

股票代码  
688553



汇宇制药

HUIYU PHARMACEUTICAL

INTRODUCTION





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# 01 | PART ONE

## Company Overview

*CARING FOR LIFE  
PURSUING EXCELLENCE  
SIMPLICITY AND INTEGRITY*

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## 160000L

Reaction Capacity  
High Potency  
Oncology,  
Cytotoxicity  
Hormone  
Sterile API

## 260+

## 20+

Project Experience  
FDFs & APIs

## IPO2023

Revenue 2023  
RMB 1.5 billion  
(USD 200 million)



## 1400+

Employees  
500+ for R&D  
200+ for QA/QC  
40+ for Registration  
600+ for Production



## CAPABILITY

Liquid & Lyophilization Vial  
Oral Solid  
Pre-filled Syringe  
Cartridge,  
Implant Injection pen



## 20+

On-site inspections from  
China, US, EU, Korea,  
Japan, etc.



# Company History

Huiyu/Seacross Pharmaceuticals was established in 2010 and got the UK GMP certification, which is considered as one of the most stringent global GMP certification within four years. Our first commercial product, Pemetrexed Disodium Injection, was launched in the UK in 2015 and in China in 2017. The sales exceeded 1.3 billion yuan in 2020 and the company was listed on the Science and Technology Innovation Board in 2021. In 2022, we passed US FDA on-site inspection, and then the first CDMO 505B2 formulation was launched in the United States.



# Products in China

**汇誉®**多西他赛注射液  
Docetaxel Injection

 **汇昕**  
注射用阿扎胞苷

**海玥®**注射用培美曲塞二钠  
Pemetrexed Disodium

**汇焯®**盐酸帕洛诺司琼注射液  
Palonosetron Hydrochloride Injection

**汇依®**紫杉醇注射液  
Paclitaxel Injection

**汇祺®**注射用盐酸苯达莫司汀  
Bendamustine Hydrochloride for Injection

**汇泊®**奥沙利铂注射液  
Oxaliplatin Injection

**汇逸®**盐酸伊立替康注射液  
Irinotecan Hydrochloride Injection

**汇可优®**注射用盐酸表柔比星  
Epirubicin Hydrochloride for Injection

**因赫坦®**左乙拉西坦注射用浓溶液  
Levetiracetam Concentrated Solution for Injection

**乐宇成®**丙戊酸钠注射用浓溶液  
Sodium Valproate Concentrated Solution for Injection

**汇阔®**氟尿嘧啶注射液  
Fluorouracil Injection

**宇力浓®**米力农注射液  
Milrinone Injection

**汇汀®**注射用盐酸吉西他滨  
Gemcitabine Hydrochloride for Injection

 **汇涿®**普乐沙福注射液  
Plerixafor Injection

**汇固®**注射用硼替佐米  
Bortezomib for Injection

**汇尔希®**氟维司群注射液  
Fulvestrant Injection

**汇赛®**注射用甲氨蝶呤  
Methotrexate for Injection

**汇山®**唑来膦酸注射液  
Zoledronic Acid Injection

**汇心定®**克拉屈滨注射液  
Cladribine Injection

**宇适安®**苯磺顺阿曲库铵注射液  
Cisatracurium Besylate Injection

**宇舒保®**注射用盐酸罗沙替丁醋酸酯  
Roxatidine Acetate Hydrochloride for Injection

**汇焯®**盐酸帕洛诺司琼注射液  
Palonosetron Hydrochloride Injection

**斯匹德®**硫代硫酸钠注射液  
Sodium Thiosulfate Injection





# Self-branded Products Overseas – Mainly Europe

Over 20 Seacross Pharma self-branded injections and other formulations are launched in the European market simultaneously.

- Azacitidine
- Bendamustine
- Pemetrexed
- Docetaxel
- IrinotecanPFS
- Levetiracetam
- Oxaliplatin
- Palonosetron
- Plerixafor
- Milrinone
- Fulvestrant
- Bortezomib
- Paclitaxel
- Paclitaxel Albumin
- Sodium Valproate
- Zoledronic Acid
- Doxorubicin
- Fluorouracil
- Epirubicin Hydrochloride
- Methotrexate
- Methotrexate Auto-Pen
- Methotrexate PFS
- Acetylcysteine
- Gemcitabine
- Calcium folinate
- Carfilzomib
- Cisatracurium
- Cladribine
- Cyclophosphamide
- Decitabine
- Sodium thiosulfate
- Teicoplanin
- Thiotepa
- Voriconazole
- Ferric Carboxymaltose
- Goserelin
- Lanreotide
- Octreotide
- Eribulin Mesylate
- ...



# Overseas Partnership – Distribution/Licensing/CMO/CDMO

Huiyu Pharma global development strategies are through distribution authorization, licensing, and CMO/CDMO at present.

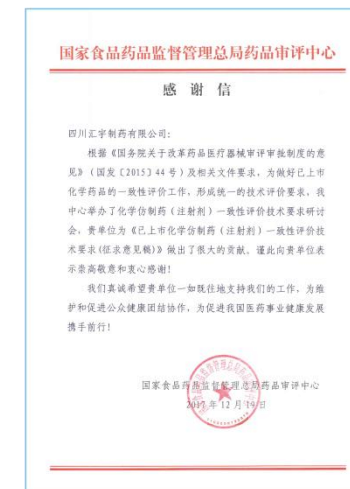
Here are some of the cooperated company brands.





# Company Honors

- Four national level major science and technology projects for new drug development
- National level green factory
- 53rd on the 2022 Top 100 Chinese Chemical and Pharmaceutical Enterprises Ranking
- UK Best Anti-tumor Injection Award
- Sichuan Provincial Nano-targeted Drug & Anti-tumor Drug Preparation Technology Engineering Laboratory
- Sichuan Provincial Anti-tumor Injection Engineering Technology Research Center
- Sichuan Academician (Expert) Workstation
- Advanced Platform for Science and Technology Innovation Work in Sichuan Province



# 02 | PART TWO

## R&D Platform

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## 丁兆 / Ding Zhao

### Dean of Huiyu Pharmaceutical Research Institute

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- At 24, PhD graduated from the Department of Pharmacology at the University of Cambridge, UK, with a focus on the structure-activity relationship between drugs and targets
- At 25, established Huiyu Pharmaceuticals, serving as President, Chairman, and Dean of the Research Institute
- At 30, led the company to export its own brand of anti-tumor injections to EU countries
- At 34, awarded the China Youth Entrepreneurship Award, organized by the Central Committee of the Communist Youth League and the Ministry of Human Resources and Social Security
- At 35, led the company to apply for listing on the Science and Technology Innovation Board with different rights for the same stock
- Gates Scholar, Outstanding Scholar from the UK Department of Education, Outstanding Scholar from the British Society of Biochemistry, Representative to the National Congress of the Chinese Association for Science and Technology, Representative to the Sichuan Provincial People's Congress, and Expert of the Sichuan Hundred Talents Program

