

Topscience Biotech

- ▶ We are a biotechnological innovative enterprise focusing on the R&D, production, sales, and service of bioactives with microbial fermentation technology and aseptic API production technology as the core.

Shandong Topscience Biotech Co., Ltd.

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Sterile HA



01

Sterile Sodium Hyaluronate



The 'sterile' sodium hyaluronate that currently exists on the market is the only sodium hyaluronate that has passed the sterility test. The sterile sodium hyaluronate launched by Topscience Biotech is produced with sterilization filtration, which is the true meaning of sterile sodium hyaluronate. The sterile sodium hyaluronate belongs to the highest-end branch of pharmaceutical grade sodium hyaluronate. Topscience Biotech is the first enterprise in China to launch a sterile sodium hyaluronate drug substance, there is no other company in the industry that has launched the same grade product at present. The sterile sodium hyaluronate produced by Topscience Biotech meets the terminal application standards of the downstream pharmaceutical field, which is a major technological innovation after pharmaceutical grade Sodium Hyaluronate.

——Quoted from 'White Paper of China Sterile Hyaluronic Acid'

Pioneer of Sterile Sodium Hyaluronate

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Event



- **Conference Name:** 2023 Biotechnology Industry Innovation Forum & New Product Launching Conference of Sterile Sodium Hyaluronate from Topscience Biotech
- **Time:** May 25, 2023
- **Location:** National Convention Center·Beijing
- **Theme:** New Power of Sterile Sodium Hyaluronate Leading the New Future

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Product Overview



Product Overview

Sterile raw materials can be divided into two categories according to the production process: one is final sterilization raw materials produced by a final sterilization process, and the other is non-final sterilization raw materials part or all of which are produced by a sterile production process.

The non-final sterilized products are sterilized using sterilization filtration to ensure product quality via strict sterile control. The sterile sodium hyaluronate raw materials produced by the sterile production process can be used directly by downstream manufacturers for sterile preparations and sterile medical devices without further sterilization procedures.

Product Specifications

Items	Specifications	Methods
Appearance	White or almost white powder or fibrous aggregate.	Ph.Eur.
Identification A. Infrared absorption B. Reaction (a) of sodium	The IR spectrum of the sample exhibits maxima at the same wavelength as that of Ph.Eur. reference spectrum of Sodium Hyaluronate. Positive	Ph.Eur.(2.2.24) Ph.Eur.(2.3.1)
Appearance of solution	Clear and the absorbance is NMT 0.01 at 600 nm.	Ph.Eur.(2.2.1) Ph.Eur.(2.2.25)
pH	5.0 ~ 8.5 (0.5% solution)	Ph.Eur.(2.2.3)
Intrinsic viscosity	Report the test value (on the dried substance)	Ph.Eur.
Protein	≤0.1% (on the dried substance)	Ph.Eur.
Chlorides	≤ 0.5%	Ph.Eur.(2.4.4)
Iron	≤ 80 ppm (on the dried substance)	Ph.Eur.(2.2.23, Method II)
Sterility	No growth of microorganisms occurs.	Ph.Eur.(2.6.1)
Bacterial endotoxins	<0.05IU/mg	Ph.Eur.(2.6.14)
Residual solvents: Ethanol	≤ 0.5%	In-house method

After years of exploration and research by Topscience Biotech, the first automated production workshop for sterile sodium hyaluronate APIs in China was officially put into production in 2022 to improve product quality and ensure sterility level.



Company Overview



02



Topscience Biotech was established in 2005 and is a biotechnological innovative enterprise focusing on the R&D, production, sales, and service of bioactives with microbial fermentation technology and sterile API production technology. Topscience Biotech's main products include biochemical APIs, tissue engineering raw materials, functional skincare ingredients, new dietary raw materials, etc.

The manufacturing site covering an area of more than 100,000m² is located in Lanshan District, Rizhao City, Shandong Province. There are more than 30 personnel with intermediate professional titles, and more than 30 Licensed Pharmacists. It has 8 GMP-compliant production workshops, and also, Topscience Biotech has established a sound quality control system conforming international standards such as ICH and GMP.

Milestone

2005

Topsience Biotech Established. Chondroitin Sulfate Sodium and Menotropins series mass production started.

