MCE®
MedChemExpress

CRO/CDMO
Service

CONTENT

ABOUT US

MedChemExpress (MCE) offers a wide range of high quality bioactive chemicals including novel life-science reagents, reference compounds, APIs and natural compounds for basic and translational preclinical research. We offer only the highest-grade products!

MCE has a dedicated customer service and technical support team with years of experience in the life science industry. Our goal is to help you achieve scientific and career success with our products and service.

MCE will be a trustworthy partner for you!

800+ employees

400+ chemists and analysts

5,000 m^2 lab space

13300 m^2 pilot plant

66000 m^2 cGMP manufacturing site under construction

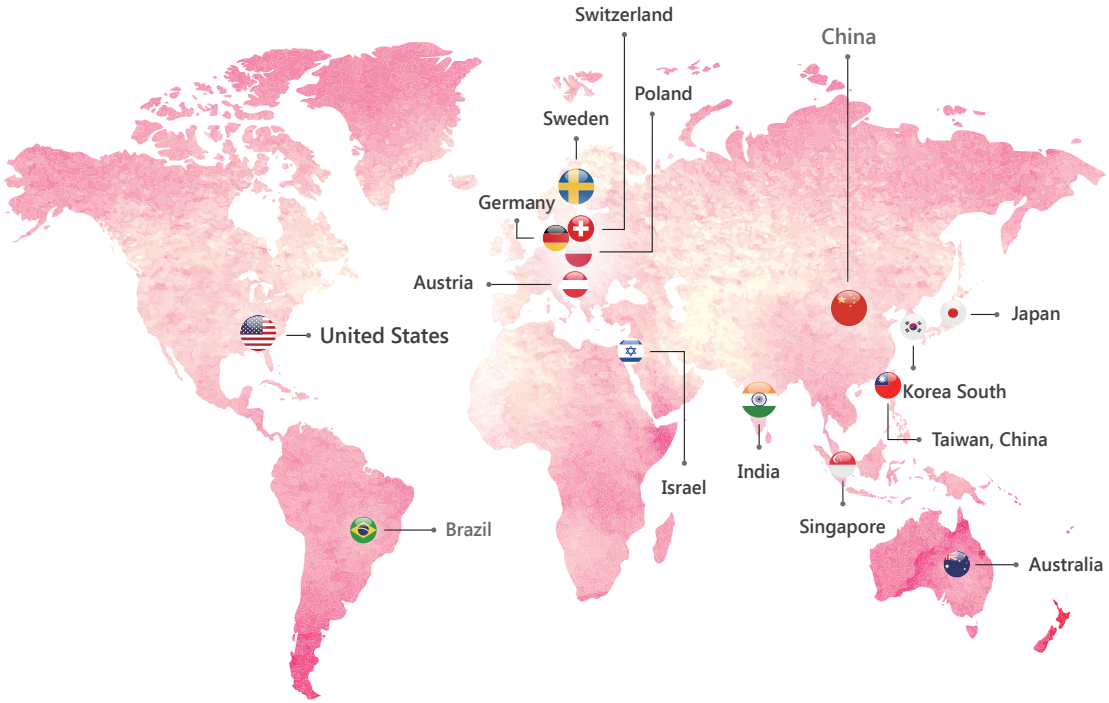
35,000 Building Blocks in stock

Our World Networks

Headquartered in New Jersey, USA.

Branches in Sweden and India.

R&D center and factory are in China.



Our Team

Relying on Haoyuan Chemexpress's strong research and development team and efficient production platform, MedChemExpress is commited to providing intregrated chemistry services ranging from design, synthesis and supply of lab scale building blocks, to custom synthesis, process development, pilot plant and commercial manufacturing of key intermediates and RSMs.

MedChemExpress (MCE)

Chem Express

Business

- BD & Warehouse in China
- BD & Warehouse in USA
- BD & Warehouse in Europe
- BD & Warehouse in India