# R&D Facility



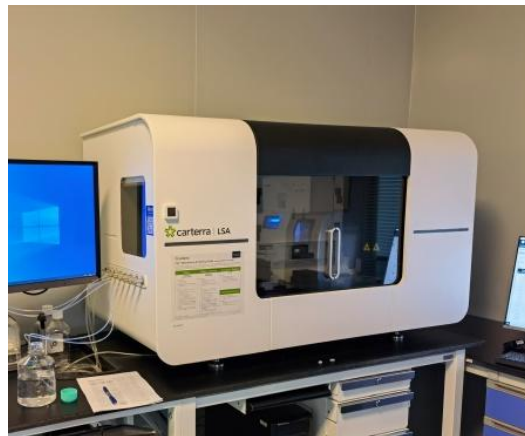
**100** Million USD  
investment



**40,000** m<sup>2</sup>



**2300+** Lab Equipment





**Innovation**

**Integrity**

**Engagements**

 **56** million USD annual researches investment

 **500+** R&D colleagues

 **+35%** R&D colleagues with Masters or PhD degrees



Huiyu Pharma can undertake both API and Formulation projects, such as oral solids, injections, freeze-drying, pre-filling syringes, injection pens, especially complex injections, i.e. Long-acting Implant, Microsphere, Nanocrystal/Nanoparticle, Liposome, Albumin, Injectable Gel, etc.

- **Generic Consistency Evaluation Platform**

A scientific, complete, and efficient consistent evaluation system for injections through project management, product experimental research, technology transfer, and international and domestic registration

- **API Quality Control and Production Technology Platform**

Having established a technology platform for chiral drug research and development, drug crystallization and purification, and drug preparation and purification, mainly focusing on anti-tumor, tumor adjuvant, and contrast agents related fields, while also extending efforts to the fields of raw materials such as cardiovascular and antibiotics



- **Complex Formulation Process Control Technology Platform**

Preparation and purification of polymer excipients, continuous nano formulation production process, twin screw hot melt extrusion, online high shear dispersion, dissolution quality control technology using suspension injection flow cell method, and micelle free drug quality control technology, etc

- **Small Molecule Innovative Drug Technology Platform**

Focusing on the research and development of new anti-tumor drugs, having established a platform for in vivo biological screening, ADME evaluation, chemical processes, PROTAC design, and screening

- **Bio-drug Innovative Technology Platform**

Involved in the fields of multi-specific antibodies, ADC, and mRNA, and established high-throughput in vitro drug efficacy screening platforms, in vivo drug efficacy evaluation platforms, PK/PD and other screening platforms



# 03

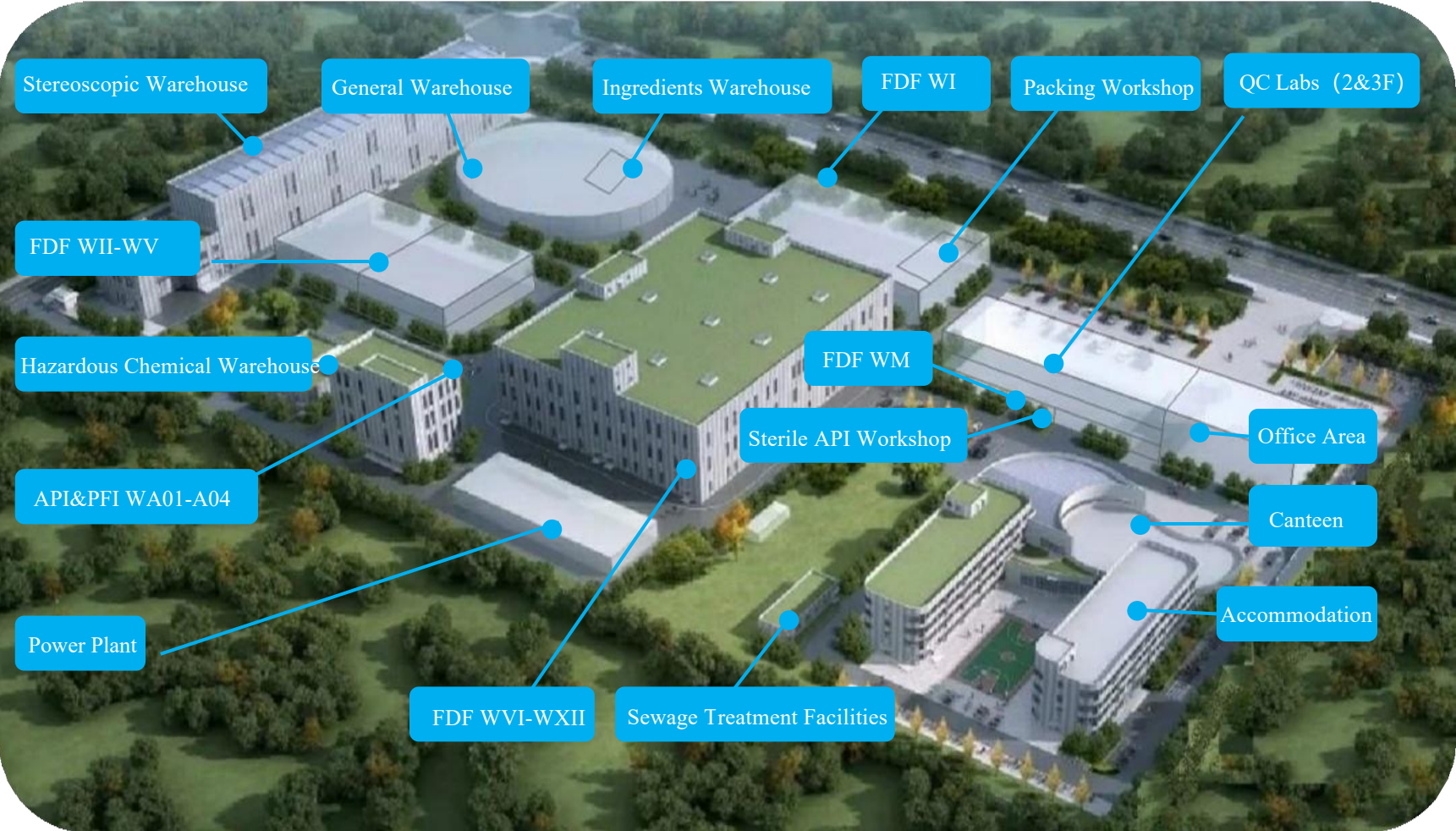
PART  
THREE

## Production Platform for Formulations

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# Formulation Facility



Address: Central Area, Neijiang City,  
Sichuan, China

Items	Total	Workshops	WI Area	Warehouses	Public Area	Office & Accommodation
Area (m²)	100,000	13,000	5,928	2,866	2,000	9,000