2009

Western site located, which lay a solid foundation for the company's long-term development and capacity expansion.

2008

Company went into the fast track for production, R&D, and sales for Sodium hyaluronate.

2017

The dedicated production workshop for pharmaceutical grade Sodium Hyaluronate was officially put into use.

2015

Topsience Biotech obtained the certificate of Suitability (CEP) for Sodium Hyaluronate. Topsience Biotech entered the supply chain of sodium hyaluronate APIs officially in EU.

2021

Obtained the "Certificate of DMF Registration (Korea)" and "Form 41 Registration Certificate (India)" respectively for Sodium Hyaluronate API, officially entering the Korean and Indian API markets.

2019

Topsience Biotech obtained the Certificate of Good Manufacturing Practice for Pharmaceutical Products, which lays a solid foundation for Sodium Hyaluronate to enter the domestic raw material drug supply market.

2023

The first production line of Sterile Sodium Hyaluronate was officially put into operation, and the Sterile Sodium Hyaluronate was officially launched in China.

Pioneer of Sterile Sodium Hyaluronate

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Technology



Professional R&D Team



Perfect Quality Management System



Advanced Inspection Equipment

Pioneer of Sterile Sodium Hyaluronate

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Production Workshops



Workshops Address:

- No. 98, Lanshan West Road, Lanshan District, Rizhao City, Shandong Province, China.
- No. 789, Yuquan 2nd Road, Rilan District, Rizhao, Shandong Province, China.

Workshops Area:

The total area of the production base is more than 100,000 m²

Employees:

220+

Workshops Categories:

Sterile sodium hyaluronate production workshops, pharmaceutical grade sodium hyaluronate production workshops, α -arbutin production workshops, etc.

Sales

Overseas regional division:

Asia Pacific: Asia (except domestic), Middle East, Central Africa,
South Africa

Europe and America: Europe, North Africa, North and South
America, Taiwan

Domestic regional division:

Department 1: Shandong, Henan, Shanxi and the north, Fujian,
Guangdong, Guangxi, Guizhou, Yunnan

Department 2: Jiangsu, Zhejiang, Anhui, Jiangxi, Hubei, Hunan,
Chongqing, Sichuan



Product Overview



03



PHARMAHYA Pharmaceutical Sodium Hyaluronate

- PHARMAHYA-OPH Sodium Hyaluronate Eye-drop Grade
- PHARMAHYA-INJ Sodium Hyaluronate Injection Grade
- PHARMAHYA-EXC Sodium Hyaluronate Excipient Grade

Pharmaceutical Sodium Hyaluronate

	Sodium Hyaluronate Injection Grade	Sodium Hyaluronate Eye-drop Grade	Sodium Hyaluronate Excipient Grade
Intrinsic Viscosity	1.2~4.0 m ³ /kg	1.2~4.0 m ³ /kg	1.2~4.0 m ³ /kg
Application	Can be used in Ophthalmologic operations, Intra-articular injection surgery, Intradermal injection, Cure for the sickness of cartilage(joint) and muscle tendon, etc.	Can be used in Cure of xeroma, Eye-drop, Eye ointment, Adjuvant medication for ophthalmic surgery, etc.	Can be used in Eye lotion, Adjunctive therapy for sprains and burns (small molecular weight), Adjuvant medication for ophthalmic surgery, Adjunctive therapy for sprains and burns (with cell factors, chemotactic factors and other relevant factors), etc.
Specification	ChP EP JP	ChP EP JP	ChP EP JP
Certification	CEP GMP KDMF Form 41 Y20210001081 Y20170000992	CEP GMP KDMF Form 41 Y20210001081 Y20170000992	CEP GMP F20210000256

