


PharmaBlock Sciences (Nanjing), Inc.

Global Leader in Providing Innovative Building Blocks

Supply from discovery, development and commercialization

www.pharmablock.com
product.pharmablock.com



PharmaBlock Sciences (Nanjing), Inc. (SZSE:300725) is a leading provider of innovative chemical 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.

Since its establishment, PharmaBlock has rapidly gained recognition for its outstanding capabilities in the design, synthesis, and supply of novel building blocks. The team has generated a large and unique collection of high-quality and diverse building blocks, which are increasingly adopted by drug hunters to enrich the structure options, improve compound quality, expand patent space and eventually accelerate drug discovery projects. PharmaBlock has also been strengthening process R&D capabilities and expanding manufacturing capacity to secure the sustainable supply of building blocks.

In this booklet, we will demonstrate how we stand out as an innovative building blocks supplier.



Overview

130K+

building blocks

60+

chemical series

18K+

delivered
within 2 weeks

19K+

in stock

1K+

SAR/SPR tool kits

3K+


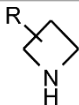




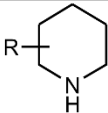
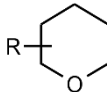

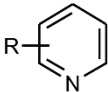
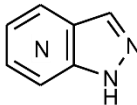
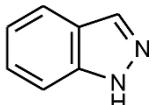
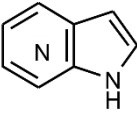
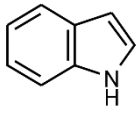
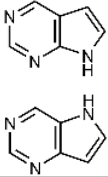
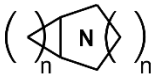

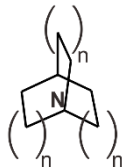
bulk products
supplied over kilo scale

Featured Collections

60+ chemical series covering the majority of small molecule R&D needs

Cyclopropanes	Pyrazoles & Other Five-Membered Aromatics
Four-membered Aliphatic Rings	Pyridines, Pyrimidines & Other Six-Membered Aromatics
Five-membered Aliphatic Rings	Indoles, Azaindoles & Deazapurines
Six-membered Aliphatic Rings	Other 5,6-Fused Aromatics
Bridged, Spiro & Fused Compounds	Quinolines & Other 6,6-Fused Aromatics

18 core series with advantages in novelty, variety & sustainable supply

					
>2500	>1900	>900	>1300	>4300	>2900
					
>6700	>1500	>2100	>2900	>500	>1500
					
>2100	>2100	>700	>2800	>4600	>3400

For product search

Please check: product.pharmablock.com

Our products are also available on Scifinder, ACD, DWCP & eMolecules

You can also send your inquiries to: salesusa@pharmablock.com.

Why Choose PharmaBlock

➤ Science Driven Building Block Design Strategy

- ❑ Key to enhance the novelty, diversity and high-quality of building blocks.
- ❑ Conducted a systematic study on marketed, clinical and preclinical drug structures, and keep weekly monitoring on the latest researches to design new chemical motifs, bioisosteric groups of commonly used functional groups for exploration of structure-activity relationship and structure-property relationship.

➤ Series Oriented Chemistry Expertise

- ❑ chemistry expertise developed around core chemical series, with the most extensive knowledge and intensive experience accumulated day after day.
- ❑ Over 250 chemists with great passion for chemistry and resolution to challenge the most tough chemistry problems.
- ❑ Diligently keep updated on the latest knowledges and technologies, and apply them to increase productivity and access new chemical space.

➤ Supply from Lab to Manufacturing

- ❑ Scalable process available for potential bulk need in drug development and commercial stages
- ❑ Better knowledge in product quality & safety property for sustainable supply



Team



We have an elite team of over 250 chemists & scientists serving for Building Blocks Business, focused on novel building blocks design, synthesis, and innovative drug discovery solutions.



Our employees share the same value and interest of the company, and PharmaBlock keeps a low turnover rate of only 5% over the past 10 years

Facilities & Equipment



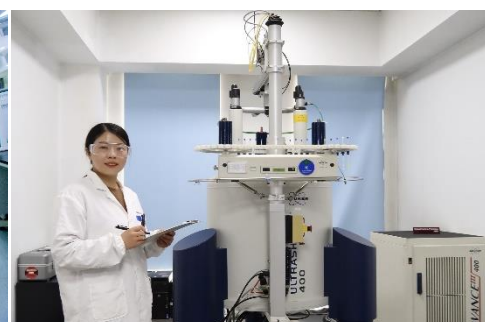
110,000+ ft² + lab space
with state-of-the-art instruments



2,243,000+ ft² + 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




PharmaBlock Sciences (Nanjing), Inc.