Production

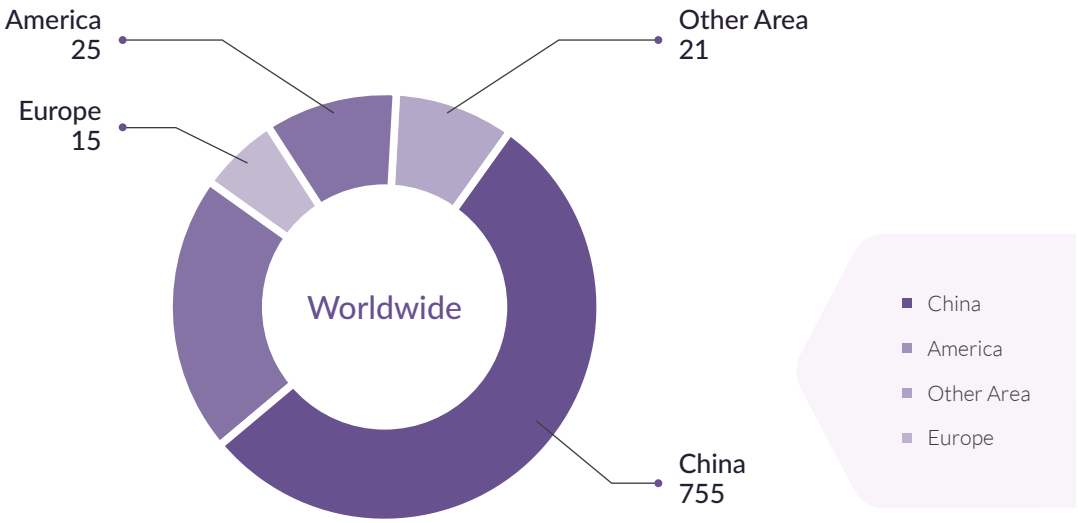
- Shanghai GMP-like Plant
- Shandong Intermediates Plant
- Gansu Haotian Pharma (GMP-Cooperation)
- Anhui API Plant (cGMP-Under Construction)
- Ruyuan HEC Pharma (FDA/CFDA-Cooperation)

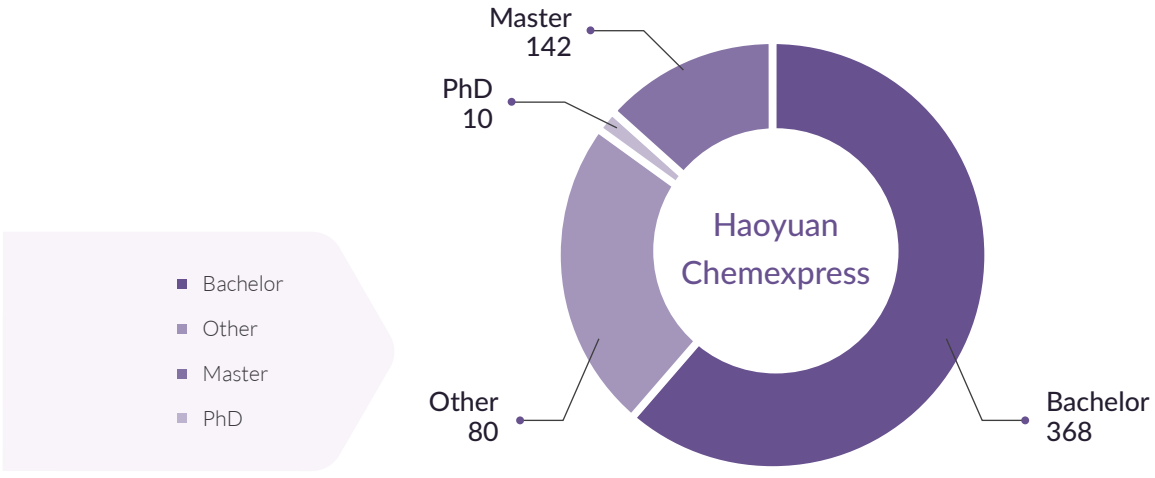
R&D

- Shanghai R&D Center
- Anhui R&D Center(Under Construction)

Our Team

We have a team of 816 personals working in different fields around the world. The company consists of three major departments: business, research and development and production.





Laboratory

Our labs are fully capable of operating R&D for dozens of new compounds at the same time, performing R&D works such as chemical synthesis, analysis, and process optimization.

- R&D labs: 4000 square meters, 200+ chemists
- Analytical labs: 1500 square meters, 100+ analysts

GMP Pilot plant

We are equipped with five kg level pilot laboratory, with twelve 50 L reactors, to ensure the smooth progress of the project from the laboratory to the pilot scale up.

Production base

Our primary cooperative intermidiate production facility is located in Shandong Province, capable of controlling reaction parameters on scales from -100 ~ 200 °C, 300 ~ 5000 L, and can even operate Grignard, nitration, cryogenic, etc reactions under custom high-pressure conditions (6 MPa).

