

# Nanjing Hanxin Pharmaceutical

## Products List

(2024 edition)

Nanjing Hanxin Pharmaceutical Technology Co., Ltd. is committed to providing international pharmaceutical products and services for biological drugs, peptide drugs and chemical drugs. The company has 200 R&D staff and 13,000 square meters of R&D labs, including fermentation, purification, peptide, enzyme catalysis, formulation, analysis and other kinds of labs, which has been recognized by the national CNAS laboratory and identified as "Nanjing Genetic Recombinant drug Engineering Technology Research Center". We can complete many kinds of drug research and development including recombinant protein, peptide, natural extractable, enzyme catalysis and chemical synthesis. The manufacturing sites have 700 staff and 200,000 square meters of facilities, and could provide the services from early clinical research to customized production during the full life cycle of drug development, including pilot-scale production, validation batch production, registration batch production and commercial production.

Hanxin Pharmaceutical has three major production bases, located in Nanjing National Economic and Technological Development Zone.

1. Production base for biologics, it can produce recombinant proteins, fusion protein drugs and polypeptide drugs. It is one of the few enterprises in China that can carry out aseptic filling and production of recombinant biological drug stock solution, vials, cartridges and syringe.
2. Production base for chemical drugs, there are more than 30 products in production, 13 GMP standard drug production lines, including ointment, cream, gel, suppository, injection, granules, capsules, tablets, progestogen solid preparations, penicillin solid preparation production workshop.
3. Production base for chemical biology products, it has a 5-ton recombinant protein expression and extraction system, as well as a supporting low pressure chromatography system, high

pressure chromatography system, lyophilizer/spray dryer to achieve the production of recombinant protein products, and 100L cell expression and supporting low pressure chromatography system, high pressure chromatography system, lyophilizer to achieve the production of antibody pilot products. The products include medical cosmetology and cosmetic materials, functional dietary supplement materials, recombinant tool enzymes, proteases, antibodies, oligosaccharides, amino acid/nucleic acid derivatives.

In addition, a production base for chemical drugs is under construction, the production plant is 40,000 square meters, and more than 10 chemical APIs are planned to be produced.

At present, the main products provided by Hanxin Pharmaceutical include API (Table 1), cosmetic raw materials (Table 2), medical cosmetology and cosmetic materials (Table 3), functional dietary supplement food raw materials (Table 4), reagents and enzyme products (Table 5), etc. The company also provides CRO services including biological/peptide drug development, injection, solid/semi-solid preparation process development, peptide and emergency drug injection, complex solid formulation, topical drug formulation, etc., and OEM services, including CDMO service for drugs and API, and OEM service for functional food finished product.

## 1. API and intermediates products

### 1.1 List of approved APIs in US

#	Product Name	CAS No.	Global DMF status	CDMF status
1	Isoproterenol Hydrochloride	51-30-9	ANDA approved in US	Apply if necessary
2	Protamine Sulfate	9009-65-8	Submitted in US	Submitted
3	Insulin Aspart	116094-23-6	Submitted in US	Apply if necessary
4	Teriparatide Acetate	52232-67-4	Submitted in US	Apply if necessary
5	Liraglutide	204656-20-2	Submitted in US	Apply if necessary
6	Semaglutide	910463-68-2	Planned submitted in 2024H2	Apply if necessary
7	Insulin Degludec	844439-96-9	Planned submitted in 2024H1	Apply if necessary
8	Ganirelix Acetate	123246-29-7	Planned submitted in 2024H1	Apply if necessary
9	Epinephrine Hydrochloride	55-31-2	Planned submitted in 2024H2	Apply if necessary

### 1.2 API Intermediates list

#	Product Name	CAS No
1	Insulin Degludec side chains L-tBuO-Pal-Glu(OSu)-OtBu	843666-26-2
2	tBuO-Ste-Glu(AEEA-AEEA-OH)-OtBu	1118767-16-0
3	(S)-2-(2-((tert-Butoxycarbonyl)amino)-3-(1-trityl-1H-imidazol-4-yl)propanamido)-2-methylpropanoic acid	2061897-68-3
4	Semaglutide Main Chain P29 Arg34-GLP(9-37)	1169630-82-3
5	Crude semaglutide	910463-68-2
6	First Acylated Semaglutide Precursor	N/A
7	Second Acylated Semaglutide Precursor	N/A

8	Liraglutide Main Chain (GLP7-37)	204521-68-6
9	Chloroacetyl Catechol	99-40-1

## 2. Finished Dosage Forms

#	Generic Name	CAS	Refer.	Spec.
1	Clavulanate Potassium and Amoxicillin for Suspension (7:1)	26787-78-0 61177-45-5	ChP	200mg:28.5mg
2	Clavulanate Potassium and Amoxicillin Dispersible Tablets (7:1)	26787-78-0 61177-45-5	ChP	400mg:57mg
3	Zinc Gluconate and Ibuprofen with Chlophenamin Granules	4468-2-4 15687-27-1 113-92-8	ChP	0.1g:0.15g:2g
4	Terbinafine HCL Tablets	78628-80-5	ChP	0.25g
5	Isosorbide Mononitrate Sustained Release Tablets	16051-77-7	ChP	60mg
6	Guaifenesin and Dextromethorphan Hydrobromide Granules	93-14-1 125-71-3	ChP	0.1g:15mg
7	Rifaximin for Suspension	80621-81-4	ChP	0.1g
8	Medroxyprogesterone Acetate Capsules	71-58-9	ChP	0.1g
9	Medroxyprogesterone Acetate Tablets	71-58-9	ChP	0.25g
10	Megestrol Acetate Capsules	595-33-5	ChP	0.16g
11	Torsemide Injection	56211-40-6	ChP	2ml:10mg, 4ml:20mg
12	Tretinoin Cream	302-79-4	ChP	15g:3.75mg

