	ANSM 26 27 28	density polyethylene bag. The holder of the certificate beavoided particles of material of human or an origin in the manufacture of the substance. Theophylline Triesphore: 33 (9) 3 88 41 30.3 - Fac. 33 (9) 3 88 41 27 71 - e-mail: ceptiledgm.eu	Pass	Ease site	e requirements referred today substances referi styleness testion trated above at hears o



Inspection History of Other Abroad Authorities



Ibuprofen, Meloxicam etc. Plants103 and 102 East Chemical Zone **Pass** June, 2014 Local FDA Etofesalamide, Glimepiride Multifunctional **Hutian Chemical Pass** Industrial Zone plant etc. November, Phenobarbital, Calcium Plants 102 and 104 East Chemical Zone Local FDA **Pass** 2014 Polycarbophil etc. Pipemidic acid, September, Plants 102 and 105 East Chemical Zone Local FDA Theophylline and 2015 No. R1-CEP 2001-210-Rev 03 Aminophylline ACETYLSALICYLIC ACID Plant 104 East Chemical Zone May 2016 Local FDA Levodopa SHANDONG XIN 14 Dongyi Road Plant 205 **Hutian Chemical** March 2017 Local FDA Metamizole Magnesium dia na **Industrial Zone** Levodopa, Trimethoprim, May 2017 Local FDA **East Chemical Zone** Barbita, and Amobarbital Plant 204 and 207 Aspirin, Salicylic Acid, and Hutian Chemical August 2017 Local FDA Nimodipine Industrial Zone Plant 204 December **Hutian Chemical** Local FDA Tribendimidine Industrial Zone 2017 Inspection History by National Authorities























Certificate Granted



















SHIONOGI & CO., LTD.













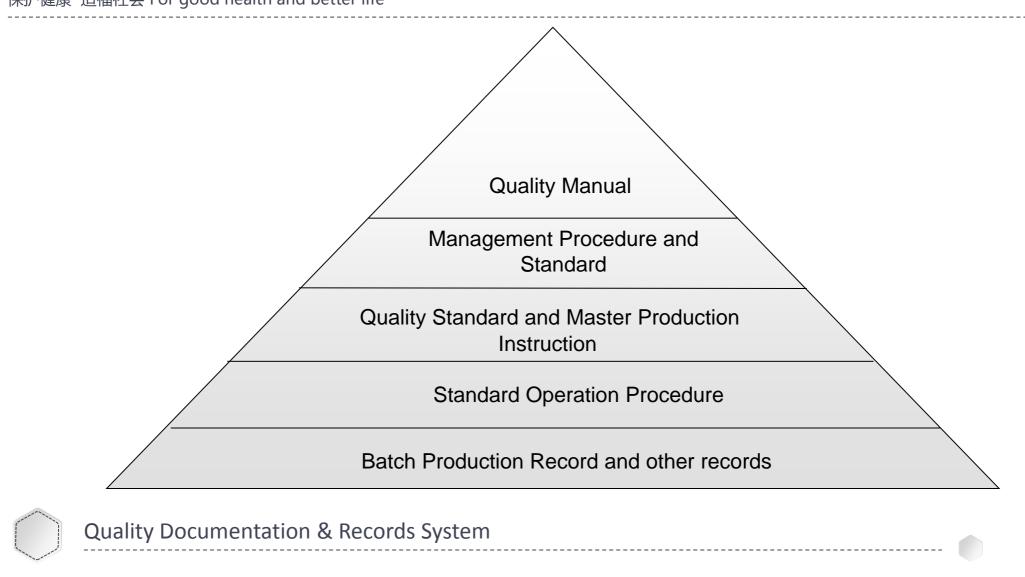
Mitsubishi International Corporation



Marketing Network

Xinhua has established a major worldwide marketing network, reaching over 60 countries. We are the regular supplies for the following multinational corporations, i.e.







Manufacturing Sites



Located in East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong,

P.R.China

Employees: 1300

1100 for production

18 for QA

40 for QC;

41 for Warehouse.