Production base

Our primary cooperative API production facility is located in Gansu Province, it covers 67000 square meters, the Gansu production base to meet GMP specifications.

OUR FACILITIES

Production base

Our cGMP production base started construction on May 23, 2018 in Cihu, Anhui Province.

Reactors: 200 L-5000 L

The main products output: 100 g-5000 kg/year

Phase Ⅰ: 66,000 m^2 - R&D Center; Workshops;

Warehouse; Sewage Treatment Center

Phase Ⅱ: 20,000 m^2

Production base

Our primary cooperative cGMP production facility is located in Guangdong Province, capable of controlling reaction parameters on scales from -70~130 °C, 50 ~30000 L, and can operate all the conventional reaction and hydrogenation under custom high-pressure conditions (6 MPa).

Analytical Instrument

Our analytical Lab is equipped with twenty-eight HPLC, three Prep-HPLC, three GC, three LC-MS and other dvanced instruments.

- Quantum-NMR
- Agilent 1260/1100 HPLC
- Thermo Fisher U3000 HPLC
- Shimadzu LC-8A/Elite P270 Prep-HPLC
- Agilent 7890B GC 7697A HS
- Agilent 1260 6120 MS
- Nicolet iS5 IR
- INESA 759 UV
- LHH-150GSP StabilityTest Chamber
- HGZ-150 Light Incubator
- Metrohm 916 Ti-Touch Potential Titrator
- ZWS-2 Moisture Analyzer
- Automatic Polarimeter WZZ-2B

Crystalline Instrument

We have an independent crystallization laboratory equipped with instruments for crystallization research

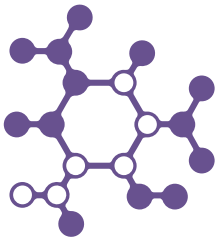
Crystalline Service Equipment

- DX-21700BH XRPD
- DISCOVERY DSC250 (AUTO) DSC
- DISCOVERY TGA55 TGA
- XPL-2 PLM
- Mastersizer 3000 PSD

OUR SERVICE

Our CRO Service

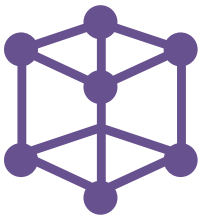
We have a team of experienced professional chemists (PhD and Masters). Our team specializes in the synthesis of building blocks and small bioactive molecules, including a variety of inhibitors, agonists, APIs and compound libraries.



Services provided by ChemsScene are as bellow:

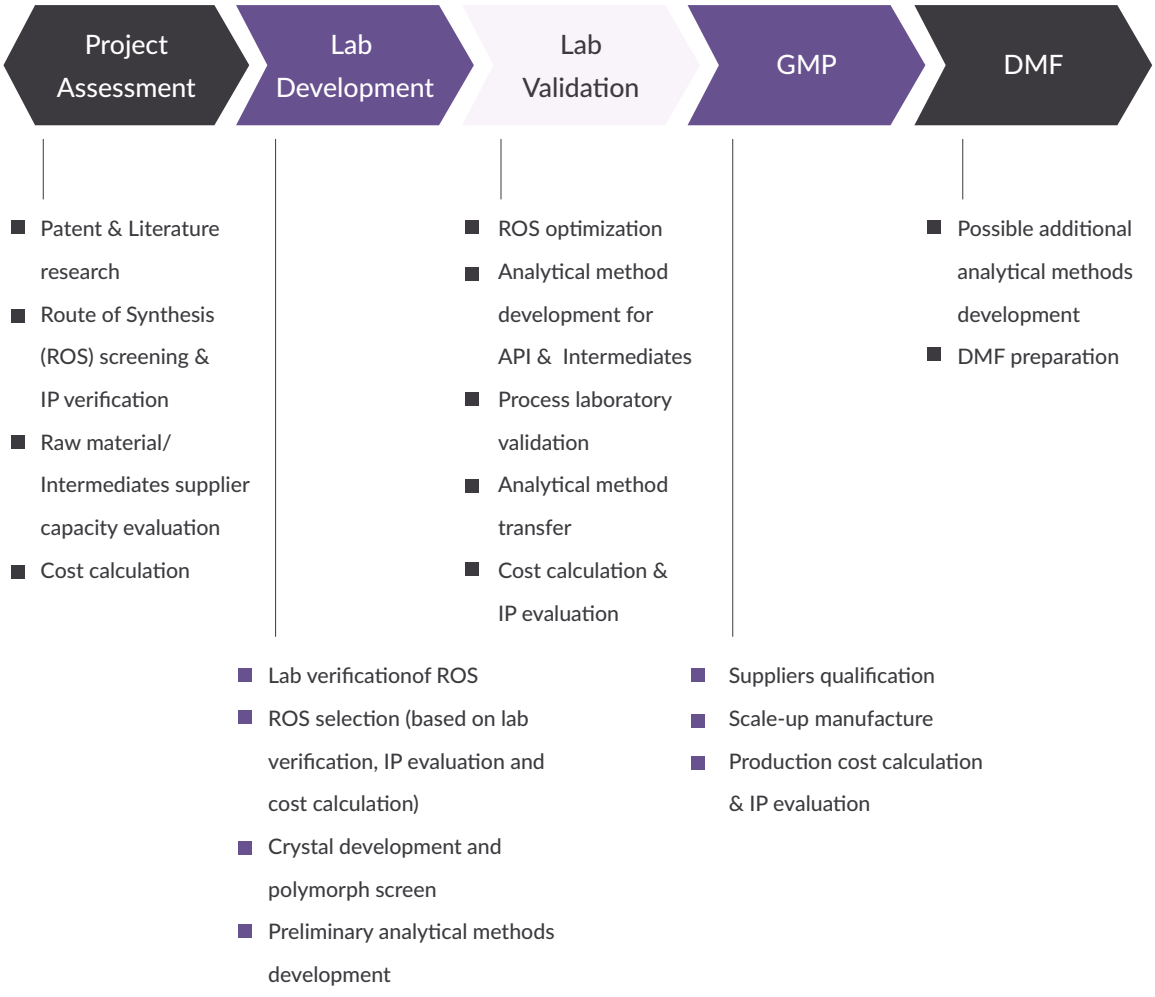
- Synthesis of reference compounds
- Custom synthesis of building blocks
- Custom synthesis of intermediates
- Multistep synthesis
- Chiral Synthesis

