ASYMCHEM



DRUG PRODUCT SERVICE

www.asymchem.com

Stock Code:002821.SZ / 6821.HK

Drug Product Development and Manufacturing Services

Asymchem Drug Product services encompass solid form screening and selection, pre-formulation studies, formulation design, development and optimization, analytical method development and validation, process development and scale-up, cGMP clinical / commercial supply production, and IND/NDA (ANDA) filing.

- API Production
- Solid Form Screening & Selection
- Pre-formulation Study
- Formulation Design, Development & Optimization
- Analytical Method Development & Validation
- Process Development & Scale up
- Clinical/ Commercial Supply GMP Production
- IND/NDA Filing

30+
NDA Projects

>1,000
Successfully Delivered Batch

12
Modern cGMP Workshop

>15,000m²
Production Area

500+
Number of Employee

>15 Years
of Expertise from Core Technical Personnel



Solid State Science and Pre-formulation Services

We have an experienced team for solid state science and pre-formulation research, with laboratories in China and the United States, providing customers with professional, efficient, and customized research services.

Service Scope

Solid-state R&D

- Salt Screening
- Co-crystal Screening
- Polymorph Screening
- Quantitative Phase Analysis
- Single Crystal Growth & Structure Determination

Pre-formulation

- Physical Properties, Crystallinity, m.p. etc.
- Particle Size Analysis
- Powder Properties
- Solubility Profile
- pKa, Log P and Log D
- Stress Stability

Pre-clinical Formulation Development Solubilization strategy

- In situ Salt Formation
- Surfactant
- Co-solvent
- Cyclodextrin

Solubilization Technology

- Amorphous Solid Dispersion
- Jet Mill
- Lipid Formulation

Analysis Services

R&D Analytical

- Analytical Method Development, Transfer, Verification and Validation
- Analytical Testing of R&D Samples and Preliminary Stability Studies
- Packaging Evaluation and Compatibility Studies
- Establishment of Quality Specifications for APIs / Excipients / Packaging / Material Release
- Rapidly Identify and Solve Complex Analytical Problems
- CMC Document Writing in Support of IND / NDA / ANDA Filing

Microbiological

- Analytical Method Development, Verification / Validation
- Microbial Testing of APIs / Excipients / Packaging Materials
- Microbiological Testing for Various Dosage Forms
- Microbial Testing of Workshop Environment and Water System

QC

- APIs / Excipients / Packaging Materials Release
- Finished Drug Products / IPC Release Testing
- Analytical Method Transfer, Verification and Validation
- Stability Studies for Finished Drug Products and Bulk Products



Clinical Supply Chain One-Stop Services

Orchestrating the End-to-End Clinical Supply Chain to Meet Your MRCT Needs



Label Design and Printing

Controlled-ambient labels, refrigerated labels, frozen labels, single-layer labels, multi-layer labels, parent labels and booklet labels



Reference Listed Drug Procurement

2-4 weeks for domestic drug delivery and 4-6 weeks for imported drug delivery



Re-packaging, Blinding and Sample Retention

Primary package modification for investigational products and comparator products, stability study



Global Storage

Global depots in more than 20 countries and regions around the world



Cold-Chain Transportation

1-3 working days for domestic delivery, 5-10 working days for global delivery

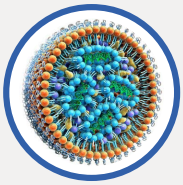


Returning, Destruction

Returned drug reconciliation, documents management

Center of Drug Delivery and Formulation（CDDF）

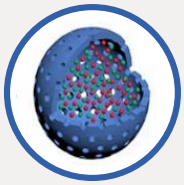
Targeted Delivery Technology



Technology Application

- Small nucleic acid (extrahepatic) delivery
- Targeted delivery of small molecules
- Liposomes

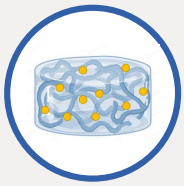
Nanotechnology



Technology Application

- Polymer drug nanoparticles
- Nanoemulsion
- Nanosuspension
- Nanocrystal

Oral Peptide Bioavailability Improvement



Technology Application

- Oral delivery of peptides
- Oral delivery of proteins
- Solubilization of poorly soluble drugs

Development and Evaluation of Novel Dosage Forms



Technology Application

- Microemulsion
- Transdermal delivery
- Sustained release injectable
- Oral sustained release dosage forms

Continuous Manufacturing



Technology Application

- Continuous 3D printing tablets
- Continuous 3D printing to replace traditional batch manufacturing
- Intelligent continuous fluid manufacturing

Oral Dosage and Topical Formulation

DP R&D

Dosage Forms

Conventional tablet, sustained release tablet, enteric coated tablet, capsule, pellet, granule, oral solution or suspension, topical formulations including gel, ointment, and emulsion

