



Hunan Huateng Pharmaceutical Co., Ltd

Company Profile

Core Business | Professional Services

Advantages



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O1 Company Profile



Hunan Huateng Pharmaceutical Co. Ltd.

Founded Date: August, 2013

Address: Headquarter - National high-tech zone, Changsha, Hunan, China

Industry park —Tongguan Kiln, Wangcheng district, Changsha, Hunan, China

Business: Focus on the development and industrialization of specialty APIs,

long-acting targeted new drugs and high-end generics

Employees: 400+ full time staff, approximately 60% are Ph.D.'s and MSc's

Investors: Series A financing led by Boyi Fund, a subsidiary of Tasly Capital,

Series B financing led by CITIC Securities





CEO- Zeping Deng, PhD.

- National "Ten Thousand People Plan" Expert
- Innovation and Research Talent of Ministry of Science and Technology of China

Since foundation, we have maintained a steady and high growth rate. On behalf of all our staff, I would like to express our sincere gratitude to our customers for your great support. We have been working diligently over the past years to provide you the most valuable products to empower your scientific research. And we will do our best in the coming years to make outstanding contributions to the development of human medicine and health!







Launched Fisrt R&D Center in Changsha, Hunan

2016

2013

Officially operated in

Changsha

CEO Deng Zeping was elected as an expert of the National Ten **Thousand Plan**

Received Series A financing Led 2019 by Boyi Fund, A Subsidiary of Tasly Capital



Industry Park completed and put into production



Received Series B Financing Led



Strive to complete the listing and develop into a first-class pharmaceutical enterprise with a capacity of 10 billion









Started

Industry Park



by CITIC



02 Core Business



CORE BUSINESS



PEG Derivatives



Pharmaceutical intermediates



API



Preparation



PEG Derivatives

Huateng Pharmaceuticals is a leading supplier of PEG derivatives (mPEGs) with the world's largest library of over 5,000 PEG derivatives, covering monodispersed and polydispersed structures with molecular weights ranging from 200 to 4w. Our wide range of functional groups covers active esters, maleimides, sulfhydryl, amino, azide, phospholipids, fluorescein, etc. We are able to provide single-selective PEGylation solutions based on site-specific modification construction, PEG double linker construction, and multi-active site drugs. And we provide quality products and services to customers worldwide for a wide range of applications in long-acting targeted drug delivery, medical device renovation, diagnostic analysis, aesthetic surgery, medical devices, and 3D printing.

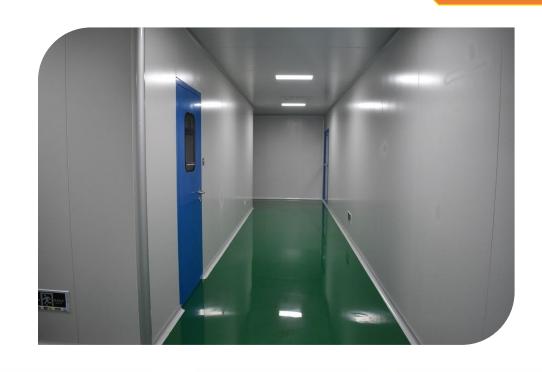


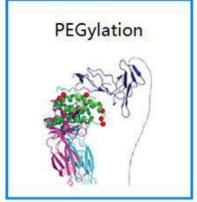


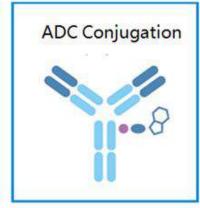
PEG Derivatives

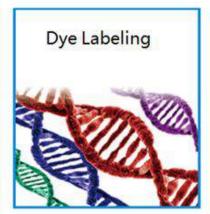
Research Area

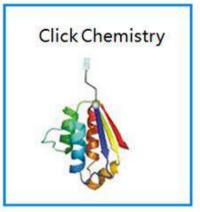
PEGs have been shown to provide improved water solubility and biocompatibility in drugs and other applications, and the ability to attach a variety of reactive functional groups to the terminal positions of these polymers has greatly increased their applications. Huateng Pharma supplies PEG derivatives worldwide, from R&D through GMP commercial quantities, for preclinical, clinical trials, and commercial products in the pharmaceutical, biotechnology, medical device, and diagnostics marketplaces.