We offer high-quality and cost-effective custom synthesis service with quantities from milligrams to kilograms scale according to the clients requirement. We are committed to deliver these compounds on time with final report as required by our clients.



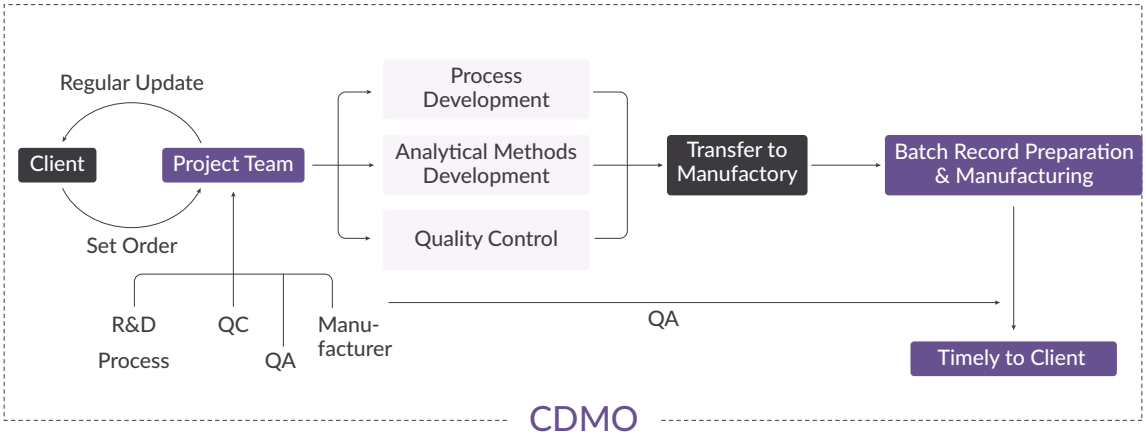
Our CDMO Service

We have built close cooperation with well known pharmaceutical companies and prestige research institutes, and have undertaken hundreds of major projects. We have gained rich experience of a number of pharmaceutical companies auditing.



Our CDMO Service

We have a complete service process to provide customers with a high standard of CDMO service.We set up an independent project team for each project.



Service Standards

- Provide services information according to customer's requirements.
- Contract validation
- Build a project team including: R&D, Process, QA, QC and Manufacturing.
- File system establishment and management.
- Update the project schedule regular intervals with customer.
- IP control and project confidentiality.
- Delivery on time.

Process Development Service

Our process research and development team consists of more than 100 experienced process chemistry experts who can meet customer needs quickly and efficiently.