# Formulation Production Capacity Overview

Total Area	GMP production facilities cover an area of 100,000 square meters
QA/QC	QA/QC inspection center covers an area of 3,000 square meters
R&D Capability	Generics, 505B2, Innovative drugs, Peptides, mRNAs, etc.
Certification	China NMPA, US FDA, UK MHRA, EU EDQM, Japan PMDA, Korean KFDA, etc.
FDF Production Capability	<p>* 14 different production lines, covering 2-100ml vials, preparation tank 30-2000L, including:</p> <ul style="list-style-type: none"><li>• <b>Fields:</b> High Potent (OEB5), Oncology, Cytotoxic, Hormonal</li><li>• <b>Technology:</b> Long-acting Implant, Microsphere, Nanocrystal/Nanoparticle, Liposome, Albumin, Injectable Gel, etc.</li><li>• <b>Injections:</b> Pre-filled Syringe, Aseptic filling, Final sterilization, Sterile powder filling, Freeze-drying</li><li>• <b>Oral Solids:</b> Tablets, Capsules, etc.</li></ul>




Listing: SSE STAR Market  
Symbol: 688553



fimea  MHRA  FDA



## FDF Workshop I    Oncology Vial Liquid & Lyophilization

Annual Capability	30 million vials (2ml)	
Certification	China NMPA, US FDA, UK MHRA, EU EDQM, Japan PMDA	
Technique Advantages	<ul style="list-style-type: none"><li>• Aseptic filling</li><li>• 2-level sterilization and filtration system</li><li>• Online weighing, Low-temperature preparation, Temperature-controlled filling, Nitrogen preparation &amp; filling, etc.</li><li>• Italian fully sealed automatic isolator filling system (temperature controllable)</li><li>• Especially suitable for products sensitive to heat</li></ul>	
Specification	2ml-100ml	
Applicable	Cytotoxic anti-tumor Liquid and Lyophilization	
Preparation Tank	30L, 100L, 300L	
Filling Speed	Stable at 240 vials/min (2ml)	
Lyo. Machine	3 x 14m²	
Registration	China, US, EU, Japan, Korea, etc.	
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Vial Washing Machine, Tunnel Heating Oven, Filling Equipment, Capping Machine, Stopper Cleaning Machine, Seal Cleaning Machine, etc.	


# FDF Workshop II&III    Albumin, Nanoparticle, Vial Liq. & Lyo.

<b>Annual Capability</b>	70 million vials (2ml)	
<b>Technique Advantages</b>	<ul style="list-style-type: none"> <li>• Aseptic filling</li> <li>• 2-level sterilization and filtration system</li> <li>• Plunger pump filling, Online weighing, Low-temperature preparation, Nitrogen preparation &amp; filling, etc.</li> <li>• TruKing O-RABS system B+A level filling environment</li> </ul>	
<b>Specification</b>	2ml-100ml	
	Workshop III	Workshop II
<b>Applicable</b>	Cytotoxic oncology injection, Albumin Nanoparticle injection (NAB)	General Liq. & Lyo.
<b>Certification</b>	China NMPA, US FDA, UK MHRA, EU EDQM	China NMPA, US FDA, UK MHRA, EU EDQM
<b>Preparation Tank</b>	100L, 500L, 2000L (for General Inj. & Lyo.) 30L, 100L, 200L, 550L, 500L (for NAB)	
<b>Filling Speed</b>	Stable at 500 vials/min (2ml)	
<b>Lyo. Machine</b>	2 x 40m <sup>2</sup>	
<b>Registration</b>	China, US, EU, Japan, Korea, etc.	
<b>Key Equipment</b>	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Vial Washing Machine, Tunnel Heating Oven, Filling Equipment, Capping Machine (2 sets, able to cap for inj. & Lyo. simultaneously), Stopper Cleaning Machine, Vial Outside cleaning machine, Microjet Homogenizer, Thin Film Evaporator (for NAB), etc.	



Annual Capability	10 million vials (20ml)	
Certification	China NMPA, EU EDQM	
Technique Advantages	<ul style="list-style-type: none"><li>• Online weighing</li><li>• Truking C-RABS system B+A level filling environment</li></ul>	
Specification	20ml, 50ml, 100ml	
Applicable	Cytotoxic Oncology Sterile Powder for Injection	
Filling Speed	Stable at 50 vials/min (20ml)	
Registration	China, US, EU, Japan, Korea, etc.	
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Vial Washing Machine, Tunnel Heating Oven, Filling Equipment, Capping Machine, Stopper Cleaning Machine, Seal Cleaning Machine, etc.	




Annual Capability	8 million pcs (0.5ml)		
Certification	China NMPA, EU EDQM		
Technique Advantages	<ul style="list-style-type: none"><li>• Aseptic filling</li><li>• Automatic film tearing robot</li><li>• Low-temperature preparation</li><li>• Nitrogen preparation &amp; filling</li><li>• Truking C-RABS system B+A level filling environment</li></ul>		
Specification	1ml, 5ml		
Applicable	Pre-filled syringe, Cartridge, Injection pen		
Preparation Tank	30L, 100L (Storage Tank 100L)		
Filling Speed	Stable at 70 pcs/min (0.5ml)		
Registration	China, US, EU, Japan, Korea, etc.		
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Filling machine, etc.		



# FDF Workshop VI&VII&X    Terminal Sterilization Injection

Annual Capability	70 million vials (2ml)		
Technique Advantages	<ul style="list-style-type: none"><li>•Terminal sterilization producing line</li><li>•Low-temperature preparation</li><li>•Titanium preparation tank</li><li>•Truking O-RABS system B+A level filling environment</li></ul>		
Specification	2ml-100ml		
	Workshop VI	Workshop VII	Workshop X
Applicable	General Liquid	High Potent Liquid	Oncology Cytotoxic Liquid
Certification	China NMPA, EU EDQM, KFDA	China NMPA, EU EDQM	China NMPA, EU EDQM
Preparation Tank	100L, 500L, 3000L, 5000L		
Filling Speed	Stable at 500 vials/min (2ml)		
Sterilization cabinet	5m³ Water bath sterilization cabinet		
Registration	China, US, EU, Japan, Korea, etc.		
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Vial Washing Machine, Tunnel Heating Oven, Filling Equipment, Capping Machine, Stopper Cleaning Machine, Seal Cleaning Machine, etc.		