Building Blocks Based CDMO

Fast & Consistent-quality Delivery in Full Compliance

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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

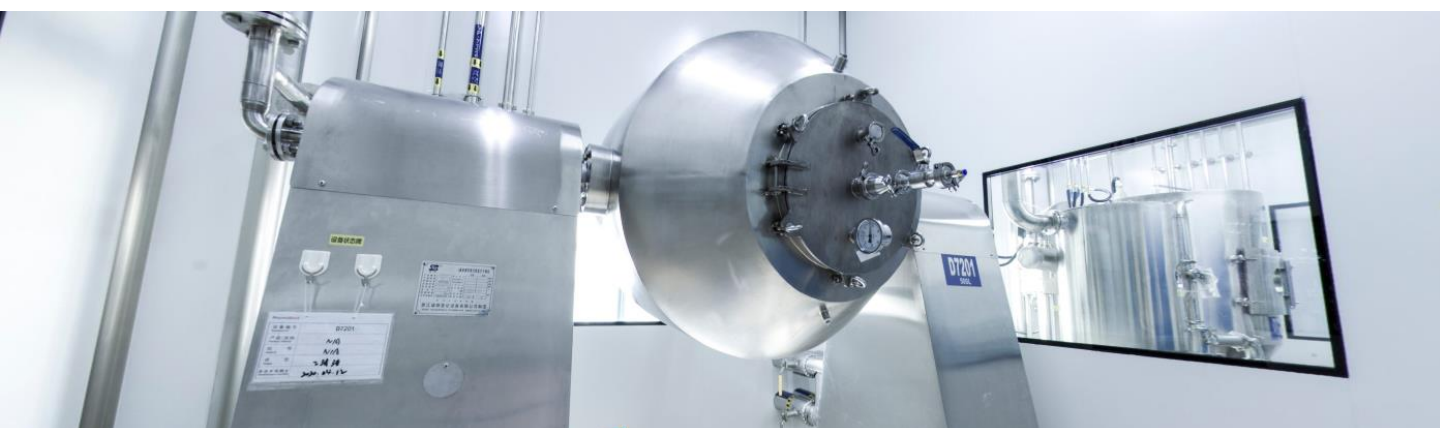
- ❑ Innovative route scouting & fast delivery
- ❑ Sustainable supply and cost control of building blocks as raw materials
- ❑ Qualified suppliers of raw materials for add stability of supply

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



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: 55m³, 200-3,000L
- ❑ Zhejiang Site:
 - ✓ Pilot plant and manufacturing of GMP/non-GMP intermediates & APIs
 - ✓ Reactor volume: 185m³, 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 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

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)



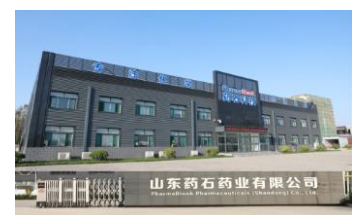
PharmaBlock USA

Process R&D
Customer Service



PharmaBlock Zhejiang

Pilot & Manufacturing (GMP)
APIs & Intermediates



PharmaBlock Shandong

Pilot & Manufacturing
Intermediates, Drug Product



110,000+ ft² + lab space
with state-of-the-art instruments



2,243,000+ ft² + pilot & mfg. sites
in full compliance

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DSC/TGA	ARC	XRPD	KF
UV-Vis	Polarimeter	MP	Stability & Photo Chambers

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Chemistry & Engineering Technologies

For Safer, Greener & More Efficient Process Development & Manufacturing

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PharmaBlock has invested in a number of innovative technologies to enable greener, safer, and more efficient process for manufacturing. We have a dedicated chemistry and engineering technology team working closely with experts in process development and manufacturing to implement optimal process solutions from pilot to commercial scale.

In this booklet, we will demonstrate our capabilities in the chemistry and engineering technologies development and application.