- Synthetic route scouting
- Process development and optimization
- Design of Experimental (DOE)
- Process safety assessment
- Catalysts screening and optimization
- Kg level SFC chiral compound separation
- Impurity identification and profiling

Our team is specialized in the use of special chemicals such as

- pyrophoric chemicals:
  LAH, NaH, L-selectride, DIBAL-H
- water or air sensitive chemicals:
  Grignard reagents, Borane reagents, Lithium reagents

We have a vast experience in the process development of the following reactions:

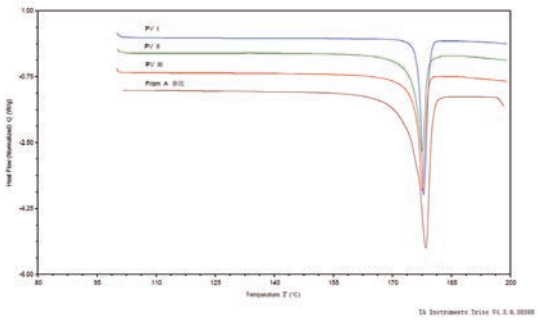
- Photolysis Reaction
- Ozonation Reaction
- Chiral Resolution by Salt Formation
- Chiral Resolution by Enzyme
- Chiral Induction Reaction
- Metal Catalyzed Coupling Reaction

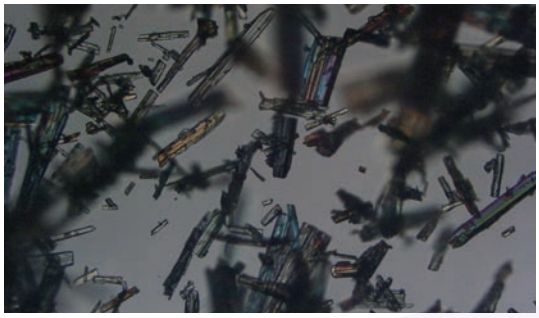
Crystallization Service

Our crystalline research team has provided high-quality crystallization research services to a number of clients.

Solid Form Screening

- Salt &/Polymorph/Cocrystal Screening High throughput screening
- Crystal form Evaluation Solubility and hygroscopicity Crystal form Stability Thermodynamic stability Polymorph conversion
- Crystal structure analysis Cultivation of a single crystal Structural analysis & refinement
- Process design & Optimization





API Crystallization R&D

- Purification R&D High purity, less key impurities
- CrystalThermodynamic R&D
  Solubility and Metastable zone width
- Process Optimization and scale up

Clinical Phase III

- Crystal structure analysis
- Patent applications

Clinical Phase II

- Crystallization process optimization & scale-up
- Crystal properties optimization

Clinical Phase I

- Salt/polymorph Clinical evaluation
- Full screening of polymorphism and advantage form
- Crystal properties design & screening

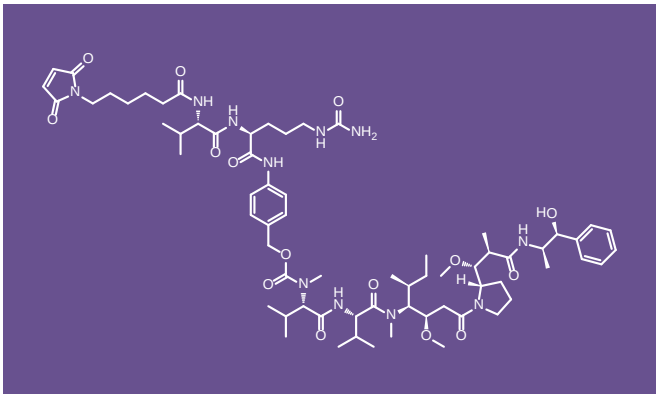
Pre-clinical

- New salt, co-crystal, polymorph screening
- Polymorph conversion, solubility evaluation
- Crystal form stability evaluation
- Candidate salt/form evaluation and confirmation
- Crystallization process design & optimization

Because of our strong process development capabilities, we have successfully realized the commercial production of many kinds of product.

Antibody Drug Conjugate (ADC) Commercial production

ADC (Antibody-Drug Conjugate) compounds possess a complex structure which made their production particularly difficult. We are well-equipped to handle the challenges of the chemical part research for these specialized products.