Annual Capability	70 million vials (2ml)	
Technique Advantages	<ul style="list-style-type: none"><li>• Low-temperature preparation</li><li>• Aseptic feeder</li><li>• Cutting and Emulsification Tank, Receiving Vessel with Agitator</li><li>• Truking O-RABS system B+A level filling environment</li></ul>	
Specification	2ml-100ml	
Applicable	Hormonal Vial Liquid & Lyophilization	
Preparation Tank	100L, 500L, 3000L	
Filling Speed	Stable at 500 vials/min (2ml)	
Lyo. Machine	3 x 40m²	
Registration	China, US, EU, Japan, Korea, etc.	
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Vial Washing Machine, Tunnel Heating Oven, Filling Equipment, Capping Machine, Stopper Cleaning Machine, Seal Cleaning Machine, etc.	



Annual Capability	70 million vials (2ml)
Technique Advantages	<ul style="list-style-type: none"><li>• Low-temperature preparation</li><li>• Truking O-RABS system B+A level filling environment</li></ul>
Specification	2ml-100ml
Applicable	Liposome, Liquid, Lyphilization
Preparation Tank	100L, 500L, 3000L
Filling Speed	Stable at 500 vials/min (2ml)
Lyo. Machine	2 x 40m <sup>2</sup>
Registration	China, US, EU, Japan, Korea, etc.
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Vial Washing Machine, Tunnel Heating Oven, Filling Equipment, Capping Machine, Stopper Cleaning Machine, Seal Cleaning Machine, etc.



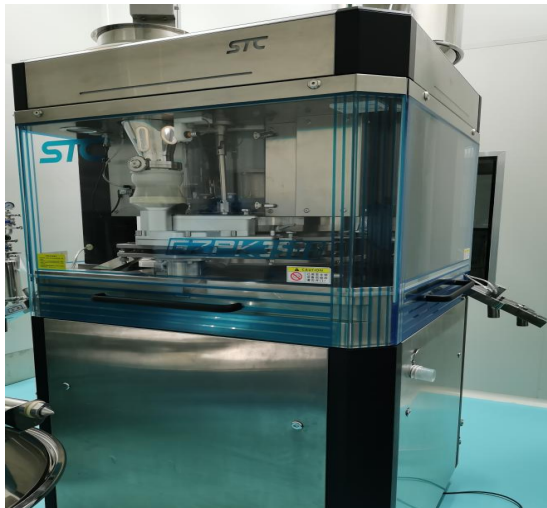
Annual Capability	5 million pcs	
Technique Advantages	<ul style="list-style-type: none"><li>• O-RABS system B+A level filling environment</li><li>• Low-temperature preparation</li></ul>	
Specification	0.25g, 0.38g, 0.51g	
Applicable	Semi-solid Pre-filled Syringe	
Preparation System	8L Double-chamber mixing tank for liquid preparation system	
Filling Speed	Stable at 2,000 pcs/h	
Registration	China, US, EU, Japan, Korea, etc.	
Key Equipment	Double-tank Liquid Preparation System, Filling and Needle-adding Equipment, Puncture-proof Device Installing System, Pulsation Vacuum Pressure Steam Sterilization Cabinet, etc.	

Annual Capability	5 million pcs
Technique Advantages	<ul style="list-style-type: none"><li>• O-RABS system B+A level filling environment</li><li>• Hot Melt Extruder</li></ul>
Specification	60mg, 90mg, 120mg
Applicable	Long-release Implants
Preparation Tank	10L
Filling Speed	Stable at 40 pcs/min
Registration	China, US, EU, Japan, Korea, etc.
Key Equipment	Pulsation Vacuum Pressure Steam Sterilization Cabinet, Filling System, Freeze-drying Machine, Quick-freezing Machine, Installment Machine, External Unpacking Machine, Internal Unpacking Machine, etc.





Annual Capability	1.5 billion pcs
Technique Advantages	<ul style="list-style-type: none"><li>• Canaan Wet Granulation Production Line</li><li>• Tianxiang Tablet Pressing Machine, able to press double layer tablets</li><li>• Xinma &amp; Hanlin Capsule Filling Machine, able to fill capsules in various processes such as direct mixing, granulation, and pellets, etc.</li></ul>
Applicable	Oral Solids
Tablet pressing speed	340,000 pcs/h
Capsule filling speed	120,000 pcs/h
Registration	China, US, EU, Japan, Korea, etc.
Key Equipment	Jet Miller, Hammer Miller, Wet Granulator, Dry granulator, Boiling and Granulating Drier, Straightening Granulator, Mixer, Tablet Pressing Machine, Coating Machine, Capsule Filling Machine, Bubble Packaging Machine