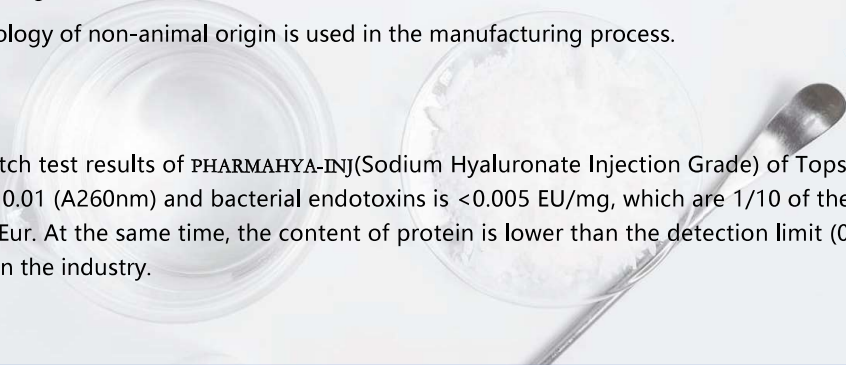
Key Advantages

- **SPECIALTY**

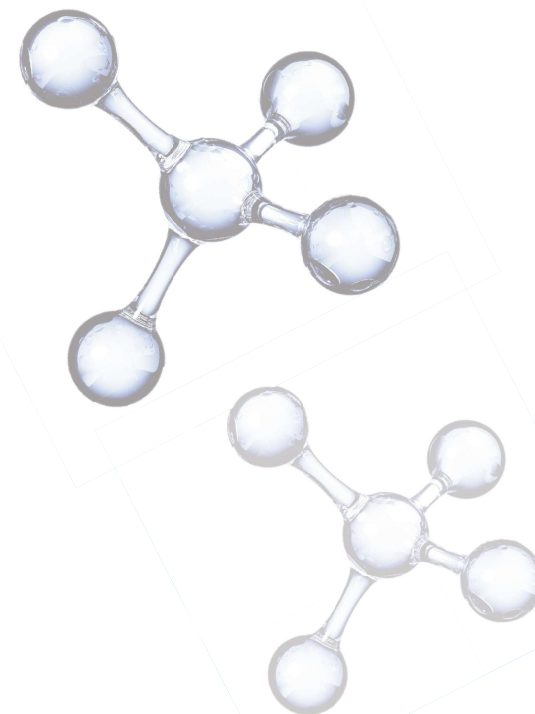
- Worldwide registrations including CEP, GMP, KDMF, Form 41, etc.
- Patented fermentation technology of non-animal origin is used in the manufacturing process.

- **QUALITY**

According to the continuous batch test results of PHARMAHYA-INJ(Sodium Hyaluronate Injection Grade) of Topscience Biotech, the nucleic acid level is 0.01 (A260nm) and bacterial endotoxins is <0.005 EU/mg, which are 1/10 of the value specified in the standard of Ph. Eur. At the same time, the content of protein is lower than the detection limit (0.03%), which is in the leading position in the industry.



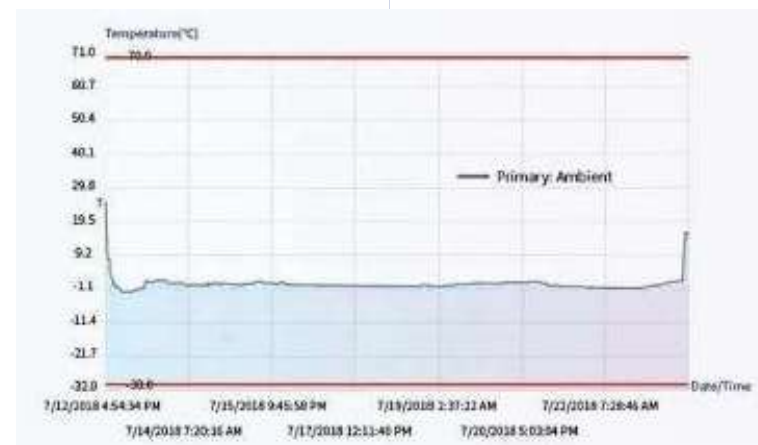
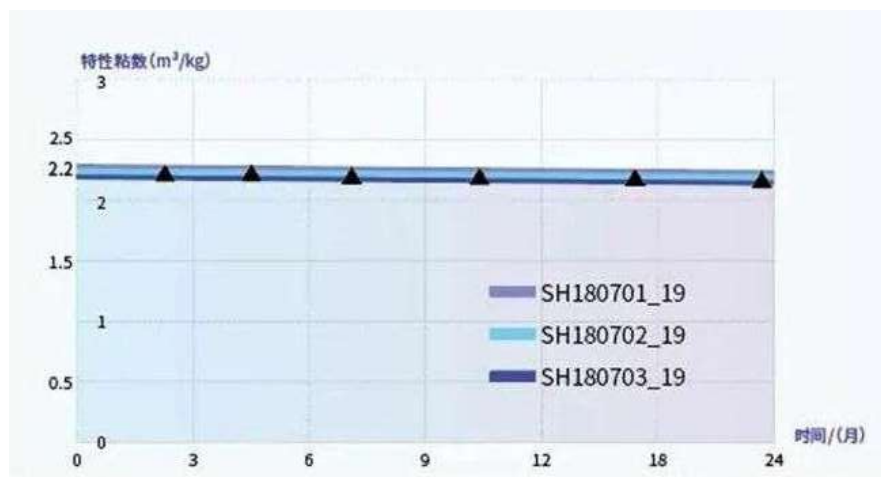
	EP 10.0	Other Product	PHARMAHYA-INJ
Bacterial Endotoxins	<0.05 EU/mg	<0.04 EU/mg	<0.005 EU/mg
Nucleic Acid	0.5	0.03	0.01
Protein	<0.1%	<LOD	<LOD



