



# Shandong Boyuan Pharmaceutical Co., Ltd.



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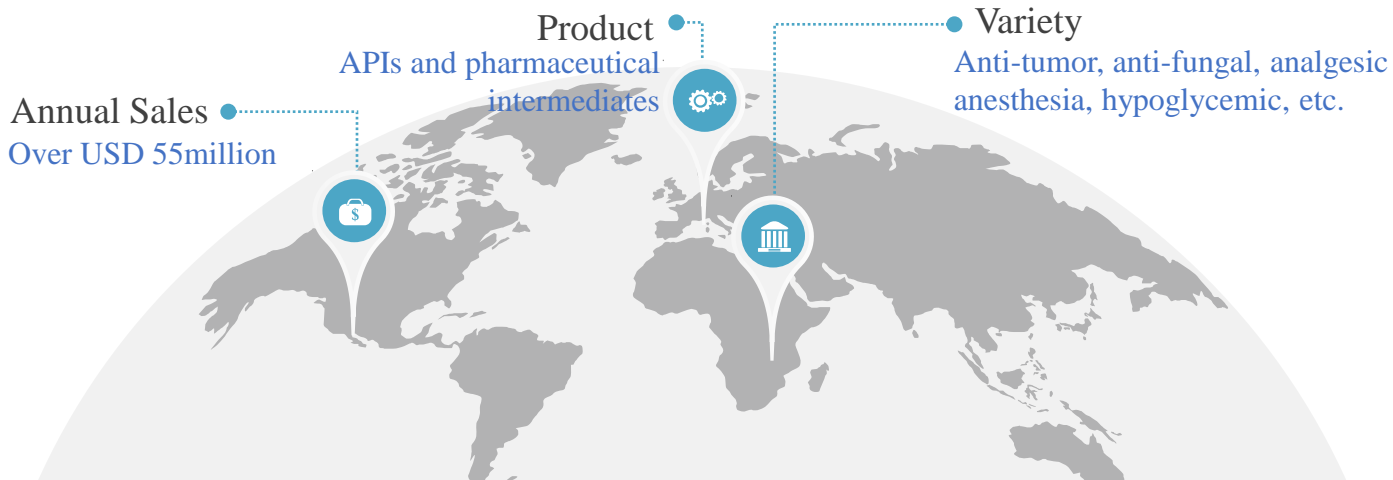
**R&D center**

01

## Company Introduction

## Company History

- ◆ Founded in Year 2001
- ◆ Formerly known as “Jinan Boyuan Chemical Co., Ltd” and “Shandong Boyuan Chemical Co., Ltd”
- ◆ Obtained the Drug Manufacturing License in Jan 2012
- ◆ 2 manufacturing plants: **Jiyang** and **Yucheng**
- ◆ R&D center: Jinan high-tech zone