# 04

PART  
THREE

## Production Platform for APIs

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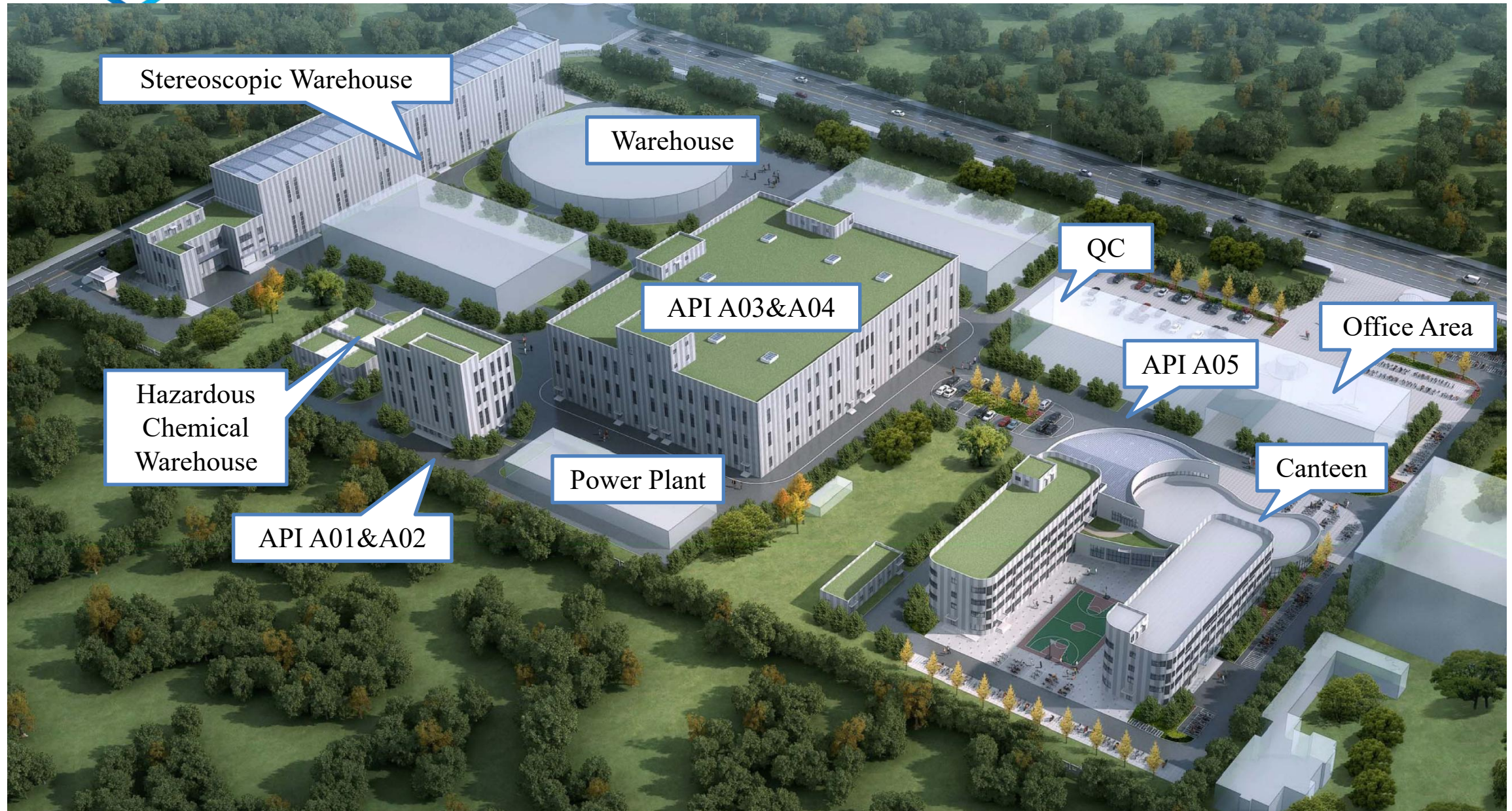
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# API Facility





# API Facility Old Site (A)





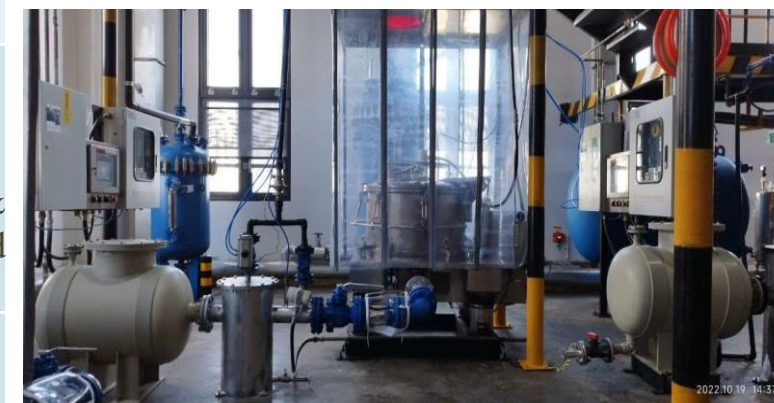
# API Facility New Site (B)





# API Factory Overview

<b>Factory Overview</b>	<b>2 factories cover 400 acres 2.75 billion yuan investment</b>
<b>Workshop Overview</b>	<ul style="list-style-type: none"><li>• 5 oncology API workshops</li><li>• 5 general API workshops</li><li>• 1 peptide synthesis and purification workshop</li><li>• 1 mRNA workshop</li><li>• 1 sterile API workshop</li><li>• 2 automatic fermentation workshops</li></ul>
<b>Certification</b>	Our API factories have undertaken 4 on-site inspections of production license, involving 15 APIs, of which 10 APIs have been registered, 3 APIs have passed China GMP compliance inspections, and 1 sterile API has passed EU EDQM and US FDA on site inspection.
<b>Production Capability</b>	<ul style="list-style-type: none"><li>• Batch size from lab, pilot, PV to commercial production</li><li>• Industrial solutions from ultra-low temperature to ultra-high temperature</li><li>• MSG, SS, Titanium, Glass reactors, size 100L~5,000L</li><li>• Capable of molecular distillation, high vacuum distillation, solvent recovery &amp; treatment (atmospheric pressure, pressurization, and depressurization) , and permeation through gasification membranes.</li></ul>
<b>Applicable</b>	Oncology, Cytotoxic, High Potent (OEB 5), Hydrogenation, Fermentation, etc.





# Oncology, Cytotoxic, High Potent API Workshop (OEB 4&5)

Applicable	Oncology, Cytotoxic, High Potent (OBE 4-5)
Certification	On-site production license verification approved
Technique Advantage	Various temperature, pressure, and corrosion resistant reactors, centrifuges, drying ovens, and other functional modules of different specifications, with a total reaction vessel solvent of 65m <sup>3</sup>
Annual Capability	1,000~50,000kg



Key Equipment					
Equipment	Quantity	Specifications	Equipment	Quantity	Specification
Reactor MSGL	26	100~6300L (-20~130℃)	Centrifuge	12	LB450-LB1000, SS coat, Lined Hallar
Reactor SS	3	500~2000L (-20~130℃)	Vacuum Drying Oven	17	8~32Plates (Room Temp.~100℃) SS/Titanium coat, Lined Hallar
Reactor Titanium	5	300~3000L (-40~230℃)	Miller	4	BXK56 400
Reactor Glass	10	30-100L (-80~230℃)	ANFD	1	1000L
Double Cone Vacuum Dryer	4	200-750L	Single Cone Vacuum Dryer	1	800L

Applicable	General Small Molecule API
Certification	On-site production license verification approved
Technique Advantage	Various temperature, pressure, and corrosion resistant reaction vessels, centrifuges, drying ovens, and other functional modules of different specifications, with a total reaction vessel solvent of up to 60m <sup>3</sup>
Annual Capability	1,000~50,000kg



Key Equipment					
Equipment	Quantity	Specification	Equipment	Quantity	Specification
Reactor MSGL	22	300~10000L (-20~130℃)	Centrifuge	12	LB450-LB1000 SS coat, Lined Hallar
Reactor SS	3	500~2000L (-20~130℃)	Vacuum Drying Oven	17	8~32Plates (Room Temp.~100℃) SS/Titanium coat, Lined Hallar
Reactor Titanium	4	300~3000L (-40~230℃)	Miller	4	BXK56 400
Reactor Glass	10	30-150L (-80~230℃)	ANFD	1	1000L
Double Cone Vacuum Dryer	4	200-750L	Single Cone Vacuum Dryer	1	800L
Distillation system	1	200L	Molecular distiller	1	N/A