Key Advantages

High purity, excellent stability.

According to the stability test of Injection Grade of Sodium Hyaluronate, PHARMAHYA-INJ has the characteristics of "excellent stability".



Temperature-controlled transportation.

According to the temperature-controlled transportation records of PHARMAHYA-INJ Sodium Hyaluronate, the temperature-controlled transportation protocol of PHARMAHYA-INJ is safe and effective.

MEDIHYA Medical Device Sodium Hyaluronate

- MEDIHYA-I Sodium Hyaluronate Medical Device I Grade
- MEDIHYA-M Sodium Hyaluronate Medical Device M Grade
- MEDIHYA-S Sodium Hyaluronate Medical Device S Grade
- MEDIHYA-T Sodium Hyaluronate Topical Grade

Chondroitin Sulfate Sodium Medical Devices



Medical Device Sodium Hyaluronate

Product	Description	Intrinsic Viscosity	Appilcation	Specification	GMP
MEDIHYA-T	Sodium Hyaluronate Topical Grade	<ul style="list-style-type: none"> • 0.2 ~ 4.0 m³/kg • Tailor-made 	• Suitable for medical device of external application.	• Tested according to Ph. Eur. Last Edition	Written Confirmation
MEDIHYA-S	Sodium Hyaluronate Medical Device S Grade	<ul style="list-style-type: none"> • 0.2 ~ 4.0 m³/kg • Tailor-made 	• Suitable for medical device of class II.	<ul style="list-style-type: none"> • Tested according to Ph. Eur. Last Edition • Bacterial endotoxins <0.05 IU/mg 	Written Confirmation
MEDIHYA-M	Sodium Hyaluronate Medical Device M Grade	<ul style="list-style-type: none"> • 0.2 ~ 4.0 m³/kg • Tailor-made 	• Suitable for medical device of class II and Class III.	<ul style="list-style-type: none"> • Tested according to Ph. Eur. Last Edition • Bacterial endotoxins <0.015 IU/mg 	Written Confirmation
MEDIHYA-I	Sodium Hyaluronate Medical Device I Grade	<ul style="list-style-type: none"> • 0.2 ~ 4.0 m³/kg • Tailor-made 	• Suitable for medical device of class II and Class III.	<ul style="list-style-type: none"> • Tested according to Ph. Eur. Last Edition • Bacterial endotoxins <0.005 IU/mg • Pass sterility test 	Written Confirmation

Chondroitin Sulfate Medical Device Grade

Production technology features:

Fish source: Using Chondroitin Sulfate Sodium extracted from shark bone as raw material, fish source is more similar to human DNA and easily absorbed by the human body.

Enzymatic hydrolysis technology: Enzymolysis by special enzymes, harmless to the human body, and will enzymatic hydrolysis of excess proteins.

Ultrafiltration technology: Chondroitin Sulfate Sodium can be purified by removing protein, impurities, heavy metals, etc.