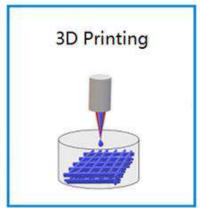


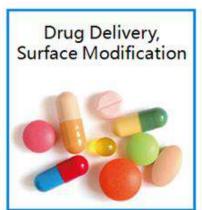














PEGylation

Huateng Pharma PEG linkers (PEGylation reagents), by increasing the molecular weight of molecules (most typically peptides, proteins, and antibody fragments), can impart several significant pharmacological advantages over the unmodified form, such as improved drug solubility, reduced dosage frequency, potentially reduced toxicity, extended circulating life, increased drug stability, and enhanced protection from proteolytic degradation.

mPEG-SC Side Chain of Anti-Diabetic Drug MW:1K,2K,3K;5K,10K;20K;30K

mPEG-Aldehyde
Side Chain of Nervous System Drug
MW:1K,2K,3K;5K,10K;20K;30K

mPEG-Succinimidyl Propionate
Side Chain of Hematological System Drug
MW:1K,2K,3K;5K,10K;20K;30K

CAS No.: 557756-85-1

mPEG-Mal
Side Chain of Anti-Diabetic Drug
MW:1K,2K,3K;5K,10K;20K;30K

$$\rightarrow 0$$

Boc-NH-PEG3-CH2COOH CAS No.: 462100-06-7



PEG Media for ADC Drugs

PEG-linkers are particularly attractive as a linker for Antibody drug conjugates (ADCs). Water solubility, lack of toxicity; low immunogenicity and well-defined chain lengths and molecular weights are specific characteristics of PEG moieties relevant to pharmaceutical applications. Huateng Pharma is dedicated to being your most reliable partner to provide a chemical synthesis and high-quality PEG linkers. We are committed to promoting the progress of your ADC discovery and development projects.

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2-((Azido-PEG8-carbamoyl)methoxy)acetic acid CAS No.: 846549-37-9 ADC Drug: Trodelvy

Mal-NH-PEG8-COOH CAS No.: 1334177-86-4 Drug: Zynlonta

Maleimide-PEG1-Succinimidyl Propionate CAS: 1807518-72-4

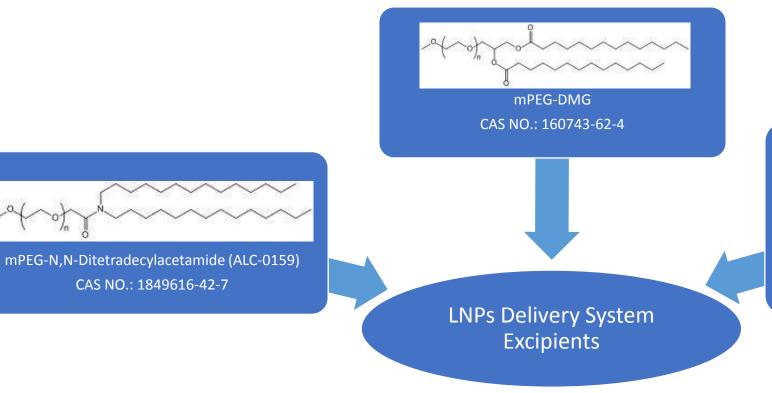
N-(Azido-PEG3)-N-bis(PEG3-t-butyl ester) CAS: 2055042-56-1



LNPs Delivery System Excipients

CAS NO.: 1849616-42-7

Lipid Nanoparticles (LNPs) are delivery systems commonly employed in the field of nucleic acid drugs. The LNP technology has been adopted for COVID-19 vaccine manufacture. Lipid nanoparticles mainly contain four components: ionizable lipids, neutral auxiliary lipids, cholesterol, and PEGylated lipids. PEG can enhance the stability and life of LNPs. Huateng Pharma provides large scale GMP manufacture of PEG derivatives for LNPs delivery system.