# Sterile API Workshop (Cytotoxic)

Applicable	Sterile API (Cytotoxic)
Certification	EU EDQM, US FDA, CN NMPA
Technique Advantage	Advanced sterilization and filtration system, Crystallization system, Filtering, washing and drying system, Automatic sterile packaging and capping system in B+A environment
Annual Capability	1000kg



Key Equipment					
Equipment	Quantity	Specification	Equipment	Quantity	Specification
Dissolution Reactor	1	200L	Sterile Miller	1	CN250/HM300
Crystallization Reactor	1	200L	Wet heat sterilization cabinet	1	0.36m3
Filtering, washing and drying system	1	DN1000	Dry heat sterilization cabinet	1	DMH-1.0m3
Sterile packaging and capping system	1	5L	B+A level clean area	1	N/A



Applicable	Peptide, mRNA
Certification	On-site production license verification approved
Technique Advantage	Advanced automated peptide synthesis equipment and split equipment, Nucleic acid synthesis equipment, Industrial chromatography, Freeze-drying machines
Annual Capability	140kg



Key Equipment					
Equipment	Quantity	Specification	Equipment	Quantity	Specification
Peptide synthesizer	1	JBP-200-2AL	Freeze-drying machine	1	LYO-10(CIP)
Peptide splitter	1	JBC-50-2AL	Industrial chromatography	1	Cs-prep300
Vacuum drying oven	2	4 plates	Dry heat sterilization cabinet	1	DMH-0.8m3
Centrifuge	1	450	D-level clean area	1	N/A
Nucleic acid synthesizer	1	ÄKTA Oligo Pilot OP2000			

# Fermentation and Extraction Workshop

Applicable	Microbial fermentation related products
Certification	N/A
Technique Advantage	Two fully automatic fermentation production lines equipped with independent CIP systems; Capable of undertaking the landing of synthetic biology related products, including fermentation, extraction and purification. Simultaneously possessing a fermentation capacity of 60T, equipped with strain screening laboratory, mold room, biological potency testing room, etc.
Capability	Max Reactor 60 Tons



Key Equipment					
Equipment	Quantity	Specification	Equipment	Quantity	Specification
Fermentation Reactor	7	60L~6000L	Board Frame	2	XAZG80/1000-U (Filter chamber capacity 1275L, Filtration area 80 m²)
Supplement Reactor	8	500L	Nanofiltration System	1	4m³/h
Extraction Reactor	3	500~5000L	Ceramic membrane system	1	10m³/d
Centrifuge	1	PSB600H (Diameter 600)	Vacuum Drying Oven	1	FZG-32 (32Plates)
Lined PTFE Chromatography Column	2	500~1200L (450~750*3000) Lined PTFE	Strain screening laboratory Biological potency determination laboratory	1	Intelligent full temperature oscillation incubator, Medical low-temperature storage box, Biosafety cabinet, Ultra clean workbench, Vertical steam sterilization cabinet, Pulsation vacuum sterilization cabinet, etc.

# 05

| PART FOUR

## Quality Control and Guarantee

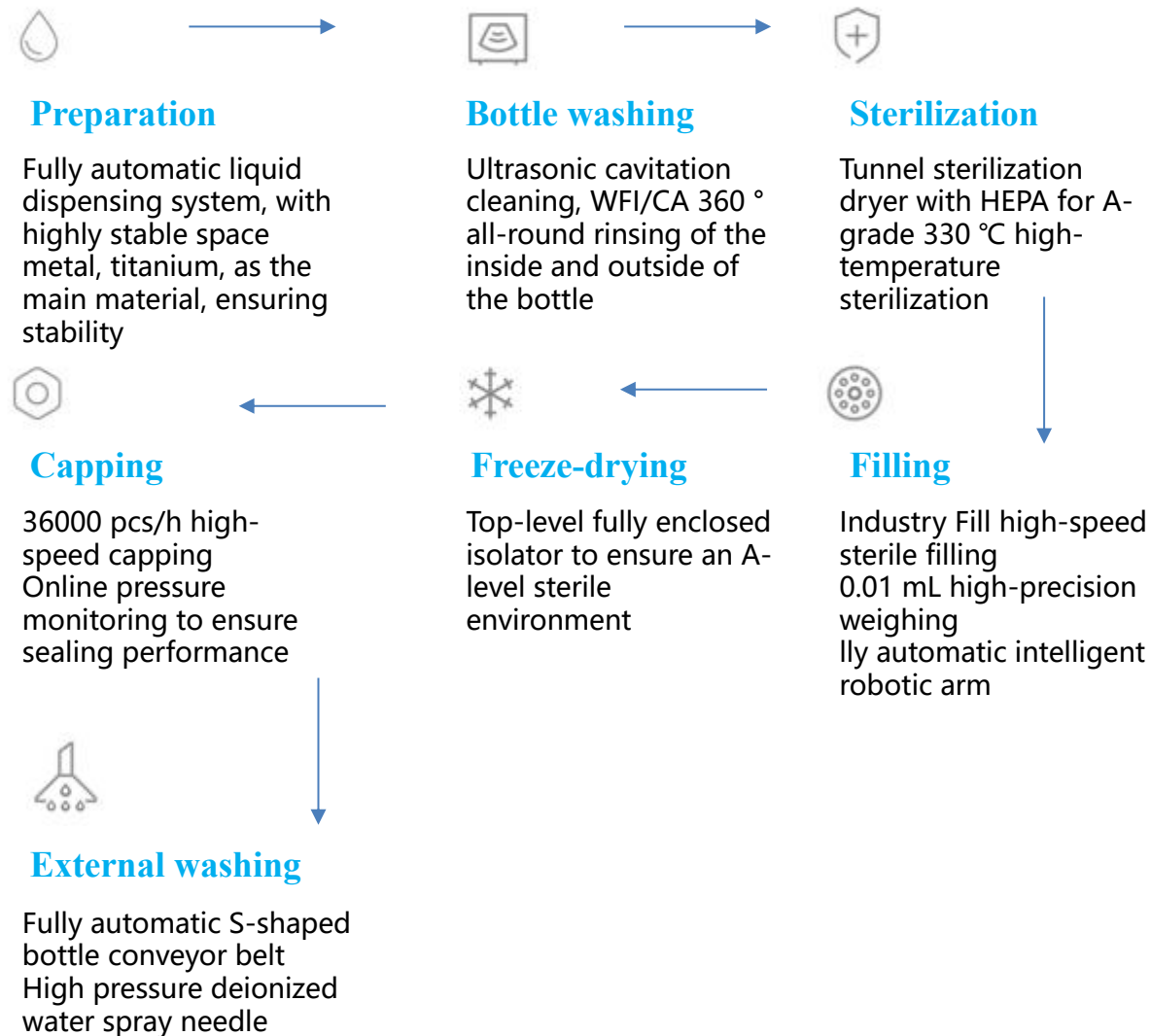
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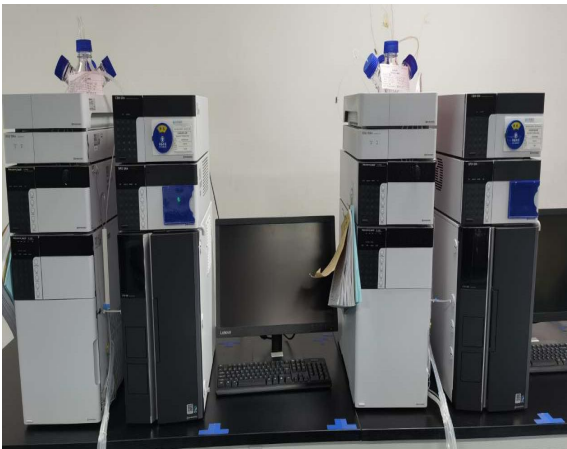