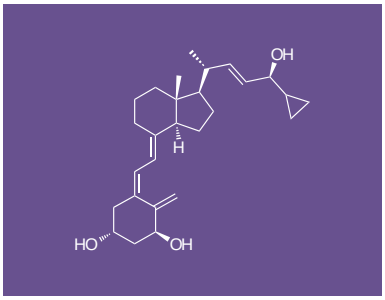
VcMMAE

Our Advantages

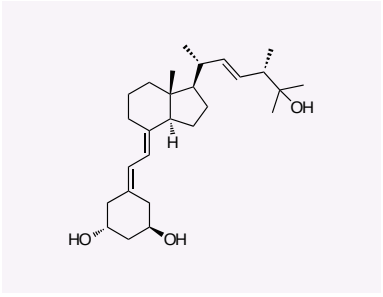
- Developed a series of compounds such as toxins and linkers.
- The series of compounds have been under thorough quality research and are eligible for commercialization.
- Declared the first clinical trial ADC product in collaboration with our partners.
- Cooperated with more than ten clients globally.

Vitamin D analogues Commercial production

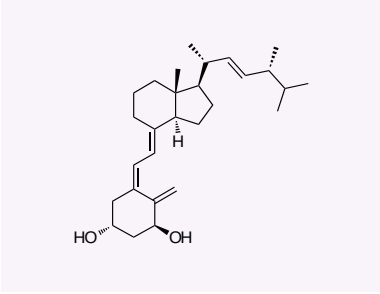
Vitamin D and its derivatives have become our iconic products, more than ten of them have been passed the pilot production stage.



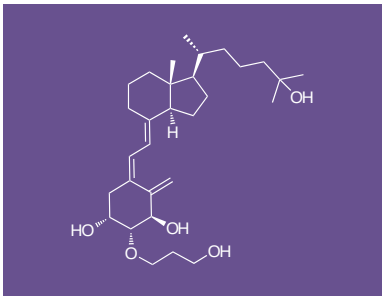
Calcipotriol



Paricalcitol



Doxercalciferol



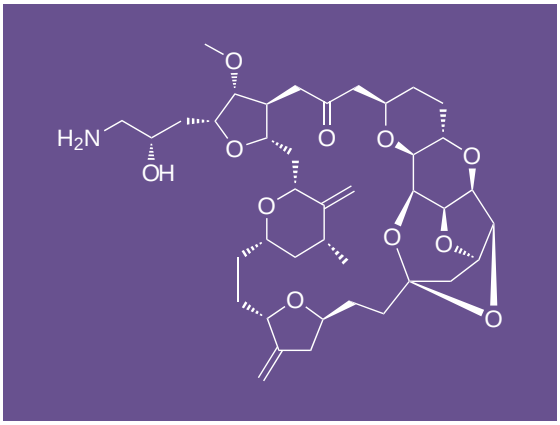
Eldecalcitol

Our Advantages

- Developed over 20 VD series compounds.
- Our Calcipotriol key intermediate are in the declaration process of Secondary DMF, and will be audited by FDA, PMDA, NMPA.
- Our active pharmaceutical ingredients have undergone complete quality research and are eligible for commercialization.
- The synthesis process has utilized sulfur dioxide reaction, ozonation reaction, photoreaction, which can be used in commercial production.

High Potency API Commercial production

We currently owns many advanced synthesis technologies and has accumulated valuable experience in the field of route design and research of multi-steps complex molecules. We have succesfully prepared complex target compounds with multi-chiral centers such as Eribulin and Trabectedin .



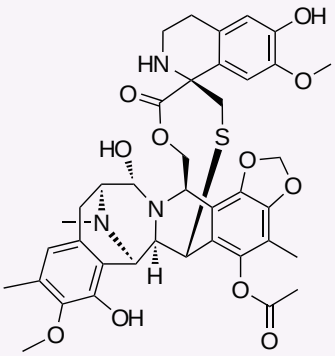
Eribulin (Halaven)

Our Advantages

- Completed the project with over 60 synthesis steps.
- Completed the validation study and commercial production.
- Conducted a thorough quality study of the products with over 16 chiral centers.
- Ability to complete the declaration

Our Advantages

- Creative chiral separation process.
- Completed the commercial production.
- Products that meet ICH quality requirements。
- Strictly control of impurity content (individual impurity< 0.1%)