Precipitation technology: Using sophisticated precipitation technology to remove the remaining large amount of protein impurities.

Quality advantages:

Protein: far lower than industry standard, < 0.1%.

Endotoxin: Comply with Medical Devices standard, < 0.05U.

Molecular weight: we can customize the molecular weight from low to high.

Related substances: The residual content of ethanol is far lower than the industry standard.

- COSMEHYA Cosmetic Grade Sodium Hyaluronate
- HYDHYA-致修 Hydrolyzed Sodium Hyaluronate
- SMOHYA-致泽 Cationic Hyaluronate
- ACEHYA-致润 Sodium Acetylated Hyaluronate
- Full Spectrum Sodium Hyaluronate
- Zinc Hydrolyzed Hyaluronate
- L-Ascorbic Acid 2-Glucoside
- Alpha-Arbutin

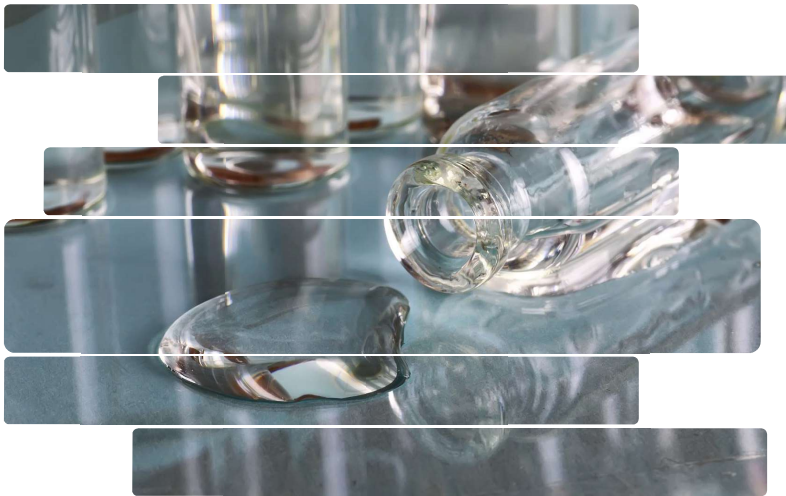


Cosmetic Grade Sodium Hyaluronate

- COSMEHYA has excellent moisturizing and lubricating properties, and is internationally recognized as a "natural moisturizing factor" .
- Sodium Hyaluronate is widely present in the interstitial cells of various tissues of the organism.

Type	Molecular weight
COSMEHYA H220	>1,800 kDa
COSMEHYA M180	1,000-1,800 kDa
COSMEHYA L100	400-1,000 kDa
COSMEHYA SL40	10-400 kDa
COSMEHYA VL01	<10 kDa