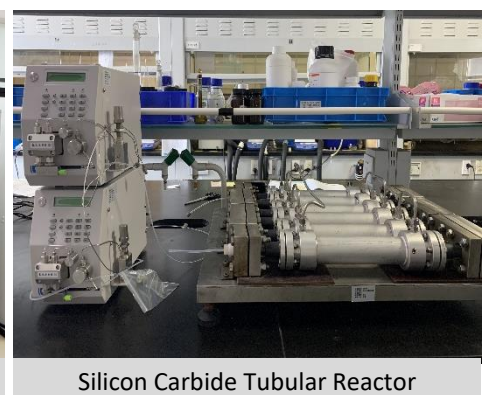
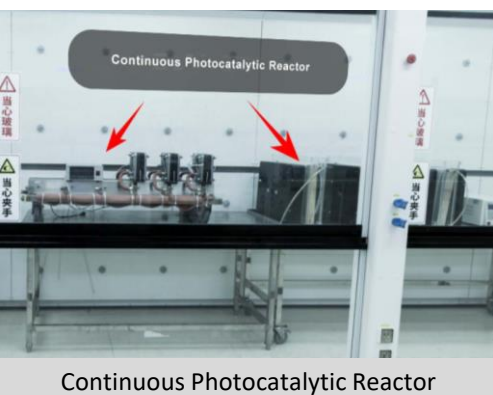


Key Technologies

- ❑ Flow chemistry
- ❑ Micropacked bed technology
- ❑ Catalysis
- ❑ Solid-state chemistry
- ❑ Crystallization
- ❑ Engineering technologies

Flow Chemistry

- ❑ PharmaBlock has successfully applied flow chemistry into multiple reaction types, including but not limited:
 - ✓ Cryogenic reaction
 - ✓ Diazo chemistry
 - ✓ High temperature and/or high pressure reaction
 - ✓ High energy chemical reaction
 - ✓ Reaction involving pungent and stinky intermediate, SM, product
 - ✓ Reaction involving toxic reagent or product
 - ✓ Oxidation
 - ✓ Nitration
 - ✓ Bromination
 - ✓ Fluorination
 - ✓ Electrolysis
- ❑ In-house engineering team that can design and assemble flow reactors of high flexibility.
- ❑ Equipped with self-assembled flow reactors with different volumes ranging from 1 mL to 15 L that are fabricated from different materials (PFA, SiC, SS316 etc.)
- ❑ Applied both in lab and manufacturing scale for different projects.



Micropacked Bed Technology

- ❑ Application in multiple reaction types:
 - ✓ Benzyl deprotection
 - ✓ Nitro reduction
 - ✓ Olefin reduction
 - ✓ Reductive amination
 - ✓ Selective pyridine reduction
 - ✓ Selective dehalogenation
- ❑ Capabilities to develop and produce different catalysts (eg. Pd(I/II), Pt, Ru etc.) to provide a better solution to extent catalyst life cycle and reduce cost.
- ❑ Capacity: Annual output exceeding one hundred metric tons
- ❑ Equipped with DCS (distributed control system) to achieve automatic detection & control of the entire device



Catalysis

➤ Heterogeneous Catalysis

On top of our constantly growing in-house catalyst inventory, we continue to research, design, develop, and manufacture the following catalysts to support our projects.

- ❑ Bead supported catalysts and cartridge catalysts used in flow process
- ❑ Powder supported catalysts used in batch process
- ❑ Customized and specialized catalysts
- ❑ Catalyst screening

➤ Biocatalysis

- ❑ Enzyme screening and route design
- ❑ Chemo-enzymatic process development and manufacturing
- ❑ Enzyme immobilization

Solid State Chemistry

- ❑ Single crystal culture and structure analysis
- ❑ Polymorph/salt/cocrystal screening and research
- ❑ Amorphous/co-amorphous screening and research
- ❑ Solid-state chemistry characterization
- ❑ Solubility and dissolution performance study
- ❑ Stability and hygroscopicity study
- ❑ Compatibility study
- ❑ IND/NDA filing and patent services
- ❑ PH, PKa, LogP and powder property study

Crystallization

- ❑ Development of various types of crystallization processes
- ❑ Solving problems of solvent residues, crystal control, purity, and yield
- ❑ PAT technology development
- ❑ Filtration, drying, particle size control, etc.
- ❑ Process development of milling, spray drying, granulation, etc.
- ❑ Fractionation process of high salt wastewater
- ❑ Process scale-up strategies study
- ❑ Crystallization equipment design and commissioning services
- ❑ Molecular simulation & AI assisted polymorph prediction
- ❑ Continuous crystallization, nanocrystal particles process development

Engineering Technologies

- ❑ Selection, design and processing of various scale equipment.
- ❑ Equipment matching, engineering services for various types of reaction.
- ❑ Micropacked Bed and flow equipment design and processing.
- ❑ Innovative continuous processes development and equipment design.
- ❑ Development of continuous separation processes, integration of equipment design.
- ❑ Equipment Hazop analysis.
- ❑ On-site commissioning support.
- ❑ Workshops and factory establishment support.
- ❑ Dynochem, CFD process simulations.