13	Policresulen Vaginal Suppository	101418-00-2	ChP	90mg
14	Miconazole nitrate suppository	22916-47-8	ChP	0.2g
15	Ketoconazole and clobetasol Propionate Cream	65277-42-1 25122-46-7	ChP	10g
16	Bismuth Potassium Citrate Capsules	57644-54-9	ChP	0.3g
17	Triamcinolone Acetonide and Econazole Nitrate Cream	76-25-5 27220-47-9	ChP	5g
18	Terbinafine Hydrochloride Gel	78628-80-5	ChP	10g
19	Bifonazole Cream	60628-96-8	ChP	15g:0.15g

### 3. Personal Care & Cosmetic Ingredients

#### 3.1 Marketed List

#	Category	Spec.	Molecular Weight	Product Advantage
1	Hyaluronic acid series	nmHA®	1KDa	Anti-wrinkle, high penetration, high moisturizing, promote skin cell regeneration, repair damaged skin, promote collagen synthesis
		Low Molecular Hyaluronate Sodium	3KDa	Rapid penetration, rapid absorption, moisturizing and collagen replenishment, deeply replenish HA in the stratum corneum and dermis.
			5KDa	
			10KDa	
			20KDa	
		Medium Molecular Hyaluronate Sodium	80KDa	Concentrated molecular distribution, epidermal hydration and moisturization.
			100KDa	
			200KDa	
			300KDa	
			500KDa	
		Large	1MDa	Form a breathable film on the skin

		Molecular Hyaluronate Sodium	1.3MDa	surface to make smooth and moist, block the invasion of bacteria, dust and ultraviolet rays, protect skin from damage
			1.5MDa	
			1.8MDa	
			2MDa	
			>2MDa	
		Crosslinking Hyaluronate Sodium	>4MDa	Local filling, lubrication of joints
2	Acetylated Hyaluronate Sodium	Low Molecular	1KDa	lipophilic,easy to penetrate and absorb, long-lasting moisturizing, repair skin barrier
		Large Molecular	20KDa	
		Customized	1K-2MDa	
3	Cationic Hyaluronate Sodium	Low Molecular	1KDa	High absorption, double moisturizing, suitable for hair care and solve dry hair problem.
		Large Molecular	1MDa	
		Customized	1K-2MDa	
4	Low endotoxin Hyaluronate Sodium	Low endotoxin	1K-2MDa	Endotoxin < 0.05EU/mg
5	PDRN	Cosmetic grade	molecular weight < 100KDa	The raw material product is a non-toxic, non-irritating safety substance, stable to heat
		Medical device grade for injection	molecular weight > 600KDa	
		Nano emulsion	/	

### 3.2 New Product will be available soon

#	Category	Spec.	CAS	Product Advantage
1	Ergothioneine	Cosmetic grade	497-30-3	It is produced by fermentation technology, with a purity of more than 99% and a total of heavy metal ions < 10ppm
2	Recombinant humanized collagen	Cosmetic grade, Medical device grade for injection	9007-34-5	Produced with microbial recombinant technology, with a purity of more than 95% and high activity.
3	Ectoine	Cosmetic grade	96702-03-3	It is natural with no irritation, could provide cellular osmotic balance, form a hydrated shell to protect cells.

We also own a cosmetics brand named HiSpring@ applying the upper list material, including cream, moisture essence, freeze-dried powder, face mask, nano spray and other products.

## 4.Functional Food Ingredients

#	Product Name	Function	Approval Status
1	Small molecule chondroitin sulfate (nmCS)	800Da, Super high bioavailability, anti-inflammatory and analgesic, no gastrointestinal side effects, less irritation.	United States GRAS Certification
2	$\gamma$ -aminobutyric acid (GABA)	Improve the ability of resist pressure, improve sleep quality, relieve pressure, and improve work efficiency.	Chinese Food Certification
3	Earthworm Protein	Thrombolysis	China Food Approval Certificate
4	Lumbrokinase	Thrombolysis	Listed
5	Ergothione	Food grade, super antioxidant	Listed
6	NMN enteric granule	It is benefit for anti-aging, immunity and the liver. In terms of acid resistance, it is far better than NMN of American and Japanese brands.	Listed

## 5. Reagent and enzyme products

#	Product Name	CAS No	Usage	Specification
1	Recombinant CPB	9025-24-5	Produced with microbial recombinant technology, which can replace animal-derived carboxypeptidase B for the removal of C-terminal basic amino acids in various biotechnology processes, such as the production of recombinant insulin and its analogues.	10mg/ vial 10mg-10g/bottle per customized
2	Recombinant Kex-II	99676-46-7	Cleavage of carboxy-terminal peptide bonds of double base amino acids, such as specific enzyme cleavage of insulin glargine, fusion expression to prepare protein/peptide drug cleavage.	10mg/ vial 10mg-10g/bottle per customized
3	Recombinant enterokinase	9014-74-8	It can be used in the production of various protein/polypeptide drugs. During the production process of GLP-1 fusion expression, recombinant enterokinase is used to remove the fusion protein located at the N-terminal of the protein, so as to remove unnecessary fusion tags.	10mg/ vial 10mg-10g/bottle per customized