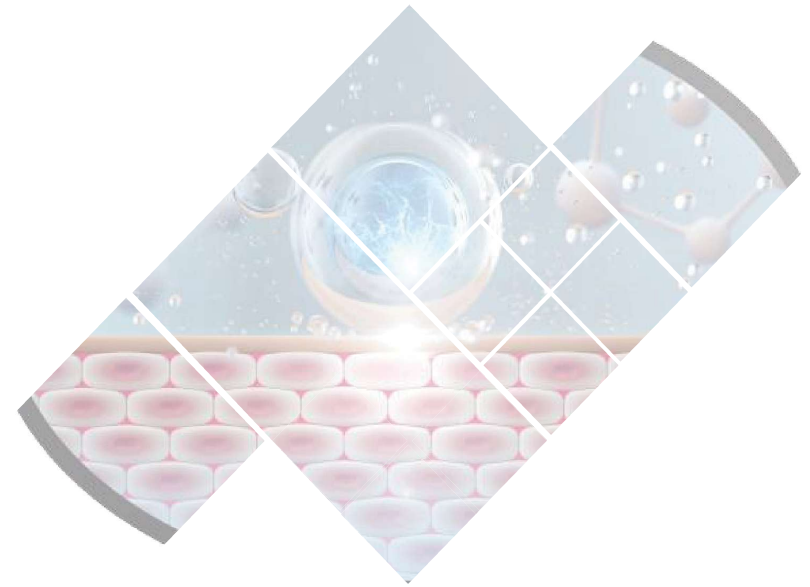
Hydrolyzed Sodium Hyaluronate



- HYDHYA 致修 has an ultra-low MW of less than 10 kDa, which makes it have high permeability. HYDHYA 致修 can penetrate the cuticle of skin, remove free radicals, nourish skin cuticle, and repair damaged cell barrier.
- HYDHYA 致修 has a good absorbing ability and can be absorbed easily by the skin to regulate cell metabolism, improve cell activity, retain skin elasticity, and resist skin aging.
- HYDHYA 致修 can promote blood circulation, effectively inhibit cell sensitivity, and form strong moisturizing support and protection functions for skin.
- HYDHYA 致修 also has high biological activity such as promoting the proliferation and differentiation of epidermal cells, which helps repair UVA injury, promoting wound healing, relieving skin sensitivity, anti-inflammation, and regulating immunity.

Sodium Acetylated Hyaluronate

- ACEHYA致润 has high safety, mild skin feeling and long-lasting moisture.
- ACEHYA致润 has a strong affinity to the skin. which can effectively reduce the evaporation of moisture from the bottom of the skin.
- ACEHYA致润 plays double hydrating and moisturizing properties functions due to its amphiphilic properties which enable the water binding ability of the Sodium Acetylated Hyaluronate in the stratum corneum than natural Sodium Hyaluronate.
- ACEHYA致润 can promote the proliferation of epidermal cells, enhance the function of the epidermal cuticle-barrier, and improve the natural resistance of skin.



Cationic Hyaluronate



- SMOHYA致泽 can be used as an exclusive moisturizing agent for personal care products. It is natural and mild, suitable for hair and scalp care.
- SMOHYA致泽 has kinds of abilities: adsorbability and high affinity.
- SMOHYA致泽 can protect the skin against the irritation of surfactant and make the skin more smooth and soft.
- SMOHYA致泽 has permeability, absorbability, and film-forming properties, to eliminate free radicals, and regulate metabolism.

Zinc Hydrolyzed Hyaluronate

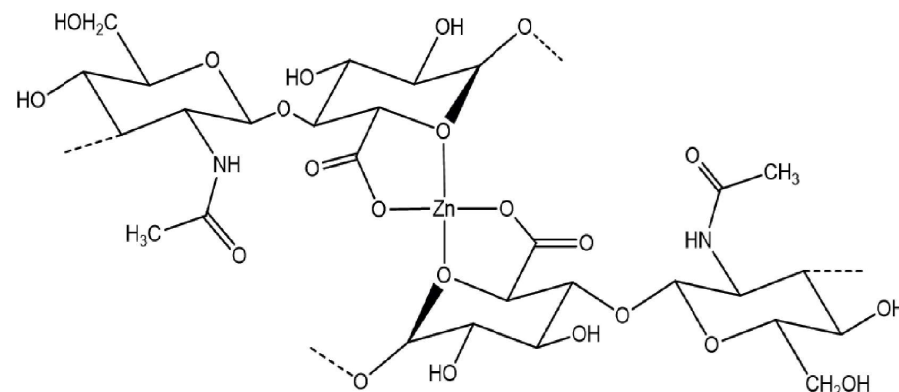
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Zinc Hydrolyzed Hyaluronate is the perfect combination of HA and Zinc with both efficacies which is developed by patented technology. It not only has the characteristics of moisturizing, repairing, and nourishing HA but also has the functions of anti-oxidation and soothing of Zinc.

2

Advantages:

- Strengthen the skin barrier.
- Decrease the expression of inflammatory factors.
- Up-regulate the ratio of collagen III/I to reduce scar formation.
- Enhance Hydration capacity.