Dye Labeling

The PEG chains alter tissue biodistribution, allowing brighter liver metastases labeling and decreased accumulation in normal organs, particularly the liver.

Application:

- ①Cell Labeling
- **②Tissue Imaging**
- ③Tumor Identification

Fluorescein

Fluorescein labeling

FITC-PEG-R

R=OH,SH,CHO,NH2,NCO,N3,Mal,Alkyne,AC,ACA,MA,Silane,GA,SA,GAA,SAA,AA,IA,EP,Mal,SC,SCM,SPA,SG,SS,GAS,SAS,CDI,NPC,OPSS,Ts,LA,Biotin,DSPE,DMPE,CLS etc

Cyanine

Cyanine Labeling

Cy-PEG-R

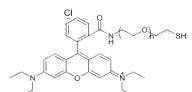
RB-PEG-R

R=OH,SH,CHO,NH2,NCO,N3,Mal,Alkyne,AC,ACA,MA,Silane,GA,SA,GAA,SAA,AA,IA, EP,Mal,SC,SCM,SPA,SG,SS,GAS,SAS, CDI,NPC,OPSS,Ts,LA,Biotin,DSPE,DMPE,CLS etc



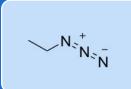
Rhodamine labeling

R=OH,SH,CHO,NH2,NCO,N3,Mal,Alkyne,AC,ACA,MA,Silane,GA,SA,GAA,SAA,AA,IA,EP,Mal,SC,SCM,SPA,SG,SS,GAS,SAS, CDI,NPC,OPSS,Ts,LA,Biotin,DSPE,DMPE,CLS etc



Click Chemistry Reagents

Click Chemistry has been widely used in bioconjugation, biolabeling and material sciences in pharmaceutical and biotech industry due to its mild conditions and high selectivity. Huateng Pharma provides various of high purity click chemistry tools with a broad range of funcitonal groups: Azide, Alkyne, DBCO, BCN, etc.



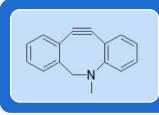
Azide Reagents

• Azide Reagents enables Click Chemistry and can be used to react with aminecontaining biomolecules, modifying carboxylic acid groups, and etc.



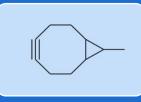
Alkyne Reagents

• Alkyne reagents can be reacted with azide-bearing compounds or biomolecules via CuAAC reaction to yield a stable triazole linkage.



DBCO Reagents

 DBCO (Dibenzocyclooctyne) reagents is one of the most reactive cycloalkynes for strain promoted alkyne azide cycloaddition (SPAAC), which enables Cu-free Click Chemistry.



BCN Reagents

• BCN reagents (bicyclo[6.1.0]nonyne) can react with azide-tagged molecules or biomolecules via copper-free Click Chemistry



3D Printing

3D printing biomaterials require biocompatibility, porosity, biodegradability and good adhesion. PEG hydrogels meet these specifications, and in particular PEG acrylate (PEG-ACLT) derivatives are widely applied in hydrogel formation via photopolymerization.



Featured Monodisperse PEGs

Huateng Pharma continuously expands its capability to provide large-scale manufacture of high purity monodisperse PEG derivatives with an extensive variety of functional groups, in both non-GMP and GMP grade. Monodisperse PEG retains the good water solubility of polyethylene glycol, and provides the same PEG benefits for PEGylated drugs, namely reducing aggregation and immunogenicity, and increasing hydrodynamic volume.

