



A Pharmaceutical Partner you can TRUST

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NANJING HANXIN PHARMACEUTICAL
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南京汉欣医药科技有限公司
Nanjing Hanxin Pharmaceutical Technology Co., Ltd.

ABOUT US

Hanxin Phapm

Nanjing Hanxin Pharmaceutical Technology Co., Ltd., established in 2017, is a member of the U.S. listed company AMPHASTAR Pharmaceuticals Group. Relying on advanced technology platforms and strong R&D capabilities, Hanxin Pharm has rapidly become a biopharmaceutical group integrating R&D, manufacturing, and marketing of innovative drugs, biological drugs, and complex formulations.

With a registered capital exceeding 150 million RMB and a laboratory area of 13,000 square meters, Hanxin Pharm undertakes the development of biopharmaceutical and chemical drugs to meet registration requirements in China, US, Europe, and other regions. Currently, Hanxin has over 100 ongoing projects. 200,000 square meters manufacturing plant, GMP certified formulation workshop, and FDA certified API workshop enable commercial-scale manufacturing of various APIs and formulations. Our sales network covers More than 6,000 hospitals and over 100,000 end-customers nationwide.

Hanxin is dedicated to technological advancement and quality-oriented development, Carefully established: 1. a complete system for new drug research and technological innovation, 2. improved quality management system and 3. international intellectual property management system.

We have built strong advanced technological platforms:

1. Synthetic biology recombinant protein/peptide platform, which is committed to high-yield strain screening and product development;
2. Protein/glycan complex characterization platform, which is dedicated to the research on macromolecules characterization;
3. Complex formulation platform, which is committed to the development of innovative drugs and highly complex generic drugs.

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ABOUT US



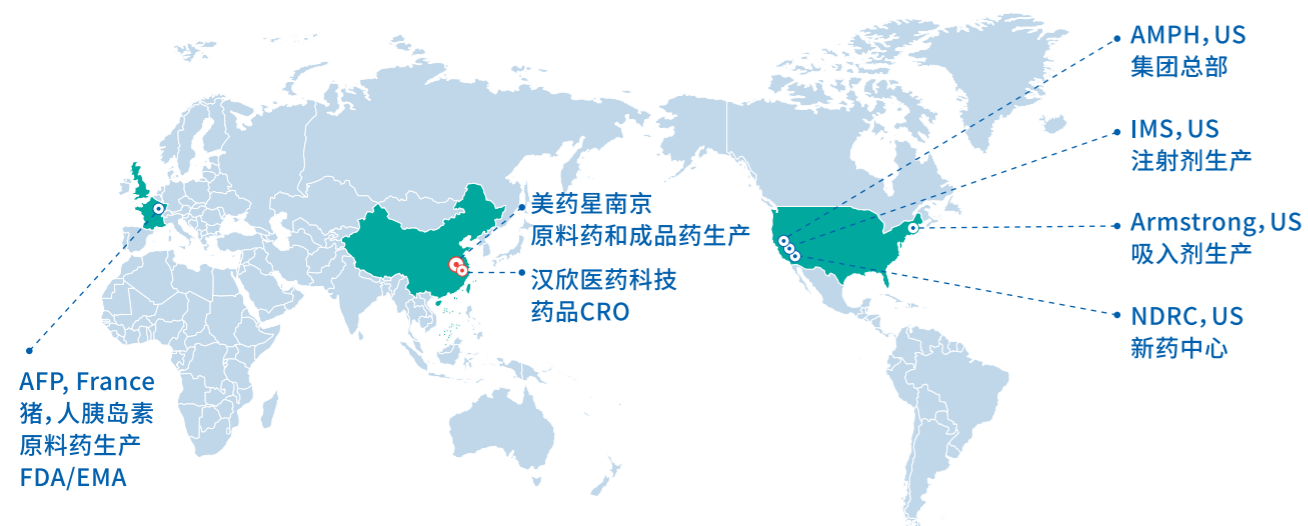
臣功制药

Nanjing Cucess Pharmaceutical Co., Ltd., founded in 1992, is a wholly-owned subsidiary of Nanjing Hanxin Pharmaceutical Technology Co., Ltd. The company is primarily engaged in the production and sales of various Chinese and Western medicinal formulations, sales of Class I medical devices, import and export of various goods and technologies, as well as medical health consultation and services. It also has multiple wholly-owned subsidiaries involved in formulation production, production of active pharmaceutical ingredients, and wholesale distribution of pharmaceutical products. Over the years, the company has achieved continuous stable growth in business and profits, establishing a positive brand image in the market.