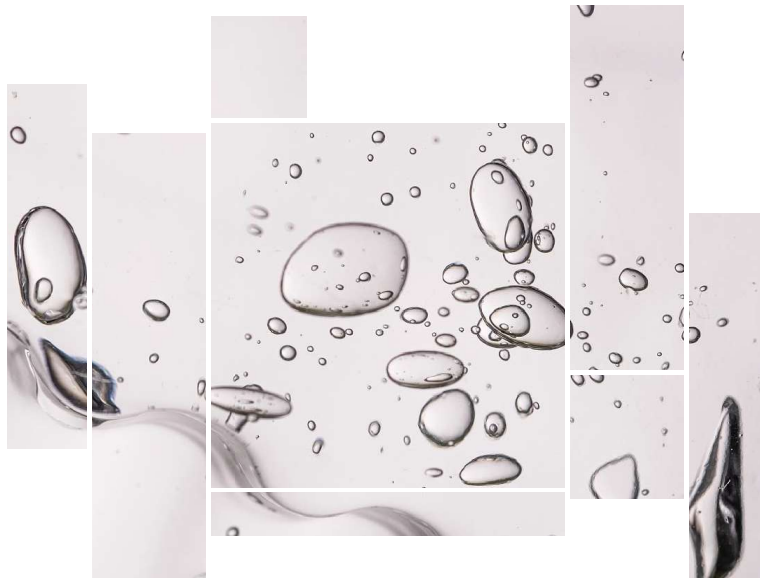


L-Ascorbic Acid 2-Glucoside

- L-Ascorbic Acid 2-Glucoside is a kind of natural vitamin C containing stable glucose stabilizers.
- Compared with other vitamin C derivatives, L-Ascorbic Acid 2-Glucoside has good stability and solubility in solution even at high temperatures, low pH and in the presence of metal ions. It can essentially inhibit discoloration and degradation of vitamin C in cosmetics while retaining all the biological activity of vitamin C.
- L-Ascorbic Acid 2-Glucoside can desalinate pigment and reduce the pigmentation of senile spots and freckles, brighten skin tone, delay aging, and protect the skin with sunscreen products.



Alpha-Arbutin



- Alpha-Arbutin is considered to be one of the most effective and safe lightening ingredients in foreign countries and the most competitive lightening spot removal active substance in the 21st century.
- The stability and durability of alpha-Arbutin is 15 times more than beta-Arbutin.
- In the whole process of reaction, hydroquinone is never generated. It has no side effects of cytotoxicity, irritation, and anaphylaxis, but the effects of moisture, healing wounds, sterilization, and anti-inflammation.

EAT

NUTRIHYA Sodium Hyaluronate Food Grade

Pioneer of Sterile Sodium Hyaluronate

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Food Grade Sodium Hyaluronate



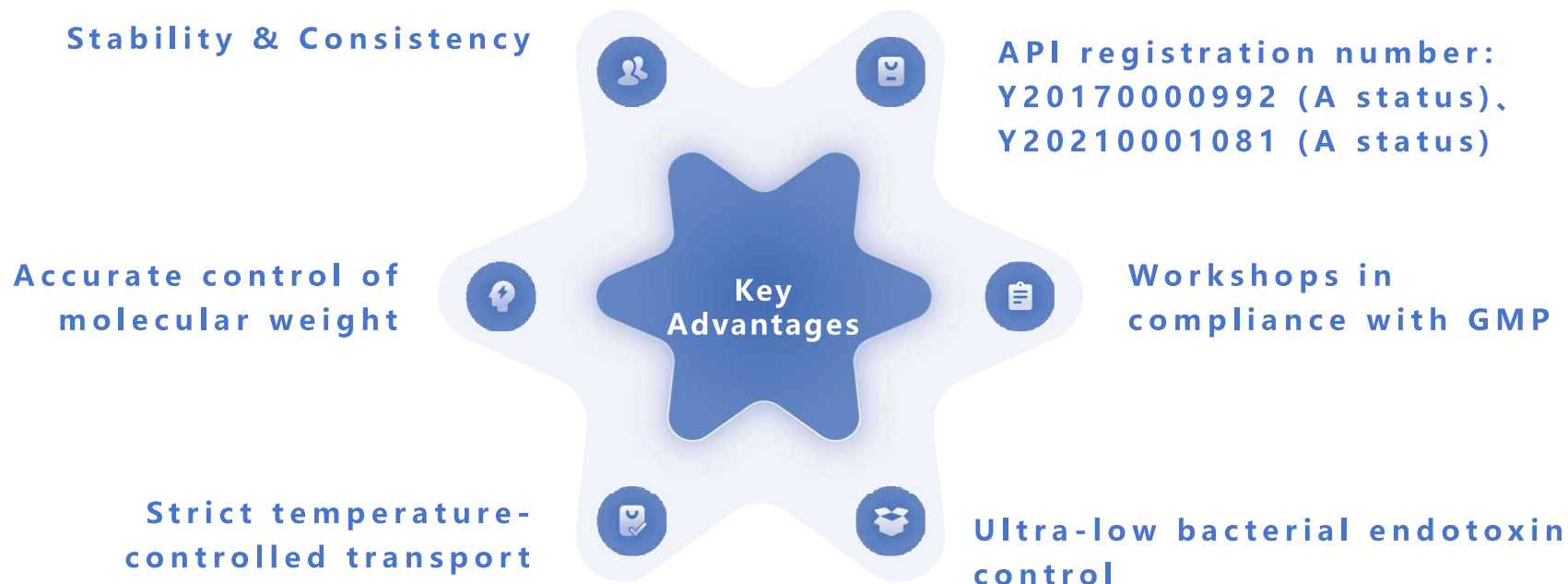
Oral intake could replenish the inadequate status in the human body. By digestion and absorption, sodium hyaluronate could make your skin moisturizing, soft, and elastic, delay aging, and prevent arthritis, arteriosclerosis, pulse disorder, encephalomalacia, and so on.