Technology Platform

- API or dry blend encapsulation / direct compression
- Dry granulation / wet granulation for capsule / tablet
- Cosmetic coating / enteric coating
- Pellet coating
- Homogenizing for emulsion

Development Experience

- Rapid development of formulation and process for oral dosage and topical formulation based on the QbD concept
- Solubilization of insoluble drugs, such as spray drying and hot melt extrusion
- Process risk assessment and establishment of control measures
- Process DoE research, process scaling up, and process validation
- Production of clinical batches and registration batches
- Commercialized production
- Evaluation and prediction of stability data

Production Capacity

We have 5 independent cGMP formulation workshops and 1 explosion-proof spray drying cGMP workshop to support the production of oral dosage and topical formulation. According to the different stages of projects, we can quickly provide production services in different stages from IND to commercialization.





Workshop

Oral & Topical Dosage cGMP Production

Location	Workshop	Area	Dosage form	Maximum Batch Size
TJ2 site	OSD-1	341 m²	Tablets/ Capsules/Gel/ Emulsion/ Ointment	150,000 units
	OSD-2	1,472 m²		1,500,000 units
	OSD-3	2,150 m²		3,000,000 units
	OSD-4	500 m²	Tablets/Capsules	300,000 units
DH2 site	β-Lactam OSD workshop	300 m²	Tablets	300,000 units

cGMP Production Capabilities for Solid Dispersion

Model	Capacity	Condition/ Protection grade
Spray Dryer 1	Water:6.6Tons/year Organicsolvent:19.8Tons/year	In cGMP use Capable of handling OEB4 compound
Spray Dryer 2	Water:19.8Tons/year Organicsolvent:66-99Tons/year	
Spray Dryer 3	Water:132Tons/year Organicsolvent:198Tons/year	
Spray Dryer 4	Water:79.2Tons/year Organicsolvent:198~330Tons/year	
Spray Dryer 5	Water:165Tons/year Organicsolvent:396-660Tons/year	
Spray Dryer 6	Water:330Tons/year Organicsolvent:660~1320Tons/year	
Hot melt extrusion Pharma 11	15 Tons/year	
Hot melt extrusion ZSE 18 HP-PH	108 Tons/year	

Topical Dosage cGMP Production Equipment

Equipment	Capacity
Vacuum Homogenizing Emulsifier	20 L
Vacuum Homogenizing Emulsifier	300 L
Preparation System	15-500 L
Tube Filling and Sealing Machine	10-80 unit/min



Parenteral Formulation

The parenteral R&D lab is equipped with a series of equipment that can simulate GMP production process in lab scale, such as weighing, compounding, moist heat sterilization, aseptic filtration, filling, glass ampoule sealing (hydrogen oxygen flame), etc.

Dosage Forms

Injections ampoules/vials/PFS/cartridge, lyophilized powders (vials), single dose/multi dose eye drops, inhalation solutions, nasal sprays, liposomes, micelles, micro emulsions, and other complex formulation

Technology Platform

- Solubilization of poorly soluble drugs, development and optimization of lyophilization process cycles, development and evaluation of sterilization method, residual oxygen control in headspace of container
- Ophthalmic drug products using blow-fill-seal (BFS) technology
- Oligonucleotide drug product development

Production Capacity

We have 6 sterile production cGMP workshops, including terminal sterilization production line (ampoules), non-terminal sterilization production line (vial), blow-fill-seal (BFS) production line, pre-filled syringe (PFS) production line, cartridge production line, and a new vial production line

Parenteral cGMP Production

Workshop	Area	Dosage Form	Container Size	Maximum Batch Size
Injectable-1 (BFS)	2,150 m²	Eye Drops, Inhalation Solution, Small Volume Parenteral Solution	0.1-10 ml	300,000 units
Injectable-2 (Vial)		Sterile Solution	2-50 ml	45,000 units
		Sterile Lyophilized Powder		30,000 units
Injectable-3 (Vial & BFS)		Sterile Solution	2-30 ml	6,000 units
		Sterile Lyophilized Powder		2,400 units
		Eye Drops, Inhalation Solution, Small Volume Parenteral Solution (BFS)	0.1-20 ml	35,000 units
Injectable-4 (PFS)	2,000 m²	Sterile Solution	1 ml / 2.25 ml	150,000 units
Injectable-5 (Cartridge)	2,000 m²	Sterile Solution	1.5ml / 3.0ml	330,000 units
Injectable-6 (Vial)	2,200 m²	Sterile Solution	1-100 ml	360,000 units
		Sterile Lyophilized Powder		170,000 units

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