## Employees

Total employees: 500+

### **Jiyang plant:**

Total: 270+, QA: 17, QC: 23, Production: 110

### **Yucheng plant:**

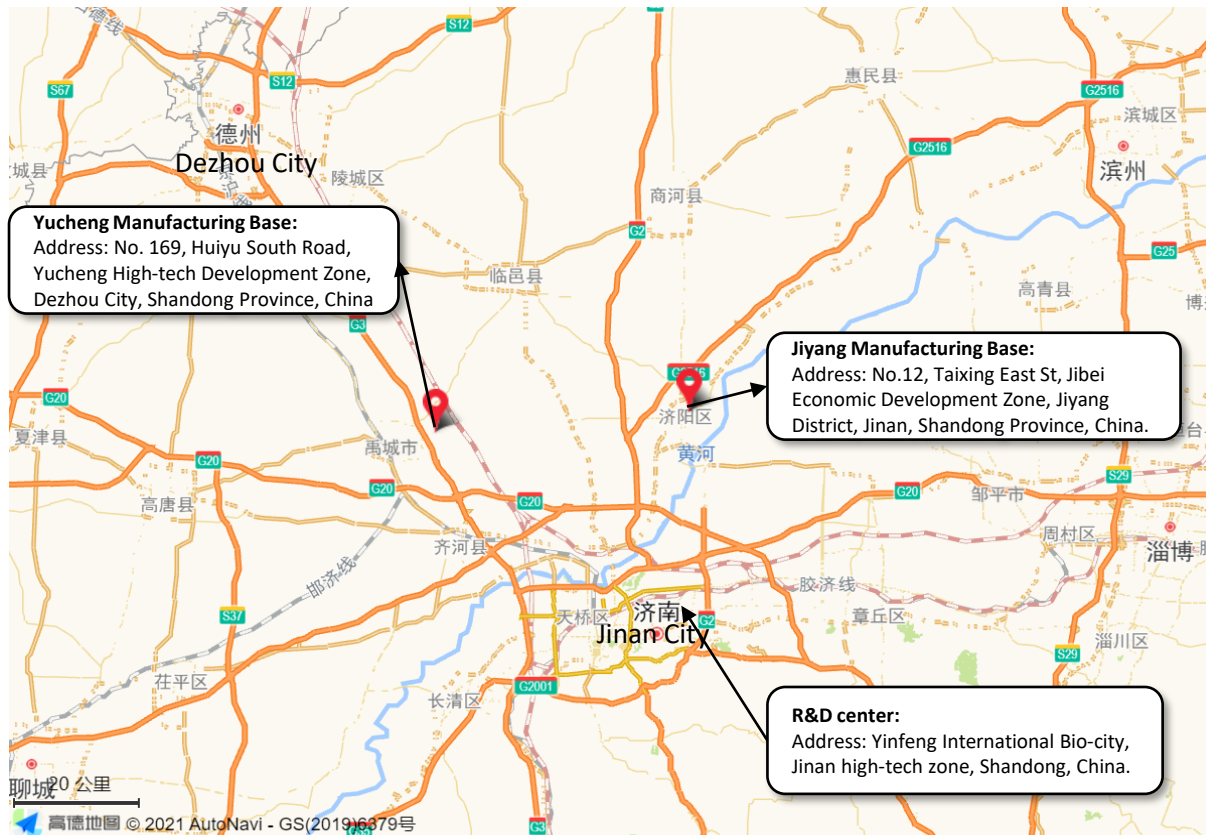
Total: 260+, QA: 9, QC: 31, Production: 170+

### **R&D center:**

Total: 60+



# Site Address



# Business License



## 营业执照

(副本)  
Business license  
Copy

1-1

USCI  
统一社会信用代码  
913701257806047873

**名称** 山东铂源药业股份有限公司  
Company name: Shandong Boyuan Pharmaceutical Co., Ltd.

**类型** 其他股份有限公司(非上市)  
Company ownership: Other shares limited company (non-listed)

**法定代表人** 张立国  
Legal representative: Zhang Ligu

**经营范围**  
许可项目：药品生产，药品委托生产，药品批发，药品零售，新化学物质生产，药品进出口。（依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以相关部门批准文件或许可证件为准）  
一般项目：基础化学原料制造（不含危险化学品等许可类化学品的制造），化工产品生产（不含许可类化工产品），化工产品销售（不含许可类化工产品），生物化工产品技术研发，技术服务、技术开发、技术咨询、技术交流、技术转让、技术推广，货物进出口，技术进出口。（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）

Scope of Business  
Licensed items: drug production, Commissioned production of drugs, Pharmaceutical wholesale, Drug retail; Production of new chemicals, Drug import and export. (Projects that need to be approved according to law can only be operated with the approval of relevant departments. The specific operation items shall be subject to the approval documents or licenses of relevant departments)  
General items: manufacturing of basic chemical raw materials (excluding the manufacturing of hazardous chemicals and other licensed chemicals); Production of chemical products (excluding licensed chemical products); Sales of chemical products (excluding licensed chemical products); Technical research and development of biochemical products; Technical service, technical development, technical consultation, technical exchange, technology transfer and technology promotion; Import and export of goods; Technology import and export. (In addition to the projects that need to be approved according to law, the business activities shall be carried out independently according to law with the business license)



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**注册资本** 陆仟万元整  
Registered capital: RMB 60000000

**成立日期** 2005年10月10日  
Date of Incorporation: Oct. 10<sup>th</sup> 2005

**住所** 山东省济南市济阳区济北经济开发区泰兴东街12号  
Registered Address: No. 12 Taixing East Street, Jibei Economic Development Zone, Jiyang District, Jinan City, Shandong Province.

**登记机关**  
Registration authority  
Administrative Examination and Approval Service Bureau  
2022年03月07日  
2022/03/07





药品生产许可证

Drug manufacturing license

企业名称: 山东铂源药业股份有限公司  
Company name: Shandong Boyuan Pharmaceutical Co., Ltd.