CAS No.	Name
7218-43-1	Alkyne-PEG2-OH
108466-89-3	Boc-NH-PEG2-CH2COOH
1365655-91-9	Boc-NH-PEG2-COOH
153086-78-3	BOC-NH-PEG2-NH2
475591-59-4	Boc-NH-PEG2-NH-Boc
139115-91-6	Boc-NH-PEG2-OH
756526-01-9	Fmoc-NH-PEG12-COOH
437655-95-3	Fmoc-NH-PEG4-CH2COOH
756525-94-7	mPEG11-SPA
3386-18-3	OH-PEG9-OH

CAS No.	Name
2151823-08-2	mPEG24-NH2
170572-38-0	mPEG7-NH2
6048-68-6	mPEG9-OH
2182602-17-9	N-(ACID-PEG3)-N-BIS(PEG3-Azide)
1644163-57-4	N3-PEG10-COOH
1271728-79-0	N3-PEG2-CH2CH2COOtBu
857891-82-8	N3-PEG8-NH2
252881-74-6	NH2-PEG3-CH2CH2COOtBu
1446282-18-3	NH2-PEG5-CH2CH2COOtBu
141282-35-1	NH2-PEG5-CH2COOH



Pharmaceutical Intermediates

Huateng Pharma has its own raw material production base, where the production management team has decades of experience in plant production and management to ensure the production of various products at the lowest cost, the fastest speed and the highest quality according to various customer requirements. We have specialized facilities for high-temperature and high-pressure reactions as well as low-temperature continuous-flow reactions, enabling us to produce a wide range of customer-oriented products with high cost performance. We are capable of producing various pharmaceutical intermediates such as intermediates for carfilzomib, oseltamivir, baloxavir marboxil, etc, from gram to metric ton scale.





Anti-Cancer Series

(2S)-2-AMino-4-Methyl-1-[(2R)-2-Methyloxiranyl]-1-pentanone trifluoroacetate CAS No. 247068-85-5 For Carfilzomib/Kyprolis

Boc-HPh-Leu-Phe-Ome CAS No. 868539-96-2 For Carfilzomib/Kyprolis

tert-Butyl ((s)-4-methyl-1-((r)-2-methyloxiran-2-yl)-1-oxopentan-2-yl)carbamate CAS No. 247068-82-2 For Carfilzomib/Kyprolis

1-BOC-4-(6-NITROPYRIDIN-3-YL)PIPERAZINE CAS No. 571189-16-7 For Palbociclib

1-Boc-4-(6-aminopyridin-3-yl)piperazine CAS No. 571188-59-5 For Palbociclib

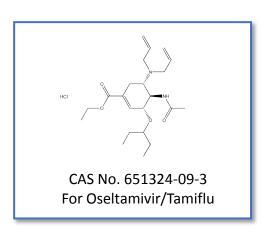
5-Bromo-2-chloro-N-cyclopentylpyrimidin-4amine CAS No. 733039-20-8 For Palbociclib

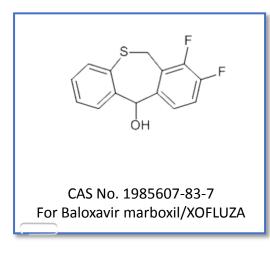


Anti-Viral Series

CAS No. 204254-96-6

For Oseltamivir/Tamiflu

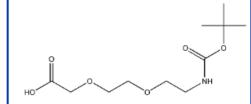








Anti-Diabetic Series-Semaglutide Intermediates



CAS. No 108466-89-3

3,8,11-Trioxa-5-azatridecan-13-oicacid,2,2-diMethyl-4-oxo-

CAS No. 871-70-5

Octadecanedioic acid

CAS. No 1143516-05-5

17-amino-10-oxo-3,6,12,15-tetraoxa-9-azaheptadecan-1-oic acid

CAS. No 843666-40-0

Octadecanedioic acid mono-tert-butyl ester

CAS No. 1662688-20-1

Fmoc-L-Lys[Oct-(otBu)-Glu-(otBu)-AEEA-AEEA]-OH

CAS. No 134978-97-5

2-(2-(2-Aminoethoxy)ethoxy)acetic acid

CAS No. 166108-71-0

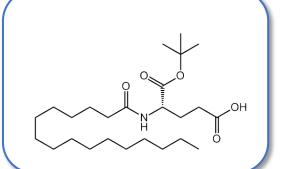
[2-[2-(Fmoc-amino)ethoxy]ethoxy]acetic acid

