

**MSSP**

# **Minsheng Group Shaoxing Pharmaceutical Co., Ltd.**

**(MSSP)**



# Minsheng Group

**Hangzhou Minsheng  
Pharma. Holding Group Co., Ltd.**

**Finished dosages with  
different forms**

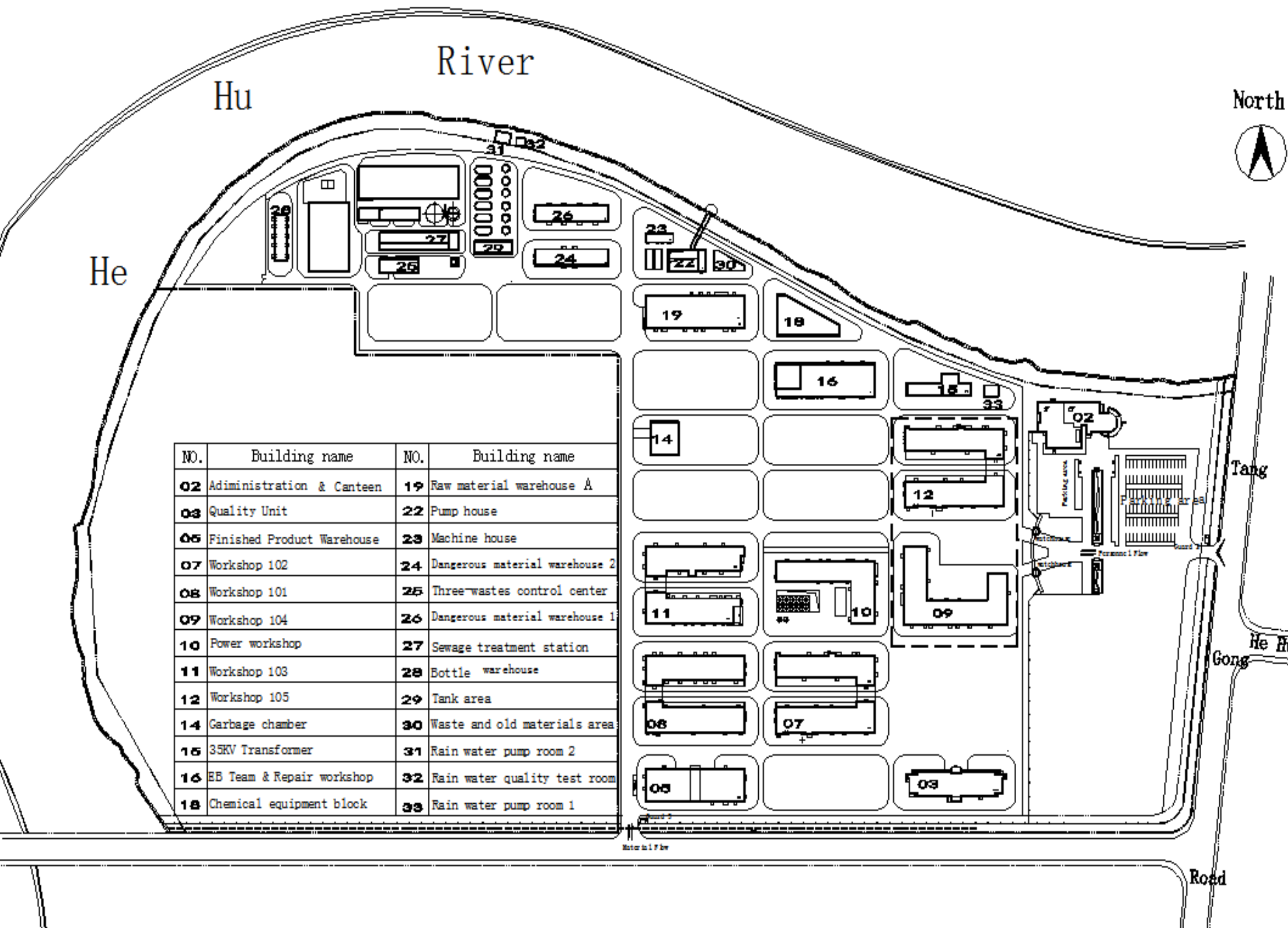
**( MSSP )  
Minsheng Group Shaoxing  
Pharmaceutical Co., Ltd.  
(APIs, US FDA approval/EU  
GMP certificate)**