## Top production equipment guarantee

The production lines follow **the German-origin design concept** of M+W Group and introduce international advanced equipment, such as ISOLATOR, CRABS, VHP sterilization, automatic feeding and unloading of freeze-drying machines, and online weighing, etc. **The world's leading level of automatic intelligent production equipment eliminates the risk of product pollution caused by human interference.** The production process achieves low-temperature production technology throughout the entire process, reducing the risk of impurity generation and active substance degradation.



# Big Brand Laboratory Equipment Guarantees Quality



## Equipment

UHPLC

HPLC

GC

IR

UV

TOC

ICP

AAS

IC

KF Titrator

## Brands

Shimadzu

Waters / Agilent/ Shimadzu /ThermoFisher

Agilent/ Shimadzu

Shimadzu

Shimadzu

Shimadzu

Agilent

Shimadzu

ThermoFisher

Metrohm

The laboratory is equipped with over a hundred sets of experimental instruments from manufacturers such as Waters, Agilent, Shimadzu, and ThermoFisher, which can meet the needs of various inspection activities. At the same time, the LIMS laboratory system is used for laboratory management.

Comprehensive configuration of testing equipment, with the ability to detect APIs, FDFs, auxiliary and packing materials.

## 色谱仪

### Chromatograph

- 4 GC
- 58 HPLC
- 2 UPLC
- 2 IC
- Agilent
- Shimadzu
- ThermoFisher

## 光谱仪

### Spectrograph

- Handheld Raman spectrometer
- UV spectrometer
- Infrared spectrometer
- Particle size analyzer at micron and nanometer scales
- Polarimeter

## 元素分析仪

### Elemental Analyzer

- Comprehensive detection and evaluation of elemental impurities
  - · ICP-MS
  - · AAS

## 分析天平

### Analytical Balance

- High precision balance, reducing inspection consumption
- 2 sets of 0.001mg analytical scales
- 3 sets of 0.01mg analytical scales

## 密封件检测

### Container Closure

### Integrity Testing

- EP/ USP/CP tests
- Heat resistant impact tester
- Internal pressure resistance tester
- Vacuum attenuation
- Microbial invasion



### Rigorous quality control system

Huiyu Pharmaceuticals has established a rigorous quality management system in accordance with Chinese GMP, EU GMP, and US FDA regulations. We have passed the on-site inspection from China NMPA, UK MHRA, EU EDQM, US FDA, Korea KFDA, Japan PMDA multiple times.

We adopt the strictest standards to ensure that every product exceeds the quality standards of the Chinese, American, and European pharmacopoeia.



# On Site Inspection History

Authority	Times	Type	Date	Target
MHRA	2	GMP Certification	2014.04.14-2014.04.18 2017.08.21-2017.08.25	Injection Workshop (I) Workshop M
Republic of Sudan National Medicines & Poisons Board	1	GMP Certification	2016.08.26-2016.08.28	Injection Workshop (I) Workshop M
South African Health Products Regulatory Authority	1	GMP Certification	2018.10.09-2018.10.13	Injection Workshop (I)
FIMEA	2	GMP Certification	2021.05.19-2021.05.25 2023.04.17-2023.04.19 2023.05.11-2023.05.16	Injection Workshop (I) Workshop M Workshop M Injection Workshop (I)- (VI) Injection Workshop (X)、Workshop A05
NMPA	10	GMP Certification (Lyophilization line)	2014.10.23-2014.10.26 2019.08.24-2019.08.27	Injection Workshop (I)
		GMP Certification(Small volume injection)	2018.01.11-2018.01.16 2021.05.11-2021.05.24	Injection Workshop (I)
		GMP Certification (Lyophilization line)	2020.06.20-2020.06.24	Injection Workshop (III)
		GMP Certification	2021.08.15-2021.08.19	Injection Workshop (III) Workshop M
		GMP Certification (Small volume injection)	2022.08.24-2022.08.27	Injection Workshop (X)
		GMP Certification (Small volume injection)	2023.01.11-2023.01.14	Workshop M
		GMP Certification (Small volume injection)	2023.08.30-2023.09.04	Injection Workshop (V)、Injection Workshop (VI)
		GMP Certification	2024.01.24-2024.01.29	Workshop M
FDA	2	GMP Certification	2022.07.18-2022.07.26	Injection Workshop (I)
			2023.11.06-2023.11.14	Injection Workshop (IV)、Workshop A05
Portuguese Ministry of Health	1	GMP Certification	2023.02.13-2023.02.17	Injection Workshop (II)



The first Chinese injection enterprise  
that passed the UK GMP certification  
for the first time in 2014

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**SIMPLICITY AND INTEGRITY**





# 06

| PART FIVE

## Overseas Registration & Sale

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# Overseas Registration and Quality Control Experience