CAS No. 134979-01-4

2-(2-(2-Aminoethoxy)ethoxy)acetic acid hydrochloride



Anti-Diabetic Series – Liraglutide Intermediates



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HN H OH

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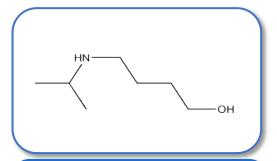
CAS NO. 536721-25-2
N-(1-Oxohexadecyl)-L-glutaMic Acid
tert-Butyl Ester

CAS No. 294855-91-7 Pal-Glu(OSu)-OH CAS No. 1491158-62-3 Fmoc-Lys(Pal-Glu-OtBu)-OH

CAS No. 204521-63-1 Pal-L-Glu(OSu)-OtBu



Antihypertensive Series



4-(Isopropylamino)butanol CAS No. 42042-71-7

For Selexipag/UPTRAV

Selexipag active metabolite

CAS No. 475085-57-5

For Selexipag/UPTRAV

SELEXIPAG/NS-304

CAS No. 475086-01-2

For Selexipag/UPTRAV

2-Cyanopyrimidine

CAS No. 14080-23-0

For Bosentan

Diethyl chloromalonate

CAS No. 14064-10-9

For Bosentan



Antihypertensive Series

5-Amino-4,6-dichloro-2-methylpyrimidine
CAS No. 39906-04-2
For Moxonidine

Methyl 4'-bromomethyl biphenyl-2-carboxylate

CAS No. 114772-38-2

For Telmisartan

4,6-dichloro-2-methyl-5-(1-acetyl-2-imidazolin-2-yl)-aminopyridine

CAS No. 75438-54-9

For Moxonidine

4-Bromomethyl-2-cyanobiphenyl
CAS No. 114772-54-2
For Valsartan

2-n-Propyl-4-methyl-6-(1'-methylbenzimidazole-2-yl)benzimidazole
CAS No. 152628-02-9
For Telmisartan

N-(Triphenylmethyl)-5-(4-Bromomethylbiphen 2-yl-)Tetrazole CAS No. 124750-51-2 For Valsartan











03 Services



Custom Synthesis

We offer world class service in chemical synthesis of a wide variety of organic compounds on the milligram to

kilogram scale at competitive price.

- Our Chemical Synthesis Capabilities
 - (1) Various small molecule compounds
 - (2) PEG derivatives with various functional group
 - (3) Medicinal chemistry and drug discovery
 - (4) Organometallic chemistry
 - (5) Heterocyclic chemistry
 - (6) Special reagents
 - (7) Scale-up production
 - (8) Academic exploration cooperation
- Project Workflow

Order Consultation

Feasibility Evaluate Approve Quotation

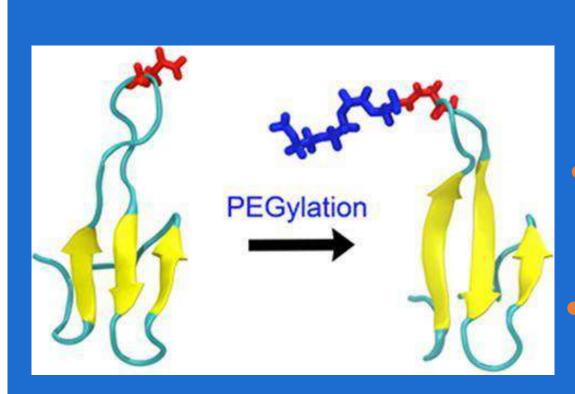
Synthetic Route Design

Porgress Report

Analytical Results Customer Apporval Product Delivery



PEGylation



Our R&D chemists provide PEGylation services in a professional and efficient manner to the preclinical stage and custom synthesis of PEGylated conjugates to meet our clients' unique PEGylation needs for proteins, peptides, oligonucleotides and small molecules.

- Providing PEGylation services as a regular customer end-product. Custom synthesis of PEGylated conjugates, PEG-proteins, PEG-peptides, PEG-polypeptides, PEG-oligonucleotides, PEG-small molecules, and more, using Huateng Pharma catalog PEGs or custom PEG products.
- Complete PEGylation method development services. Under this service model, we will provide PEGylated sample as well as the easily scalable and transferable PEGylation method development package.