统一社会信用代码: 913701257806047873

USCI: 913701257806047873 山东省济南市济阳区济北经济开发区

住所(经营场所): 泰兴东街12号  
Registered Address: No. 12 Taixing East Street, Jibe Economic Development Zone, Jiyang District, Jinan City, Shandong Province.

法定代表人: 张立国  
Legal representative: Zhang Liguo

企业负责人: 张立国  
Head of company: Zhang Liguo

质量负责人: 苏曼  
Head of quality: Su Man

日常监督管理机构: 山东省药品监督管理局区域检查第一分局  
Daily supervision and management organization: The 1st regional Inspection Branch of SDMPA

投诉举报电话: 12345 (12315)

Complaints and report TEL: 12345 (12315)

有效期至: 2026年04月25日  
Validate to: 2026/04/25

许可证编号: 鲁20160312

License number: SD20160312

分类号: Dh

Classify no: Dh

生产地址和生产范围:

山东省济南市济阳区济北经济开发区泰兴东街12

号; 原料药;

山东省德州市禹城市高新技术产业开发区惠禹南路169

号; 原料药\*\*\*

Manufacturing address and scope:  
No. 12 Taixing East Street, Jibe Economic Development Zone, Jiyang District, Jinan City, Shandong Province, China. API;

No. 169, Huiyu South Road, Yucheng High-tech Development Zone, Dezhou City, Shandong Province, China. API\*\*\*



