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**海南双成药业股份有限公司**

Hainan Shuangcheng Pharmaceuticals Co., Ltd. (HNSP)



**With Shuangcheng Pharma  
Start A Win-Win Collaboration**

**Based in Hainan Free Trade Port**

# About Us



The company is headquartered near Haikou airport on Hainan Island, China with R&D and manufacturing facilities at the Haikou site, and has new facilities in Ningbo, about 1.5 hours' drive from Shanghai's Pudong Airport (PVG). HNPS also has a subsidiary company in Italy.



HNPS is rapidly expanding in China and elsewhere around the world, and is presently seeking collaboration and partnerships with pharmaceutical companies in the U.S., Europe and other regions.

Founded in 2000, Hainan Shuangcheng Pharmaceuticals Co., Ltd (HNPS) is a publicly-traded company and engaged in development, manufacturing and marketing of both APIs and drug products. Having excellent know-how in peptide chemistry, HNPS is a leader in the field of peptide manufacture, with current U.S. FDA and AIFA (Italian Medicines Agency) approved production.



# First-Class Facilities

Current Manufacturing Site at Haikou (less than one hour from HAK airport)



58,000 m<sup>2</sup> of land (14+ acres):  
Office space: 4,271 m<sup>2</sup> (4.6K sq.ft.);  
Manufacturing space: 37,567 m<sup>2</sup> (404K sq.ft.)



- ◇ Founded in 2000
- ◇ Engaged in R&D, manufacturing and marketing of both APIs and drug products
- ◇ Inspected by USFDA & EMA & NMPA
- ◇ 5 production lines covering APIs, lyophilized product, injection and cartridges
- ◇ Providing CDMO and CMC services



### Capacity:

Peptide API workshop: 200-300 kg per year  
Lyophilized product workshop: 120 M vials per year  
Injection workshop: 1 M vials & 20 M cartridges per year



Ningbo Shuangcheng Pharma (NBSP) (~1.5-hour drive from PVG airport)

210,000 m<sup>2</sup> of land (51+ acres):  
Office space: 12,000 m<sup>2</sup> (129,000 sq.ft.)  
Manufacturing space: 198,000 m<sup>2</sup> (2.13 million sq.ft.)

- ◇ Established in 2014
- ◇ Holding subsidiary of HNSP
- ◇ Engaged in R&D, and drug product manufacturing
- ◇ Inspected by USFDA & NMPA
- ◇ 2 production lines covering oncology injectable and oral solid dosage forms
- ◇ Providing CDMO and CMC services

### Capacity:

Oncology workshop  
Lyophilized powder for injection: 10 M vials per year  
Small-volume injection: 20 M vials per year  
Oral Dosage workshop  
Tablets: 700 M tablets per year  
Capsules: 300 M capsules per year



# Excellent Quality System



## International GMP Inspections

| No. | Inspection             | Inspected by   | Time      | Product   | Complied or not |
|-----|------------------------|----------------|-----------|-----------|-----------------|
| 1   | GMP Inspection         | US FDA         | Aug. 2013 | API       | √               |
| 2   | Unannounced Inspection | US FDA         | Jan. 2016 | API       | √               |
| 3   | GMP Inspection         | AIFA (Italian) | Feb. 2016 | API & FDF | √               |
| 4   | PAI                    | US FDA         | May 2017  | API & FDF | √               |
| 5   | Unannounced Inspection | US FDA         | Apr. 2019 | API & FDF | √               |
| 6   | PAI                    | US FDA         | Oct. 2019 | FDF       | √               |
| 7   | PAI                    | US FDA         | Jun. 2023 | API & FDF | √               |

Shuangcheng Pharma follows and complies with:

- ◇ ICH guidelines
- ◇ cGMP regulations (EU and U.S.)
- ◇ NMPA GMP (China)



2016 Unannounced Inspection by US FDA



2016 PAI Inspection by AIFA



2017 PAI Inspection by US FDA



2023 PAI Inspection by US FDA



# Broad Range of Products



Bivalirudin for Injection



Eptifibatid Injection



Bortezomib for Injection



Paclitaxel (Albumin bound)



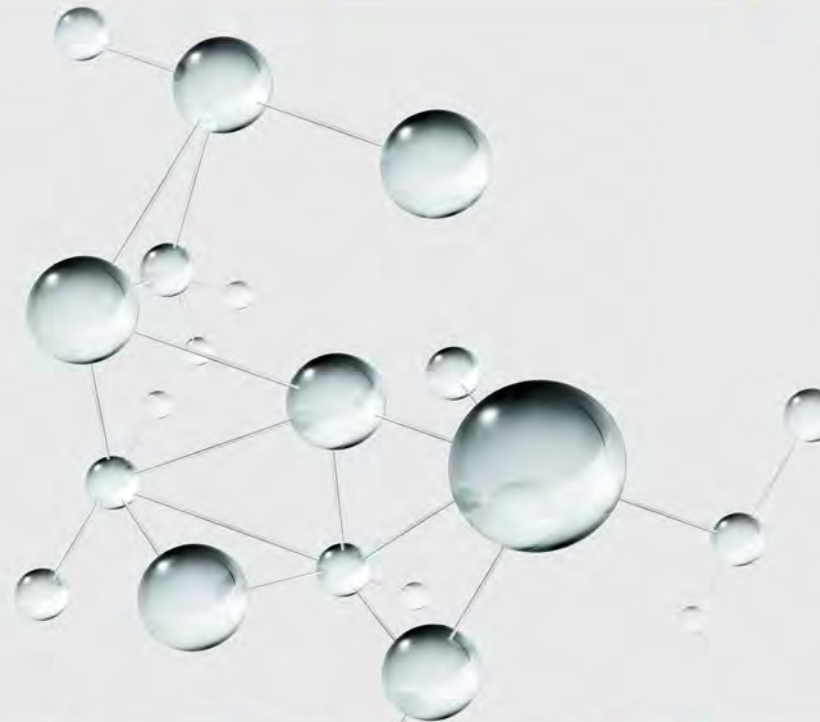
Octreotide Acetate Injection



Vasopressin Injection



Products approved, filed or to be filed to NMPA, the U.S. FDA or EMA



HNSP currently has more than 12 peptides and 27 drug products (peptides and small-molecules) in a total 43 presentations in pipeline.



# Effective Marketing Network

## ● Domestic Market

Dedicated professional marketing and sales team  
More than 400 competitive agents  
More than 600 cooperative medical sales companies  
HNSP leading products sold in more than 1,000 cooperative hospitals

## ● International Market

Products marketed in the U.S.A and Mid-East, etc.  
More products will be exported to other markets around the world



## ● Partnering



## International Marketing



- 01 **Partner with** pharmaceutical companies
- 02 **License out** HNPS products
- 03 **License in** products
- 04 **Co-develop with** pharmaceutical companies

Together  
Make A Difference To Pharma Industry



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