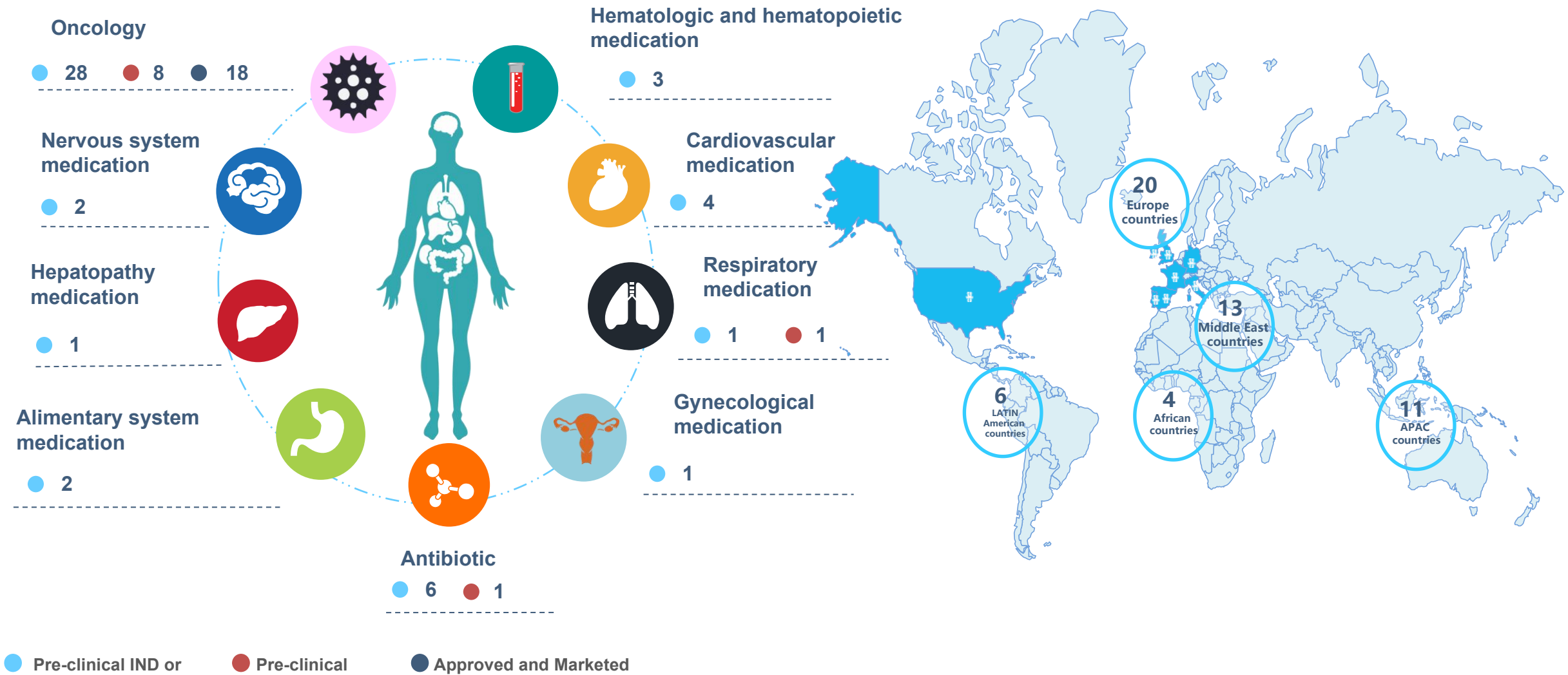
## Rich experience in European registration and quality control

1. Registration colleagues basing in both China and Europe
2. Direct communication with EU/UK officials and reviewers
3. Independent dossier writing, BE research and experimental design, EMA official clinical consultation, etc.
4. 74 pieces of European & UK MAH approvals
5. Perfect quality system, from product import and export to Europe to quality testing/release before commercial launch, etc.
6. A comprehensive pharmacovigilance system
7. Rich experience in GMP certification and guidance
8. Over 12 years of experience in EU registration laws and regulations

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# Overseas Registration Achievements





## Rich experience in European marketing and sales

- 
1. Over 10 years of deep cultivation in the UK/EU markets, with branch offices in 8 countries, including the UK, Germany, France, Italy, Spain, etc.
  2. Direct market coverage in 7 major European countries
  3. Years of experience in collaborating with European brands from multiple multinational corporations
  4. High market recognition of independent company brands
  5. 100% localized operation and comprehensive sales channels
  6. European standard secondary packaging & product traceability system, testing and release, market access, PV and after-sales, etc.
  7. Covering over 25 countries in the EU market through direct and mixed sales models
  8. Having undertaken the registration and agency sales of products from multiple large domestic and foreign enterprises in Europe

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## Overseas Sales Achievements

- Self owned or authorized partners have signed cooperation agreements with nearly 100 countries, covering 6 continents.
- Products such as irinotecan hydrochloride injection, docetaxel injection, and zoledronic acid injection have won multiple rounds of regional bidding procurements organized by the British government, with priority to supplying public medical institutions in the UK, such as Queen Elizabeth Hospital, Royal London Hospital, and Cambridge University Affiliated Hospital.

### Overseas Market Overview



### Success overseas bidding cases

- Irinotecan Hydrochloride Injection: won 5 rounds of bidding since 2015
- Docetaxel injection: won 4 rounds of bidding since 2016
- Zoledronic acid injection: 6 rounds of bidding since 2017
- Azarcytidine for injection: won 2 rounds of bidding since 2020

# 07

| PART SIX

## Why Us

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## WHY US?

### ● Rapid Response from R&D, Manufacturing, Registration Technique Support

Huiyu scientists graduated from world-renowned universities such as Harvard, Cambridge, and Peking University will provide fast response to customer needs, with years of project management experience.

### ● Global Top-Grade Quality System

Throughout the entire production lifecycle, Huiyu quality risk management has been well established and certified by China NMPA, EU EDQM, US FDA, Japan PMDA, Korea KFDA, etc.

### ● Facility Meets All Kinds of Production Needs

From API to Formulation, Huiyu facility capacity covers complete production requirements of all specifications, multiple dosage forms, complex reactions, and special materials, etc.

### ● Overseas Registration with Decades of Experience

With 8 overseas branches, Huiyu international registration and sales team provide integrated services.

# Thank you for your support!

## Vision

Becoming a respected international pharmaceutical enterprise

## Mission

Providing globally effective, high-quality, and affordable drugs for patients

Making cancer a controllable chronic disease


## Value


Caring for Life, Pursuing Excellence, Simplicity and Integrity


# CMO/CDMO EXPERTS IN QUALITY AND RELIABILITY


Caring for Life - Pursuing Excellence - Simplicity and Integrity

## Thank You

 : [www.seacrosspharma.com](http://www.seacrosspharma.com)  
[www.huiyupharma.com](http://www.huiyupharma.com)

 : +86 17608 10 20 30

 : [Isabella.tao@seacrosspharma.com](mailto:Isabella.tao@seacrosspharma.com)  
[xingchen.tao4137@huiyupharma.com](mailto:xingchen.tao4137@huiyupharma.com)

 : Chengdu Tianfu International Bio-town, Sichuan, China