In many developed countries such as the USA, EU, and Japan, it's widely applied in functional food.

Advantage:

- Can increase skin moisture and improve dry skin.
- Can modulate inflammation
- Can make people energetic and youthful.

Key Advantages



Company Advantages 04

Certificates



Pharma MFG License



GMP



CEP(CoS)



FDA Form 41



KDMF



Halal



EU Written Confirmation



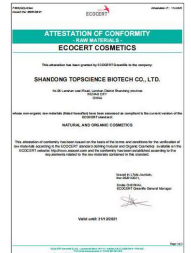
Kosher



ISO 9001, ISO 14001, ISO 45001



Vegan



ECOCERT & COSMOS

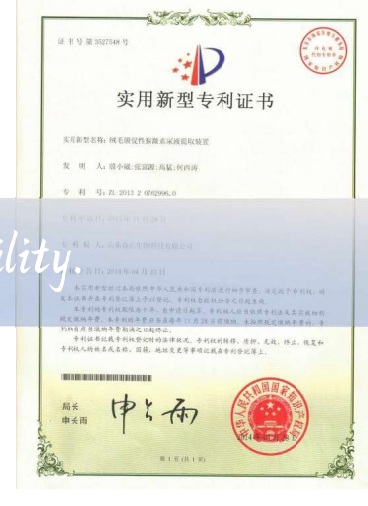
Pioneer of Sterile Sodium Hyaluronate

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- Specialized and New Enterprise
- National Small Giant Enterprise
- National High-tech Enterprise
- Innovative Enterprise in Shandong Province
- Confirmation certificate of the pioneer status of sterile sodium hyaluronate



Invention Patent



Topscience Biotech has 30+ patents, including invention and utility.

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Pioneer of Sterile Sodium Hyaluronate

E

Environment

Biological treatment: in line with national environmental protection policy requirements.

Implement standards such as sewage treatment standard GB/T31962-2015 and pharmaceutical industry atmospheric pollutant emission GB37823-2019.

ISO14001 Environmental Management System

S

Social

The company strictly abides by various laws, regulations, and employment policies. It formulates human resources policies and procedures such as the "Staff Code of Conduct" and "Shandong Topscience Biotech Co., Ltd. Employee Handbook" to ensure that the company adopts fair, just, and open employment principles. , fully protecting the legitimate rights and interests of employees.

ISO45001 Occupational Health and Safety Management System Certification.

G

Government

The shareholders' meeting is the highest authority. The shareholders' meeting exercises the decisive power to decide the company's business policies and investment plans, review and approve the company's annual financial budget plan, final accounts plan, and other decisive powers. By the requirements of the Company Law, Articles of Association, and Rules of Procedure for the General Meeting of Shareholders, the Company ensures the compliant operation of the General Meeting of Shareholders, actively provides convenience for shareholders to exercise their rights, and effectively protects the legitimate rights and interests of shareholders.

THANK YOU

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