CDMO/CMO Services

In order to better serve customers, we have built a CDMO technology platform, equipped with professional R&D, production and QC teams, established a pilot and scale-up production workshop that meets GMP standards.

We are able to provide:

- Customized R&D and production of APIs, intermediates and other chemicals ranging from grams to tons
- Process optimization and rapid scale-up of APIs, intermediates and other chemicals of existing synthetic processes
- Development of a more environmentally safe production process





04 Advantages



Advantage 1: Strong Production Capacity

800+ sets of advanced facilities

Intelligent production system

Independent production base

Comprehensive environmental support facilities





The manufacturing site of Huateng Pharma finished construction and put into operation in 2020, with a total investment of 300 million RMB. Covering an area of over 34,000m², it is able to accomplish the complete transformation of lab scale to pilot plant to full-scale production, with an annual output value of over RMB 1 billion.



800+ Sets of Advanced Facilities

Four buildings with a total of 20,000 square meters of modern multifunctional production workshops, with more than 800 sets of high-quality facilities, such as 5000-liter and 2000-liter reactors, centrifuges, double cones, air compressors, freezers, etc.



Enamel reactor

Stainless steel hydrogenation reactor



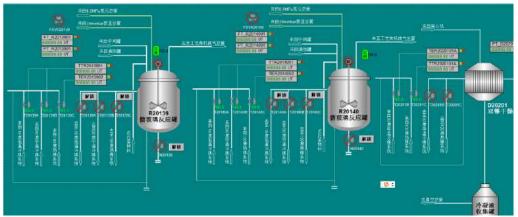
Intelligent Production System

An interconnected real-time database is established through the integration of DCS, SIS, MES, ERP, WMS, SCM and other systems. Meanwhile, we can achieve unified management and real-time automatic control of intelligent equipment by automatically collecting, processing and analyzing various data online such as inspection and testing, pressure, temperature and PH in the production process. In addition, we also build "intelligent manufacturing" matrix such as automatic software control system, automatic reaction system, intelligent condensation and heat exchange system, purification and drying system, data acquisition and monitoring system, manufacturing execution system and data mining and analysis system to realize seamless information transmission and achieve integration of production and operation.









Distributed Control System (DCS) main interface



DCS & SIS system equipment room

Safety Instrumented System (SIS) main interface



Comprehensive Environmental Support Facilities

Hi-tech instruments have been introduced to help develop and upgrade the production process, effectively improve the reaction efficiency, reduce energy loss at source, and reduce waste gas, waste water and waste residues emissions.

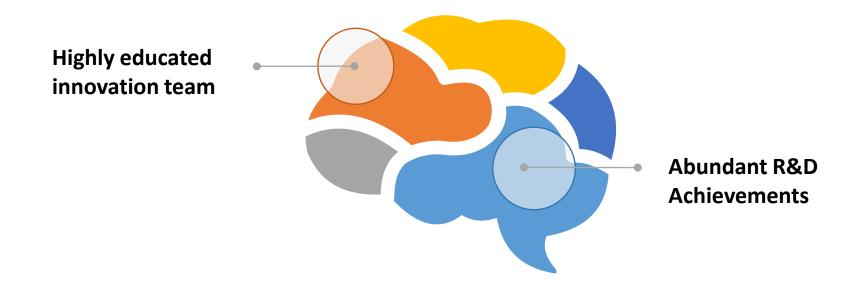
Comprehensive training is given to workers on the production line to improve their operational skills and enhance the technical level of energy management.

Increase the investment in environmental protection equipment and facilities, establish a sewage treatment station, carry out daily environmental monitoring work, and strictly achieve the standard discharge.





Advantage 2: First-class R&D Team







Highly educated innovation team

Innovation is the eternal driving force of a company's development. Huateng Pharma has set up an R&D team of more than 160 members, mainly doctors and masters.