发证机关: 山东省药品监督管理局

Issued authority: SDMPA

签发人: 史国生

Issuer: Shi Guosheng

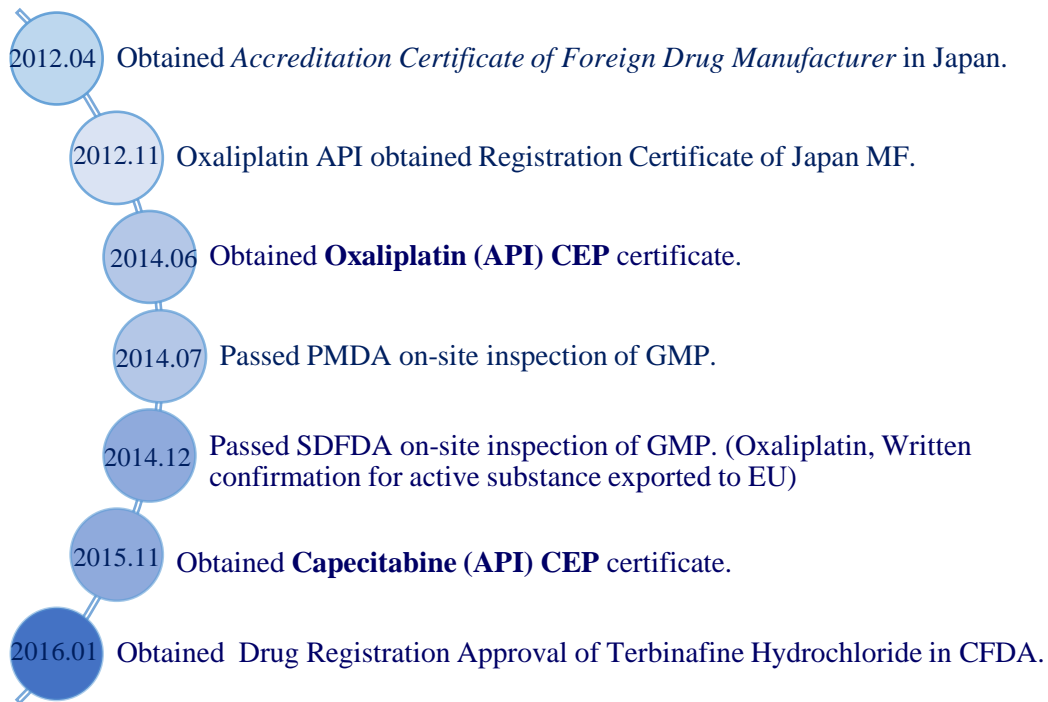


2021年04月26日



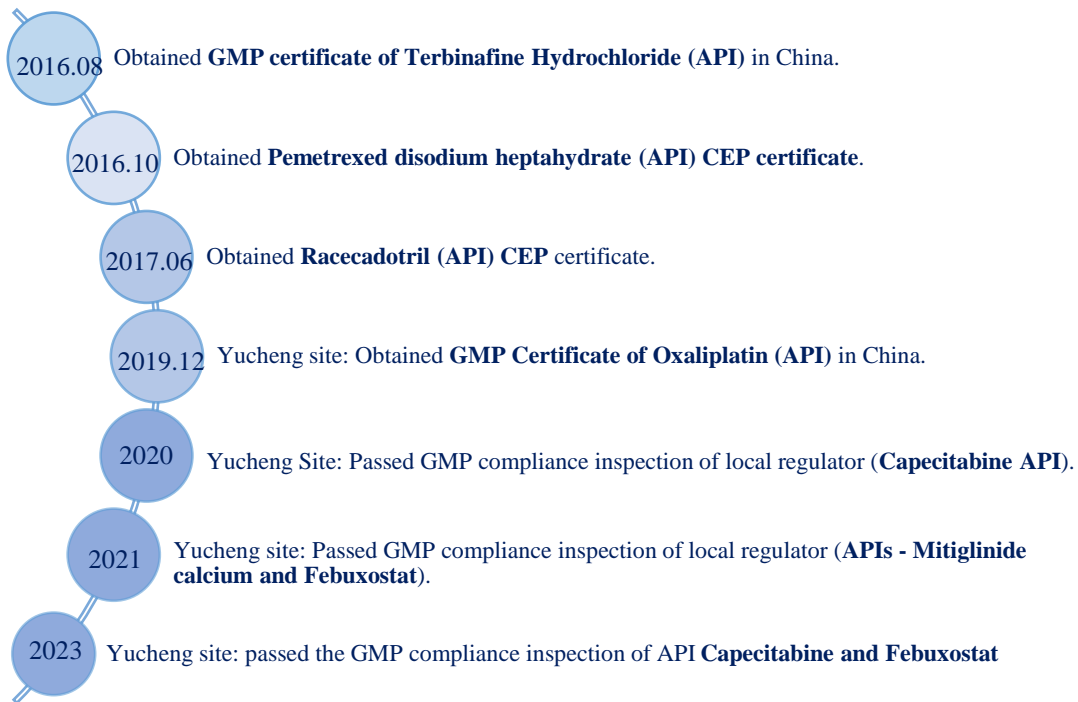
## 》》》 Milestones

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## 》》》 Milestones

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02

Quality System

## Quality policy

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Quality is our priority

Establish a broad & comprehensive system

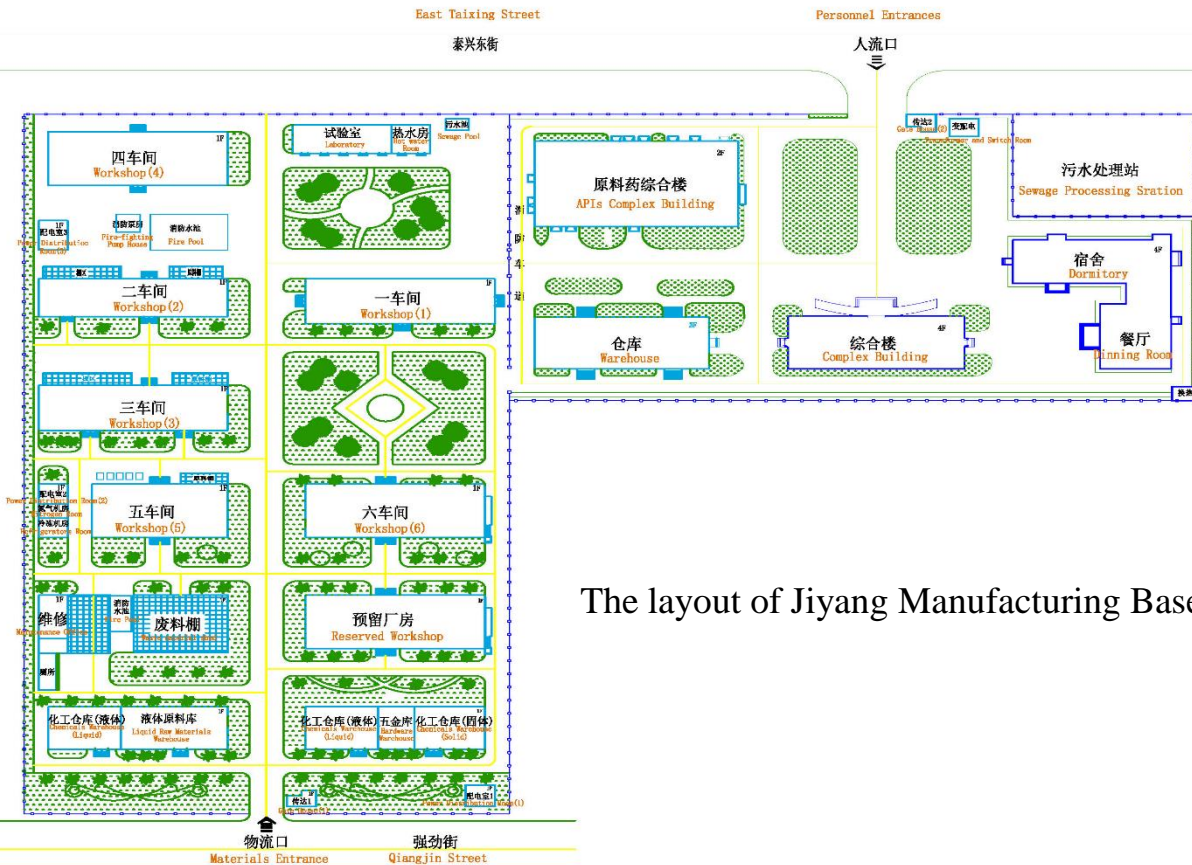
Always improving

Satisfactions

03

**Manufacturing sites**

# 》》》 Jiyang Manufacturing Base



The layout of Jiyang Manufacturing Base

## ➤➤➤ Jiyang Manufacturing Base

- Total area: 30000m<sup>2</sup>
- Total 10 workshops including 6 synthesis workshops and 4 API workshops;
- Well equipped QC lab, HPLCs & GCs use on-line system;
