

PharmaBlock Sciences (Nanjing), Inc.

## Building Blocks Based CDMO

Fast & Consistent-quality Delivery in Full Compliance

[www.pharmablock.com](http://www.pharmablock.com)  
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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, supplying from discovery, to development and commercial; building blocks driven libraries for drug discovery; development and manufacturing of RSMs, intermediates, APIs and drug products for drug development and commercial.

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

- ❑ Optimal route scouting
- ❑ Quick 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

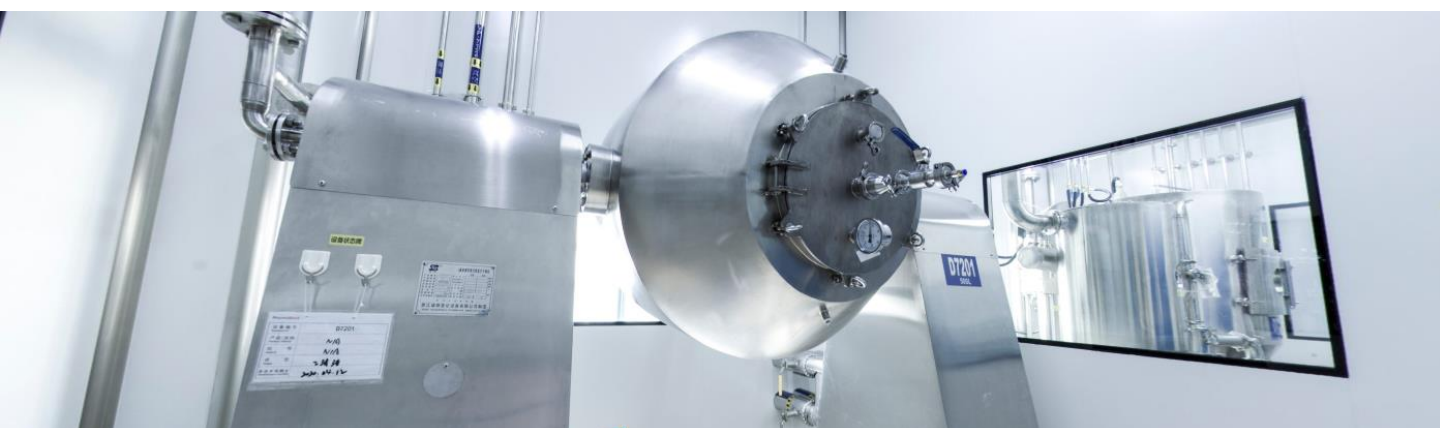
- ❑ Innovative route scouting & fast delivery
- ❑ Reliable supply
- ❑ Various methods for cost control
- ❑ Better knowledge in chemical properties to ensure quality & safety control

### Innovative Technologies

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

### Complete CDMO Service System

- ❑ Complete Quality, EHS & IP protection system
  - ❑ Professional PM & delivery teams
- ❑ GMP manufacturing facility (FDA GMP inspected with no Form 483s)



## 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



## 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 Shandong
- ❑ 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<sup>3</sup>, 200-3,000L
- ❑ Zhejiang Site:
  - ✓ Pilot plant and manufacturing of GMP/non-GPM intermediates & APIs
  - ✓ Reactor volume: 185m<sup>3</sup>, 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 &gt; 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 humidities 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

60+ 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**

Headquarters/R&D Center



**PharmaBlock USA**

Process R&D/Customer Service



**PharmaBlock Zhejiang**

Pilot & Mfg. of APIs & intermediates



**PharmaBlock Shandong**

Pilot & Mfg. of intermediates



**110,000+** ft<sup>2</sup> + lab space  
with state-of-the-art instruments



**2,243,000+** ft<sup>2</sup> + pilot & mfg. sites  
in full compliance

### Selected Equipment

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