At present, the R&D center has applied for more than 300 invention patents, and won many awards such as "National High-tech Enterprise", "National Intellectual Property Advantage Enterprise", etc.



Abundant R&D Achievements

In the field of PEG derivatives and PEGylated drug development, we have developed more than 5000 kinds of products and accumulated a large number of scientific and technological innovations.







Advantage 3: Perfect Quality Management System







Comprehensive Quality
Management

Strict Quality
Control Process

Strong Quality
Assurance Capability







萬泰認證

CERTIFICATE OF REGISTRATION

This is to certify that the Management System established by

Hunan Huateng Pharmaceutical CO.,Ltd.

Registered Address: No. 1308, Unit N, C2 Building, Lugu Enterprise, No. 27 Wenxuan Road, Gaoxing Zone, Changsha City, Hunan Province, P. R. China

Audit Address: 13th Floor, C2 Building, and Unit 2, E1 Building, Lugu Enterprise, No.27 Wenxuan Road, Gaoxing Zone, Changsha City, Hunan Province, P. R. China

Unified Social Credit Code: 91430100074975337J

Has been assessed to comply with the requirements of the international standard

GB/T 19001-2016idt ISO9001:2015

Scope of certification

Development and Production of Fine Chemical Products (PEG Derivatives)
Chemical Products of Pharmaceutical Intermediates (Antiviral,
Cardiovascular and Cerebrovascular Series) (Excluding Hazardous and
Monitored Chemicals, Except for Production Licenses)

NO: 15/19Q1157R00 DATE OF ISSUE: Aug.12, 2019 VALID UNTIL: Aug.11, 2022 The Certificate Information Can be Obtained by Visiting http://www.cnca.gov.cn.















Wangocasolorg

The surveillance audit shall be conducted at least trace each year within the validity of registration certificate, and the interval between two surveillance such is shall not exceed 12 months.

The certification congenisation must conduct surveillance audit regularly and the registration certificate continues effective after the eligible.

surveillance mails.
The compliance label will be attached to this registration certificate after the eligible surveillance study. The compliance label will be attached to this registration certificate after the eligible surveillance which the certification scope within the required of administrative license or national mandatory certification requirements.



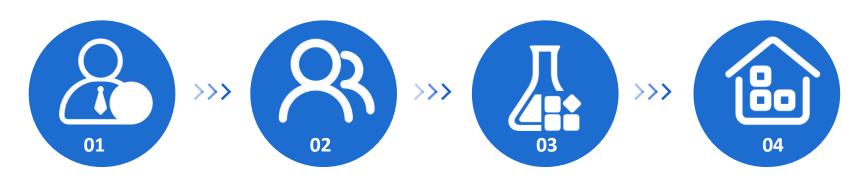
It is our top priority to provide high quality products to our clients. We set up strict QA/ QC standards to ensure world-class products are supplied to the market.

All the procedures are guided through our established Quality Management System with certified ISO:9001 standard.



Strict Quality Control Process

We have a perfect quality control system to strictly control product quality from the screening and auditing of raw materials, outgoing/incoming inspection, staged product testing and staff operation specification.



Strengthen supplier screening and control mechanism

Standardize site operation management

Strictly follow SOP standard operating procedures

Dividing storage space and sub-storage in accordance with national norms and standards



Strong Quality Assurance Capability

We are equipped with nearly 100 sets of high-end analytical and testing instruments and automatic reaction equipment, such as 400 MHz NMR system, Agilent LC/MS, Waters HPLC, Agilent Intelligent GC system, etc., which can ensure fast and efficient completion of various customized orders from customers.









Gel Chromatograph



400 MHz NMR system Agilent LC/MS

Waters HPLC

Infrared analyzer



Advantage 4: High Standard Warehouse Storage



There are 2 class A warehouses of 750m², 1 class C warehouse of 3600m² and 12 storage tanks of 50m³. And it is equipped with intelligent detection system, which can monitor warehouse temperature, humidity and ventilation conditions in real time.





Partnership of Win-win Cooperation

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Website: https://en.huatengsci.com





Thank You!