Area occupied: 36,000m²

Leading Products: Caffeine

Ibuprofen

Levodopa

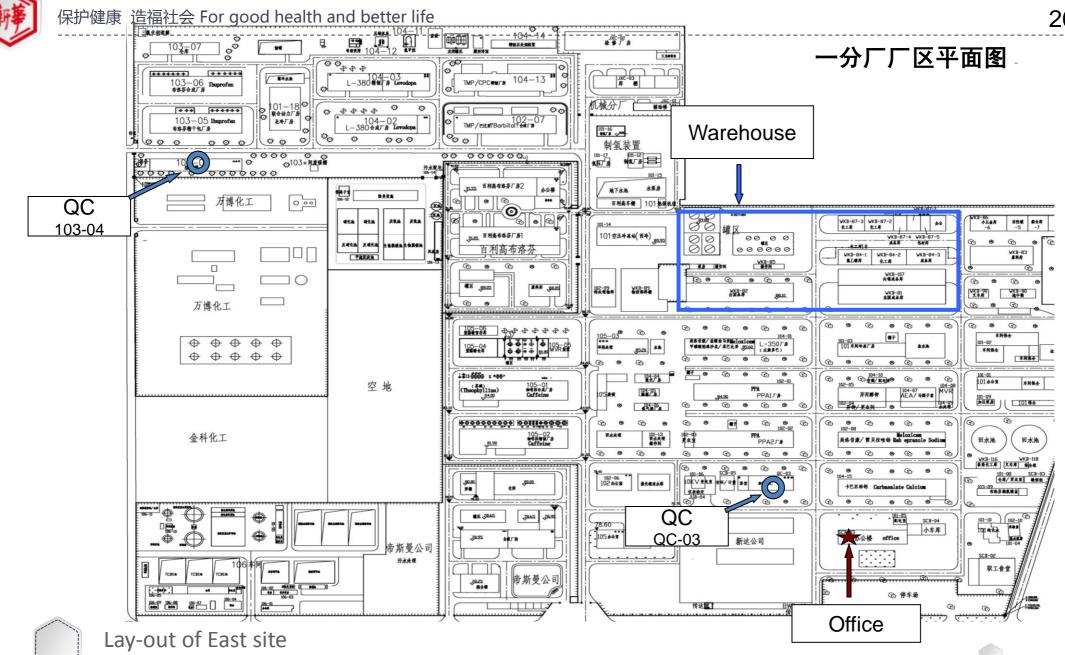
Trimethoprim



East Site









Workshop No.	Leading Products	Remark
Workshop No.101	Power Supply	
Workshop No.102	Phenobarbital Pipemidic Acid	
	Meloxicam	Approved by KFDA
Workshop No.103 Ibuprofen		Approved by FDA and EDQM
Workshop No.104	Levodopa Trimethoprim	Approved by FDA and EDQM
Workshop No.105	Caffeine Theophylline	Approved by FDA and EDQM



Workshop & Leading Products



Working days: 5 days/week

Working shifts: 3 shifts/day and 8 hours/shift

Regular working hours:

a.m.: 8:00-12:00

p.m.: 13:00-17:00

Lunch time:

a.m.: 11:30-12:00



Production Time Arrangement



Located in Hutian Chemical Industrial Zone, Zibo, Shandong, P.R.China

Employees: 1153

889 for production

8 for QA

26 for QC;

34 for Warehouse

Area occupied: 28,700m²

Leading Products: Aspirin

Metamizole

Phenazone

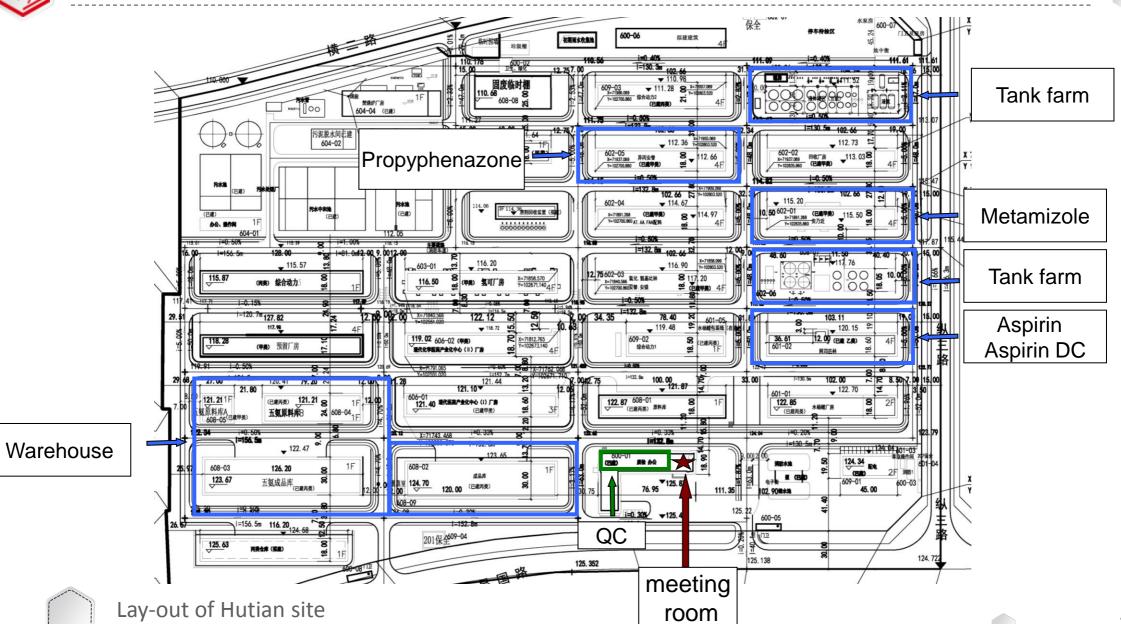
Propyphenazone





Hutian Site







Workshop No.	Leading Products	Remark
Workshop No.201	Power Supply	
Workshop No.203	Hydrocortisone	Under construction
Workshop No.204	Propyphenazone	
Markshan No 20E	Metamizole	
Workshop No.205	Phenazone	
	Aspirin	Approved by FDA and TGA
Workshop No.207	Aspirin Refined DC Aspirin	Approved by FDA



Workshop & Leading Products



Working days: 5 days/week

Working shifts: 2 shifts/day and 12 hours/shift

Regular working hours:

a.m.: 8:00-12:00

p.m.: 13:00-17:00

Lunch time:

a.m.: 11:30-12:00



Production Time Arrangement



4 Safety Percaution



As a chemical pharmaceutical company, various species of chemical raw materials are used in the production precess, most process are completed under the conditions of high or low temperature, high or negaive pressure, so accident is asily caused. In order to guarantee your safety and health, please abide by the following safety requirement when entering production area:

- Please visit accompanied by Xinhua staff, don't be left behand
- Don't touch any equipment valve or switch;
- Don't somke, take pictures and videos in production area;
- Don't use cell phone into the special ares
- In special and emergency circumstances, please obey the guidance of your companion, and gather in the safty zone.



Safety Percaution



We welcome your kind suggestions
during inspection
to Shandong Xinhua
so as to keep the continuous improvement
for our Quality System!