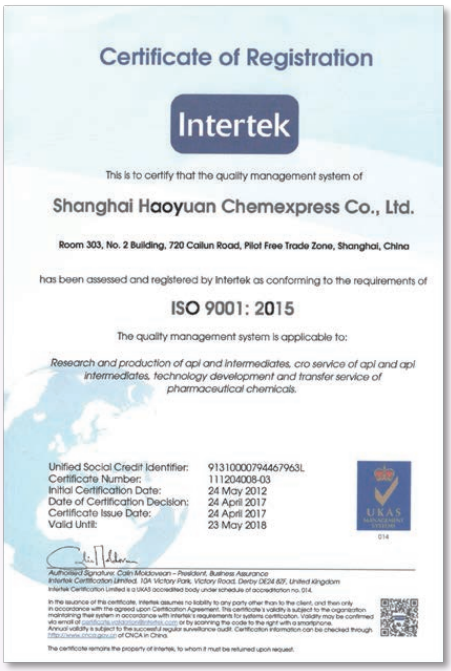


Trabectedin (Yondelis)

COMPLIANCE

Quality System

We have a quality assurance team which have 10 years experiences. In recent years, we have been audited by a number of foreign companies, including the United States, the United Kingdom, Japan, India, Switzerland, Italy and Spain.



Certificate of Registration

Intertek

This is to certify that the quality management system of

Shanghai Haoyuan Chemexpress Co., Ltd.

Room 303, No. 2 Building, 720 Cailun Road, Pilot Free Trade Zone, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2015

The quality management system is applicable to:

Research and production of api and intermediates, cro service of api and api intermediates, technology development and transfer service of pharmaceutical chemicals.

Unified Social Credit Identifier:	91310000794467963L
Certificate Number:	111204008-03
Initial Certification Date:	24 May 2012
Date of Certification Decision:	24 April 2017
Certificate Issue Date:	24 April 2017
Valid Until:	23 May 2018

Authorised Signature: Colin Moldovean – President, Business Assurance

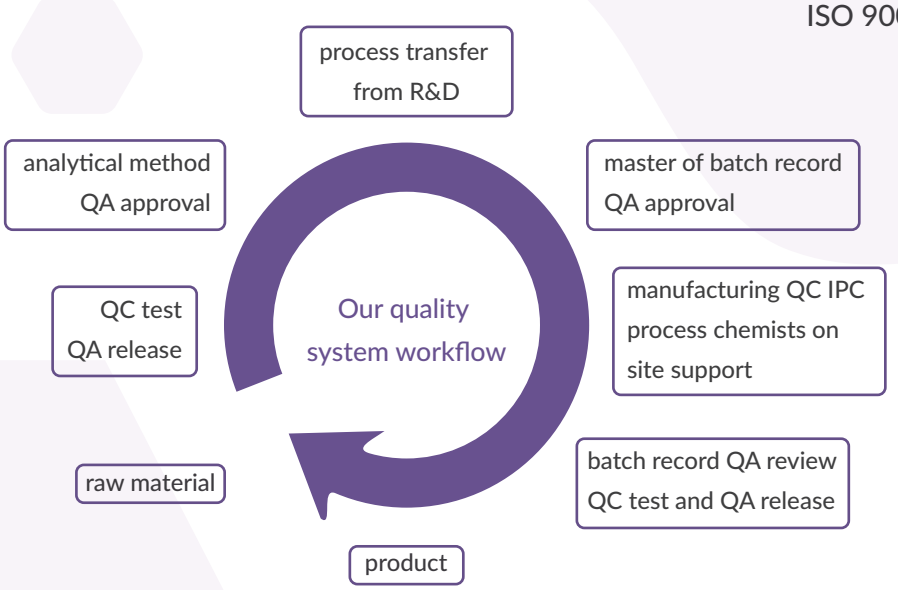
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. Annual validity is subject to the successful regular surveillance audit. Certification information can be checked through http://www.ccnipa.com of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.

ISO 9001:2015



Quality System

We have established the working procedures of qualification, validation, review and release, working standards management in accordance with GMP guideline for our Shanghai GMP lab. So that we can realize the commercial production of HIAPI such as Eribulin.