BACKGROUND OF GROUP

Amphastar Pharmaceuticals Inc., a publicly listed company in the United States, is a biotechnology pharmaceutical company headquartered in Los Angeles.



PRODUCTION LINE ADVANTAGES

美药星(南京)制药有限公司

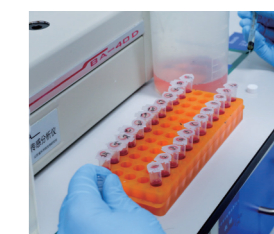
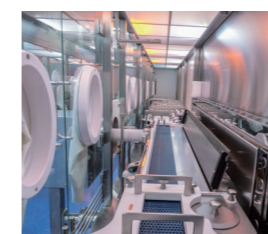
Our production base spans **200,000** square meters and adheres to FDA declaration requirements for constructing factories and workshops, strictly complying with US and EU standards and EHS quality management systems.

We have undergone **5** inspections by the US FDA, all of which were successfully cleared, with two instances receiving a "Zero 483" result.

We offer over **20** types of active pharmaceutical ingredients, encompassing various fields such as genetic recombination, biological extraction, and chemical synthesis (including GLP-1 analogs and insulin analogs).

Additionally, we operate **four** formulation production lines capable of producing pre-filled syringes, vials (including lyophilized vials), cartridges, and gels. These lines support seamless scale-up from laboratory-scale to commercial production.

Products under patent within the validity period are for research purposes only and not for commercial use.



- With a global presence (NASDAQ: AMPH), its subsidiaries are located across the United States' east and west coasts, Europe, and China.
- With years of experience in the market, Amphastar Pharmaceuticals has focused on the research, production, and sales of injectables and inhalants.
- Boasting a team of approximately 2,000 employees in the United States,
- The company achieved robust financial performance in 2023 with a sales revenue of \$644 million and a net profit of \$140 million.

MANUFACTURING FACILITY

南京臣功制药股份有限公司 (全资子公司)

46,183 square meters of production base with a reserved development land of 22,000 square meters. The construction of the factory and workshops according to GMP declaration requirements strictly adheres to the drug production quality management requirements in terms of production management and quality control.

All 13 drug production lines have passed GMP compliance inspections, covering tablet formulations (conventional, penicillin, hormone), dry powder suspensions (conventional, penicillin), hard capsule formulations (conventional, hormone), granule formulations, cream formulations, suppository formulations, gel formulations, lyophilized powder injections, and small-volume injection formulations (non-final sterilization).

There are 17 products available for sale, covering respiratory, anti-infective, oncology, digestive, cardiovascular, urinary, nervous system, gynecology, dermatology, and other systemic medications.

| SN | Production Line | Formulation /Product | Clean liness Level | Batch Size | Annual Production Capacity | Equipment |
|----|---|--|--------------------|---|--|---|
| 1 | Small-volume injection (non-terminal sterilization) | Multi-specification non-terminal sterilization ampouleproducts | B+A | 50L-1500L, 200,000 units/batch (calculated based on 5ml) | 50 million units per year | Residual oxygen ≤ 1.2%, high-voltage discharge leak detection |
| 2 | Cream Gel Ointment | Multi-specification cream and gel products | D | Cream, gel: 70-1500L, 40,000-100,000 units (calculated based on 15g/unit) | Cream, gel: 30 million units per year | Fully automated packaging line |
| 3 | Suppository | Multi-specification suppository products | D | 50-500L, 75,000-200,000 units (calculated based on 2g/unit); 2 batches per day. | 75 million units per year | Fully automated packaging line |
| 4 | Small-volume injection (terminal sterilization) | Multi-specification products | C+A | 40L-800L, 40,000-200,000 units/batch Specifications: 1-5ml, 10ml, 20ml | 100 million units per year | Residual oxygen ≤ 1.2%; high-voltage discharge leak detection |
| 5 | Tablets, capsules | Multi-specification tablet and capsule products | D | Tablets: 250,000-700,000 tablets (calculated based on 0.4g/tablet). Capsules: 300,000-1,000,000 capsules (calculated based on 0.3g/capsule) | Tablets: 175 million tablets per year; Capsules: 125 million capsules per year | Dry granulator, wet granulator, fully automated double aluminum packaging production line |
| 6 | Granule line | Multi-specification products | D | 200-1000KG/batch | 225 million bags per year 75 million bags per year | Dry granulator, wet granulator, fully automated strip packaging production line Wet granulator, three-sided sealing automatic packaging line |

Lianyungang Cuccess Pharmaceutical Co., Ltd. (subsidiary)

35,333 square meters park. Capable of producing general chemical raw materials, oncology raw materials, hormone raw materials, etc.

