PharmaBlock

PharmaBlock Sciences (Nanjing), Inc.

Building Blocks Enhanced CDMO

Fast & Consistent-quality Delivery in Full Compliance

www.pharmablock.com
product.pharmablock.com

PharmaBlock Sciences (Nanjing), Inc. (SZSE:300725) is a leading provider of innovative chemistry products and services throughout the pharmaceutical R&D process and commercial production.

Its core businesses include: a rationally designed building blocks collection, chemical products and services from drug discovery to development and commercialization, and development and GMP manufacturing of RSMs, intermediates, APIs, and drug products.

Led by an experienced management and core technical team, PharmaBlock is providing development and manufacturing solutions of intermediates, drug substance and drug products for development and commercial stages. Taking full advantage of building blocks availabilities, along with its know-hows in chemistry, process development, analytical development, manufacturing, and engineering technologies etc., the team has distinguished itself for capabilities to tackle challenging chemistry, secure reliable supply, control cost with full compliance of quality and EHS etc.

In this booklet, we will demonstrate how we stand out as a building blocks based CDMO supplier.

Services

- Route scouting for optimal ROS
- Quick and sustainable supply of building blocks and RSMs
- FFS and FTE for process research and development of intermediates and APIs
- Impurity studies and synthesis
- Analytical development & quality control
- cGMP manufacturing of intermediates and APIs
- Formulation research and development
- CMC regulatory filing support

Why Choose PharmaBlock

Unique Advantages Based on BBs

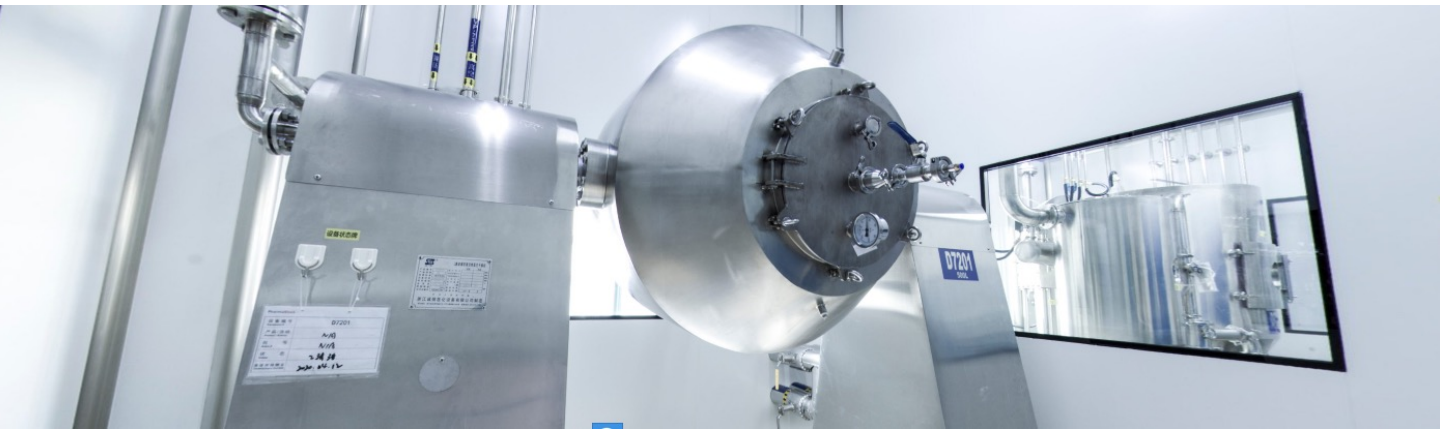
- Innovative route scouting & fast delivery
- Sustainable supply and cost control of building blocks as raw materials
- Qualified suppliers of raw materials for add stability of supply

Innovative Technologies

- For safer, greener & more time-, cost-, space-efficient solutions
- Flow chemistry, micropacked-bed tech, bio-catalysis, heterogeneous catalysis, crystallization, solid state chemistry & engineering technologies

Complete CDMO Service System

- Well established Quality, EHS & IP protection system
- Professional project management & delivery teams
- GMP manufacturing facility (FDA GMP inspected with no Form 483s issued)