- Production facilities are equipped with purified Water system, HAVC system and tother public utilities;
- Plant is equipped with waste treatment system.



# Yucheng Manufacturing Base

- Put into production since 2020.
- Total area: 106668 m<sup>2</sup>.
- Quality system: Established in line with the GMP standard, following a strict quality management system and conforms with the international standards.
- Facilities: The Yucheng manufacturing site has 2 producing units (Unit Y02 & Y03), QC lab, warehousing, purified water system, power distribution, boiler, waste treatment, tank farm and other auxiliary facilities.
- Product: Nonsterile API and intermediates.
- Production clean area: class D
- HPLCs & GCs in QC lab are connected to on-line system (Empower enterprise).



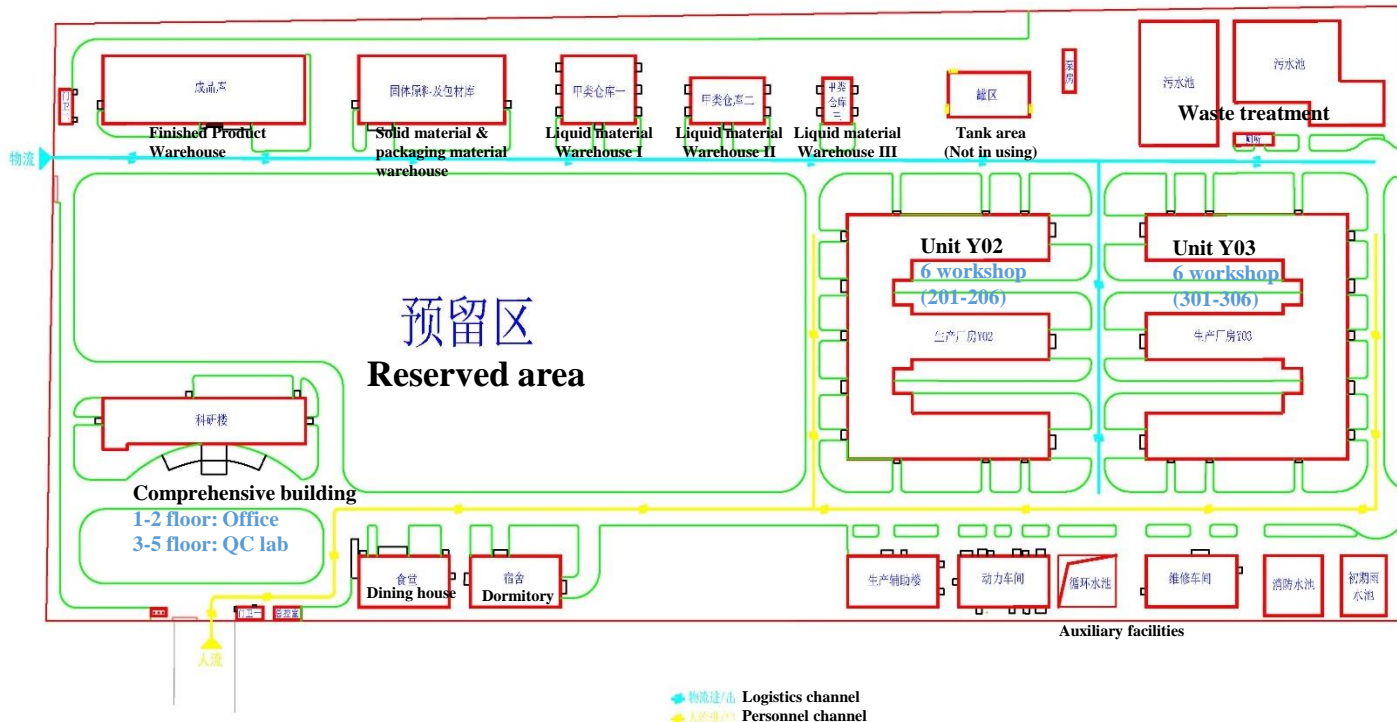
**Comprehensive building**  
(QC lab is on 3rd-5th floor)