**Healthcare Products,  
Feed additives, etc.**

**Binjiang Pharma.  
(cGMP plant, US FDA approval,  
Praziquantel tablets apply for  
WHO PQ with USP PQM help)**

# MSSP

## Layout diagram of Minsheng Group Shaoxing Pharmaceutical Co., Ltd



# MSSP

**Cleaning area: 16**

**Classification: D**



**Workshop: 5**

**Reactors: 220**



**USP / EP Purified  
Water system**



# MSSP



- **Facility: Shaoxing, China**
- **Total area: 235,000 m<sup>2</sup>**
- **Staff: 600**
- **Mainly produce nearly 30 kinds of APIs (50% sold abroad)**

- **US FDA inspection: 9 times**
- **EU GMP inspection: 2 times**
- **Experiences with long collaboration with international big Pharma.**



## International Registered APIs

<b>Latest inspection</b>	<b>Products</b>	<b>Agency</b>
<b>Nov.2016</b>	<b>Alanyl Glutamine</b>	<b>Austrian AGES</b>
<b>Apr. 2017</b>	<b>Florfenicol (Process A/B)</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Flunixin Meglumine</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Praziquantel</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Atropine Sulphate</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Omacetaxine</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Alendronate Sodium</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Pyrantel Pamoate</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Pyrantel Tartrate</b>	<b>US FDA</b>
<b>Apr. 2017</b>	<b>Morantel Tartrate</b>	<b>US FDA</b>
<b>2016</b>	<b>Mecobalamin, Fursultiamin HCL, Riboflaxin-5-phosphate sodium</b>	<b>Japan</b>

## Authorities Inspection History

### US FDA inspection: 9 times

- **First time : Apr. 2001**
- **Latest one: Apr. 2017**

### EU GMP inspection: 2 times

- **Nov.2013 by Austiran AGES**
- **Nov.2016 by Austiran AGES**

## **Praziquantel API WHO PQ (1)**

- 2002** MSSP manufactured Praziquantel
- 2014** CPhI Germany, USP PQM approached MSSP for WHO PQ  
MSSP had no sense on receiving free technical assistance from either domestic or international organization
- 2015** MSSP submitted Praziquantel APIMF to WHO PQ
- 2015** WHO PQ first inspected MSSP
- 2014-2015** USP PQM continually contacted MSSP, MSSP finally accept free technical assistance from USP PQM
- 2015** US FDA inspection: 483 of 3 observations



## **Praziquantel API WHO PQ (2)**

- 2016** USP PQM professional and valueble works (site visits, GAP analysis, CAPA assistance for WHO PQ inspection.)
- 2016** USP PQM provided technical assistance on CTD APIMF questions from WHO PQ
- 2016** Before the 2<sup>nd</sup> WHO PQ inspection, USP PQM provided a mock inspection to MSSP, help MSSP to do GAP analysis and complete CAPA

## **Praziquantel API WHO PQ (3)**

**2017 USP PQM participated 2<sup>nd</sup> WHO PQ inspection**

**2017 2<sup>nd</sup> WHO PQ inspection resulted positive outcome**

**2017 US FDA inspection for all the products shipped to USA including Praziquantel API: 483 of 4 observations**

**PQM provided reference standard and comparator for our WHO PQ project**

**USP PQM desk technical assistance is always available and timely.**

**MSSP**

**We'd like to thank USP PQM and  
USAID for the free technical  
assistance to MSSP's  
Praziquantel API for WHO PQ**

**MSSP**

**Thank you**