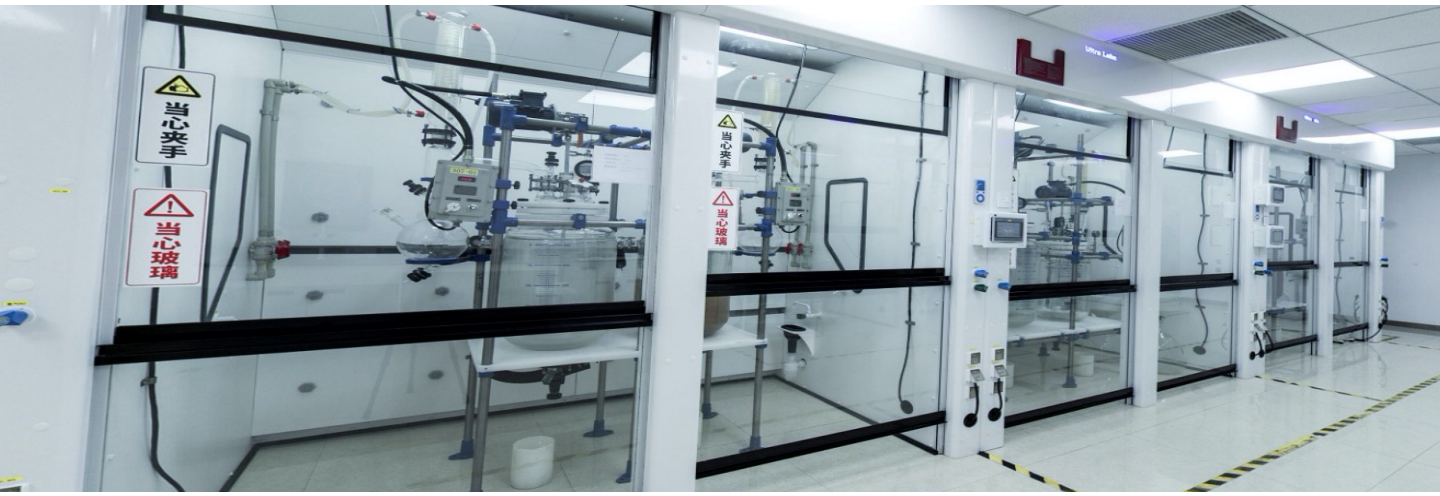
Drug Substance Development

Fast & Optimal Route Scouting

- In early development, speed of delivery is the thumb rule.
- Takes safety, efficiency, purity, cost, ease of scale-up, security of raw material supply, and impact on environment into consideration, and aim to design an optimal, fit-to-purpose route for customers' projects.

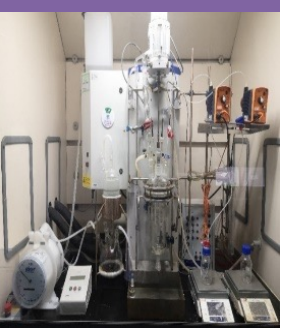
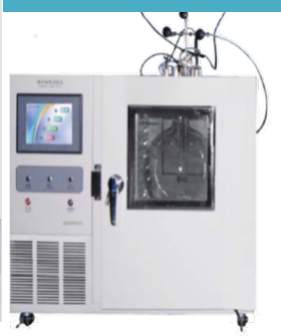
Process Development, Optimization and Validation

- Robust & phase appropriate process development, driven by quality improvement, cost & PMI reduction
- Working closely with analytical R&D teams to access data on quality, impurity identities & properties etc.
- Process design based on QbD concept
- Professional chemical engineering team working with R&D and QA for process validation



Process Safety Assessment

- Comprehensive safety evaluations begin immediately once a project is accepted and run parallel to process development activities
- CNAS certified

RC1e	ARC	DSC	RSC	ELT
				

Drug Substance Manufacturing

Multi-purpose

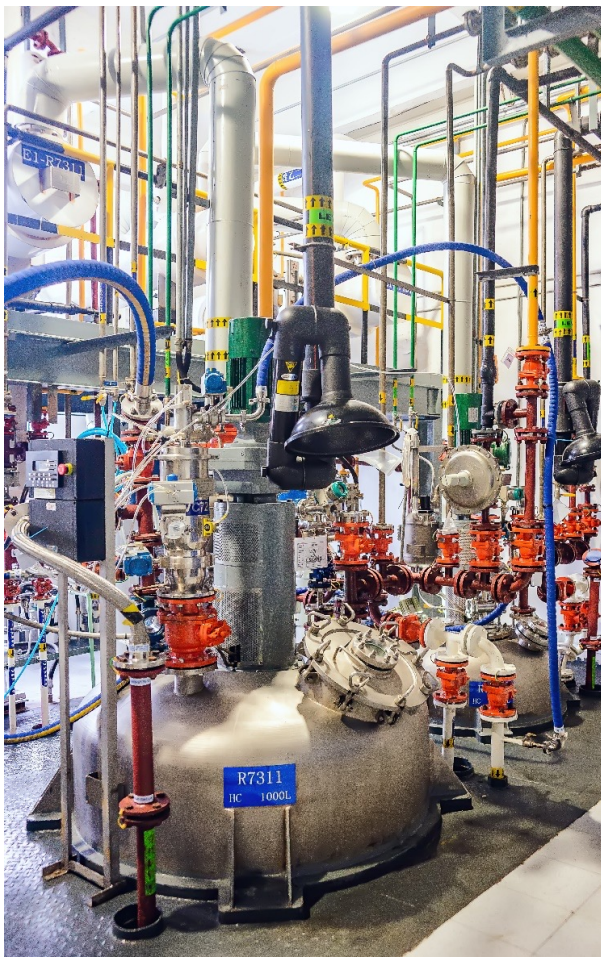
- Reactors of different sizes from 50 L to 6,300 L, able to handle a wide range of quantities from grams, to kilos, and tons, with a seamless, streamlined technology transfer.
- Multiple operation units to undertake a broad range of chemistries at all scales.