**Unit Y02 & Y03**  
(Each unit has 6 workshop)



# Yucheng Manufacturing Base



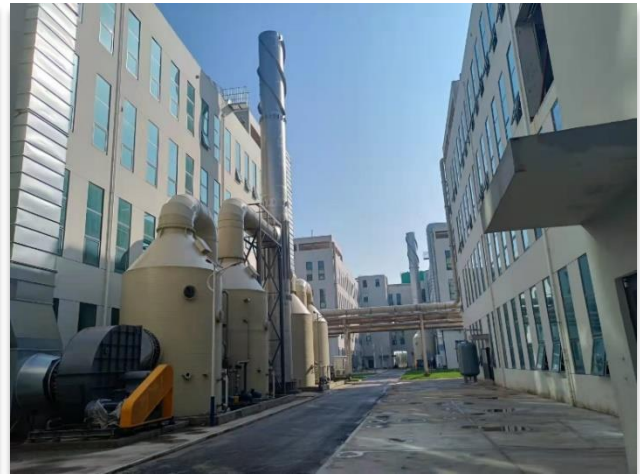
The layout of Yucheng Manufacturing Base

# Yucheng Manufacturing Base

- EHS system
  - Documentation system of Safety, Environment, Health has been established.
  - Discharge system has been established to ensure that wastewater and waste gas meet the national standards.
  - Hazardous waste disposal are carried out according to relevant national regulations.



Wastewater treatment facility



Waste gas treatment facility

04

R&D center

## ➤➤➤ R&D center



- ◆ *Boyuan Pharmaceutical R&D Center was established on January 1, 2012.*
- ◆ *R&D center moved to Yinfeng International Bio-City in Jinan Hi-Tech Zone on December 22, 2021.*



### Facility

- ✓ Dedicated building;
- ✓ Construction area: 2800m<sup>2</sup>;
- ✓ Construct with international advanced design, equipped with VAV fresh air control system to ensure the air quality in the laboratory and the protecting of personnel health.



### Equipment

- ✓ Equipped with more than 50 sets of analytical instruments such as HPLC, HPLC-MS, GC, GC-MS, ICP-MS etc.
- ✓ Equipped with glass reactor, autoclave, ultra-low temperature freezers, rotary evaporators, magnetic stirrers, precision ovens, stability test chambers and other equipment which can meet the kilogram-class process development.



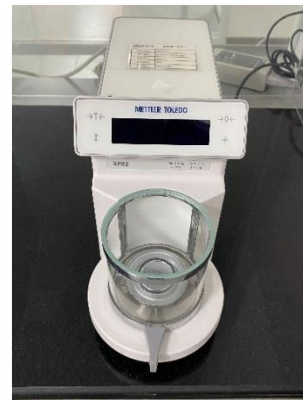
### Personnel

- ✓ A professional and efficient R&D team with great innovation ability;
- ✓ 60+ team members which have well education experience in medical, chemistry or biology;
- ✓ Over 40% of team members have at least 5 years of working experience in process development, quality research or international registration.

➤ Interior pictures



➤ Interior pictures



**THANKS**