COOPERATION ADVANTAGES

Excellent Quality:

Committed to outstanding quality

Cost Control:

Strict adherence to US and EU standards and EHS quality management system in production and operation

Stable Production Capacity:

Commercialized production of various API, intermediates, and formulations

Flexible Collaboration:

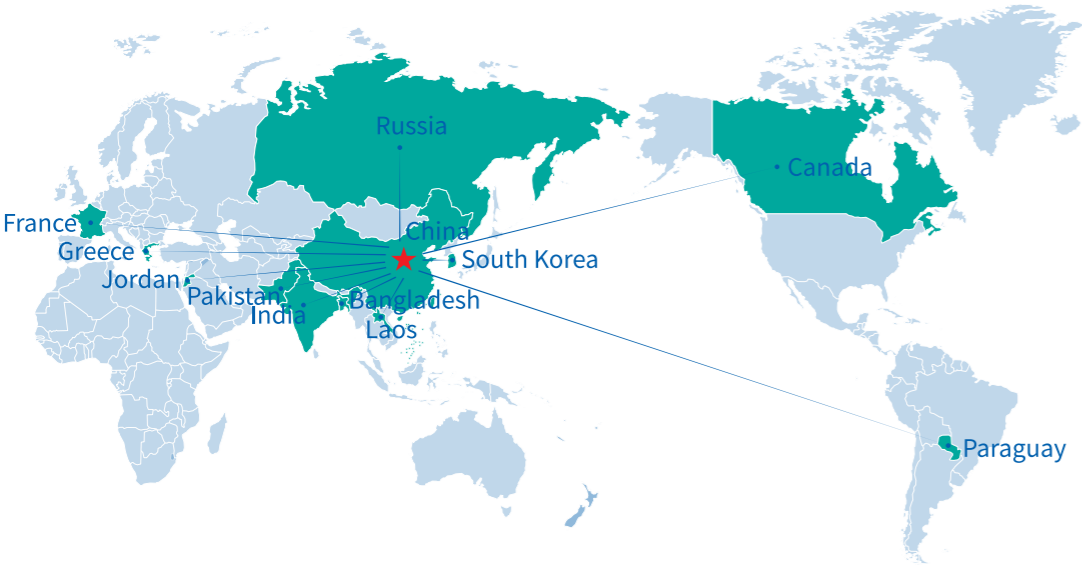
Provision of intermediates, multi-level API, as well as CRO and CDMO services for formulations



SALES CAPABILITY

Global Presence, Wide Collaboration

Sales Advantages



PRODUCT INTRODUCTION

| Product | Semaglutide |
|---------------------|--|
| CAS No. | 910463-68-2 |
| Molecular Formula | C ₁₈₇ H ₂₉₁ N ₄₅ O ₅₉ |
| Formula Weight | 4113.6 |
| Purity | ≥99%/ (for injection) |
| Grade | ≥97%、≥98% (for tablet) |
| Application | Used for glycemic control in adults with type II diabetes and may help people with obesity lose weight as well |
| Qualification files | USDMF, GMP |
| Storage | Preserve in tight containers, protected from light, and store in a freezer-25~-15°C |
| Technology | Developed tablet and injection production processes |

部分合作伙伴



| Product | Insulin Aspart |
|---------------------|--|
| CAS No. | 116094-23-6 |
| Molecular Formula | C ₂₅₆ H ₃₈₁ N ₆₅ O ₇₉ S ₆ |
| Formula Weight | 5825.5 |
| Purity | >99% |
| Grade | for injection |
| Application | The formulation is used for glycemic control in patients with type I and type II diabetes mellitus |
| Qualification files | USDMF, BLA |
| Storage | Preserve in tight containers, protected from light, and store in a freezer-25~-15°C |

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