Reliability

- Professional and experienced engineering and production team
- Located in national & provincial level chemical industry parks, with complete infrastructure and policy support.
- Process safety must be assessed for each scale-up project before moving into the workshop.

Quality

- cGMP compliant at Zhejiang, FDA inspected with no 483 form issued
- ISO 9001 certified at USA, Nanjing and Shandong Sites
- US site cGMP compliance targeted summer 2021
- Passed a number of client audits from top pharmaceutical and biotech companies and third party authorities



Capacity

- Shandong Site:
  - ✓ Pilot plant and manufacturing of Intermediates
  - ✓ 2 works shops in use
  - ✓ Reactor volume: 55m^3, 200-3,000L
- Zhejiang Site:
  - ✓ Pilot plant and manufacturing of GMP/non-GPM intermediates & APIs
  - ✓ Reactor volume: 185m^3, 300-6,300L
  - ✓ 8 workshops planned, 3 workshops in use

Chemistry & Engineering Technologies

For green, safe and more time-, cost-, space-efficient process development & manufacturing

1 Flow Chemistry

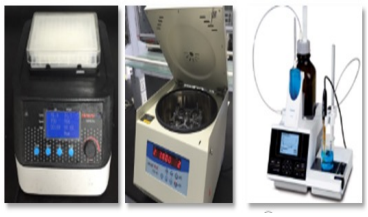
hundred kilo scale

2 Micropacked Bed Technology

yearly output>100 MTs

3 Biocatalysis
Heterogeneous Catalysis

hundred kilo scale



4 Solid State Chemistry
Crystallization

5 Engineering Technology

Analytical Development & Quality Control

- Analytical method development, validation and transfer in comply with ICH guidelines
- In process control and release testing in comply with GMP requirement
- Forced degradation (stress) study for the detection of impurities or degradation products
- Stability studies under varied temperatures and humilities per ICH guidelines
- Impurity isolation and identification using prep-HPLC, LC-MS, GC-MS, FT-IR and NMR spectroscopy
- Genotoxic and elemental impurity method development and validation
- Reference standards characterization and qualification
- Microbial limit testing

Regulatory Affairs Service

- Team members are trained in areas of R&D, GMP compliance, and registration, with 50+ DMF, ANDA, IND and NDA submission and approval experiences, covering 10+ markets including China, US, EU, Japan, etc.
- Original submission for API intermediate, API and drug products
- Reply to the deficiency letter
- E-CTD formats and submission, if required;
- Post registration dossiers maintenance

Team

500+ chemists & scientist
70+ hold a PhD degree,
40%+ hold a master degree and above.
The team is led by a group of veterans who have extensive experience covering every section of CMC.

Our employees share the same value and interest of the company, and PharmaBlock keeps a low turnover rate of only 5%.

Facilities & Equipment

PharmaBlock Nanjing

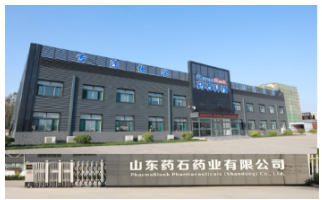
Discovery & Process R&D
Formulation R&D
One-stop CDMO Platform
(under construction)

PharmaBlock USA

Process R&D
Customer Service

PharmaBlock Zhejiang

Pilot & Manufacturing (GMP)
APIs & Intermediates



PharmaBlock Shandong

Pilot & Manufacturing
Intermediates, Drug Product

110,000+ ft^2 + lab space
with state-of-the-art instruments

2,243,000+ ft^2 + pilot & mfg. sites
in full compliance

Selected Equipment

400 MHz NMR Spectrometer	GC-MS System	UPLC/HPLC-MS System	HPLC/UPLC
GC	HPLC-MS-MS	QTOF	IC
SFC	ICP-MS	PSD	RC1e
DSC/TGA	ARC	XRPD	KF
UV-Vis	Polarimeter	MP	Stability & Photo Chambers