Regulatory affairs	SOP Number
Instrument Qualification	SOP-EN-005
Analytical Method Validation	SOP-QC-030
RM Release and Approval	SOP-QA-002
Working Standards Management	SOP-QC-008

GMP Lab

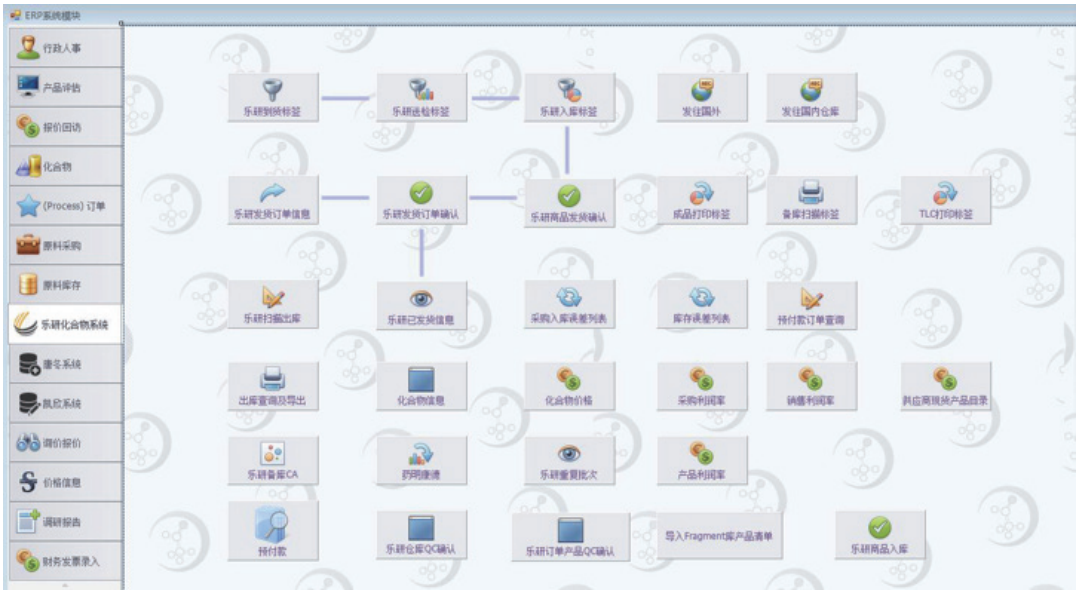
Our Shanghai GMP lab have been inspected by several pharmaceutical companies from Asia and Europe.

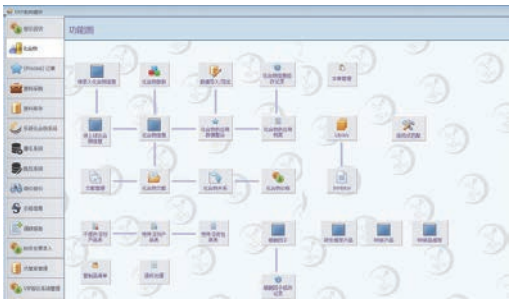
Inspection History of Shanghai GMP lab

Customer	Date of Inspection	Conclusion
Nissan Chemicals (Japan)	April 2019	Approval
Cerbios (Switzerland)	April 2019	Approval
Lonza (Switzerland)	Dec. 2017	Approval
DRL (India)	June. 2015	Approval
Sun Pharma	May. 2015	Approval

COMPLIANCE

ERP System





Our ERP system is independently developed to maximize the efficiency of the project management and protection of client data and Intellectual Property.

Intellectual Property Protection

We have paid close attention to the management of, and adherence to intellectual property rights, We strictly execute regulations on archive management and information processes, so as to respect the interests of all engaged parties.

- Laboratory access security system
- Notebooks, MOR's and others are locked in the archived room under strict access
- Project details are shared on a need-to-know basis only
- New employee confidentiality and invention assignment agreements, duty of confidentiality carries forward outside of employment contract

EHS management

We have set up EHS Dept, which focuses specifically on the environmental responsibility, workplace health and safety. We strictly abide by local environmental laws and regulations.

Adequate technology assessment

Safe and clean production

Strict process monitoring

Effective waste disposal management

Environment, Health, Safety

Constantly improved EHS goal is established to conduct internal audits and management reviews regularly to monitor and improve EHS performance.

Potential environmental risks and hazards is systematically identified and controlled to prevent environmental pollution occupational diseases and industrial accidents.

Respect employees, pay attention to their occupational health, and protect their rights and interests.

Develop a green, secure procurement strategy and have great influence on suppliers'environment, occupational health and safety management.

Cultivate a corporate culture based on EHS continually and enhance employee EHS responsibility .

Reduce energy consumption actively and promote cleaner production continually.

CRO/CDMO Service

Building Blocks / Pharmaceutical Intermediates / Chemical Reagents

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MedChemExpress USA

Tel: 609-228-6898 Fax: 609-228-5909 E-mail: sales@MedChemExpress.com

Address: 1 Deer Park Dr, Suite Q, Monmouth Junction, NJ 08852, USA