



TOPSCIENCE 众山

SODIUM

HYALURONATE

EXPERT

Company Profile

Topscience Biotech was established in 2005 and is a biotechnological innovative enterprise focusing on the R&D, production, sales, and service of bioactive with microbial fermentation technology and aseptic API production technology as the core. Topscience Biotech's main products include biochemical APIs, tissue engineering raw materials, functional skincare ingredients, new dietary raw materials, etc. The main product sodium hyaluronate can be applied to medicine areas (such as orthopedics, ophthalmology), medical beauty (dermal fillers), cosmetics, health food, etc., to provide excellent quality and safety compliance raw material support for global partners to carry out differentiated competition.

The manufacturing site covering an area of more than 100,000 m² is located in Lanshan District, Rizhao City, Shandong Province. There are more than 30 personnel with intermediate professional titles or above, and more than 30 Licensed Pharmacist. It has 8 GMP-compliant production workshops, and also, Topscience Biotech has established a sound quality control system in accordance with international standards such as ICH and GMP. Strict and efficient control throughout the entire process from purchase of raw materials to final product release is implemented. We have passed multiple on-site inspections by domestic and foreign drug regulatory authorities and well-known pharmaceutical companies.

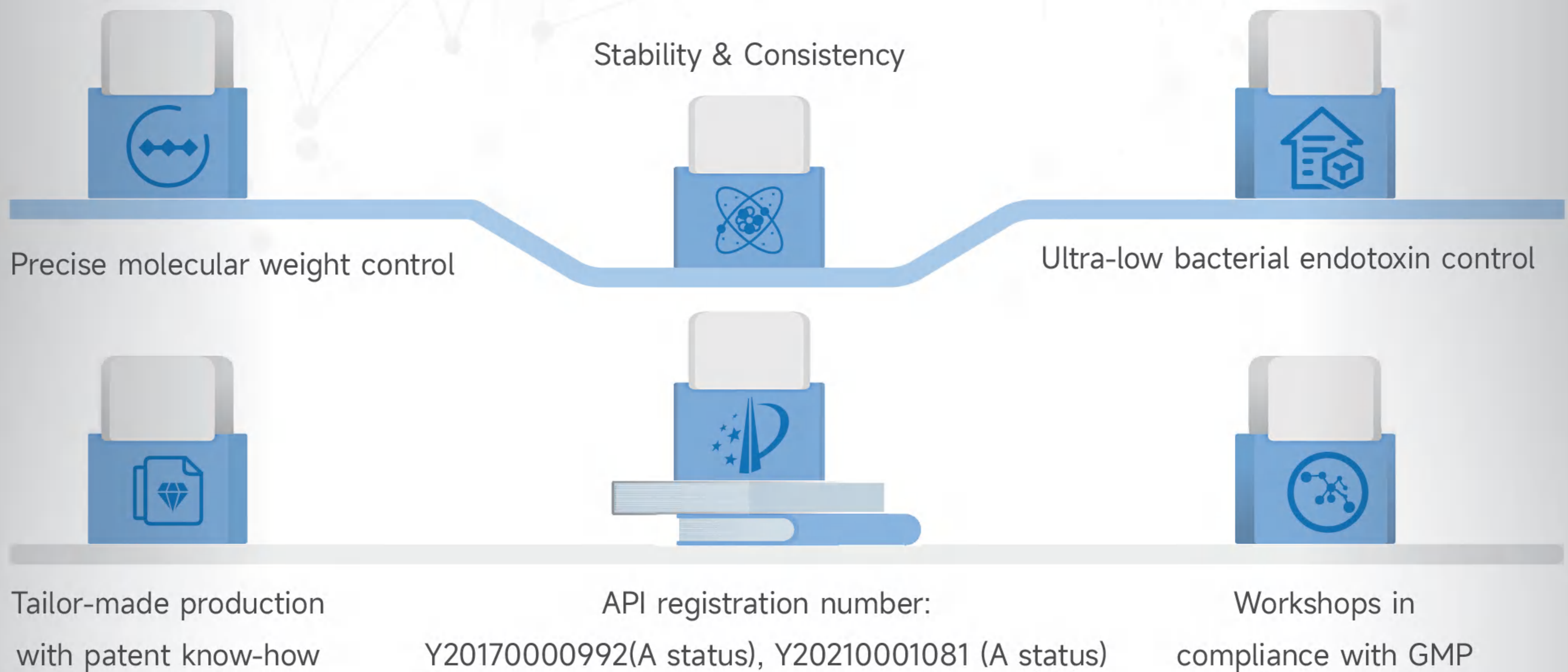


The company was founded in

2005



Product Advantages



Product List

STERILEHYA Sterile Sodium Hyaluronate

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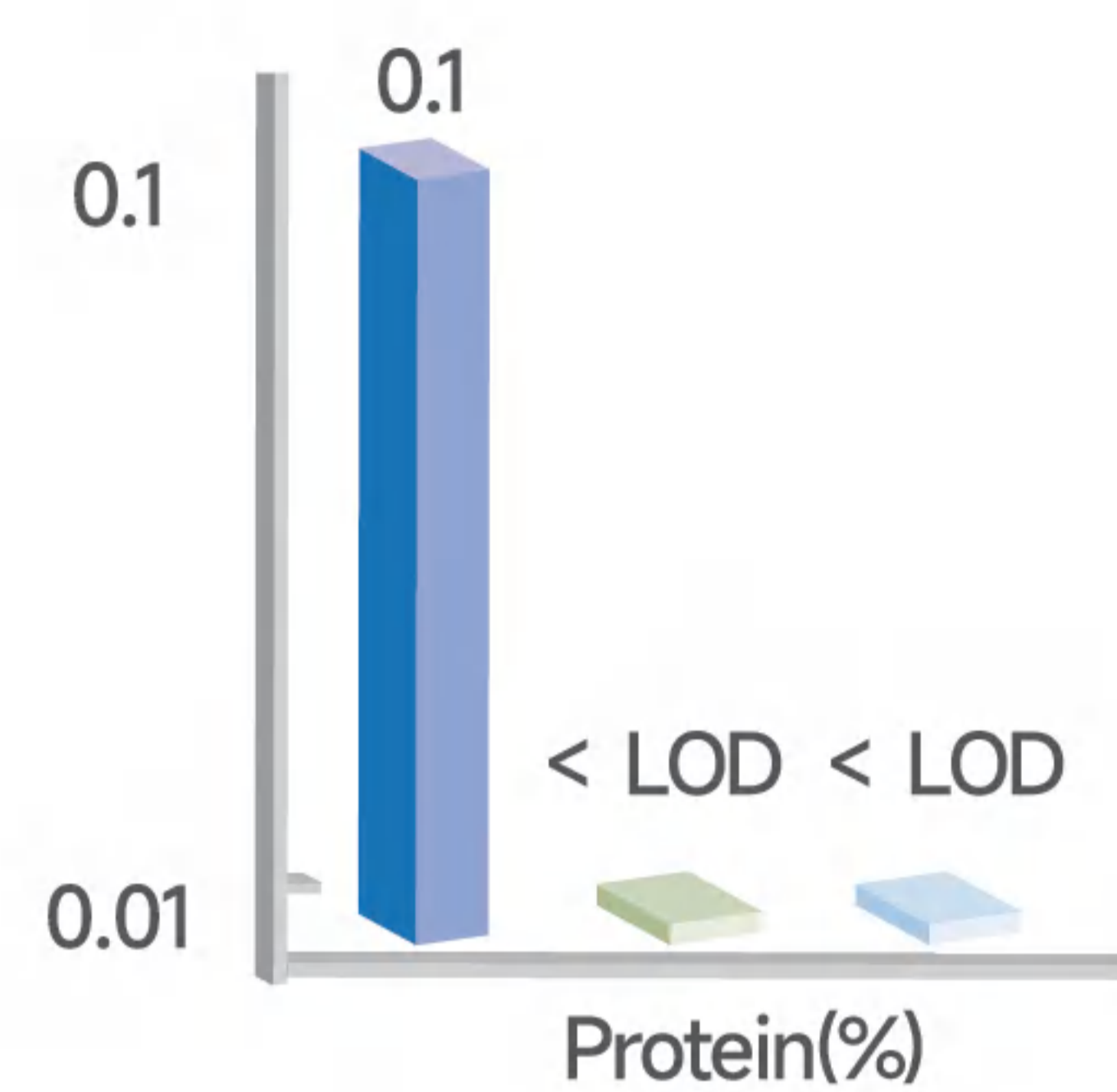
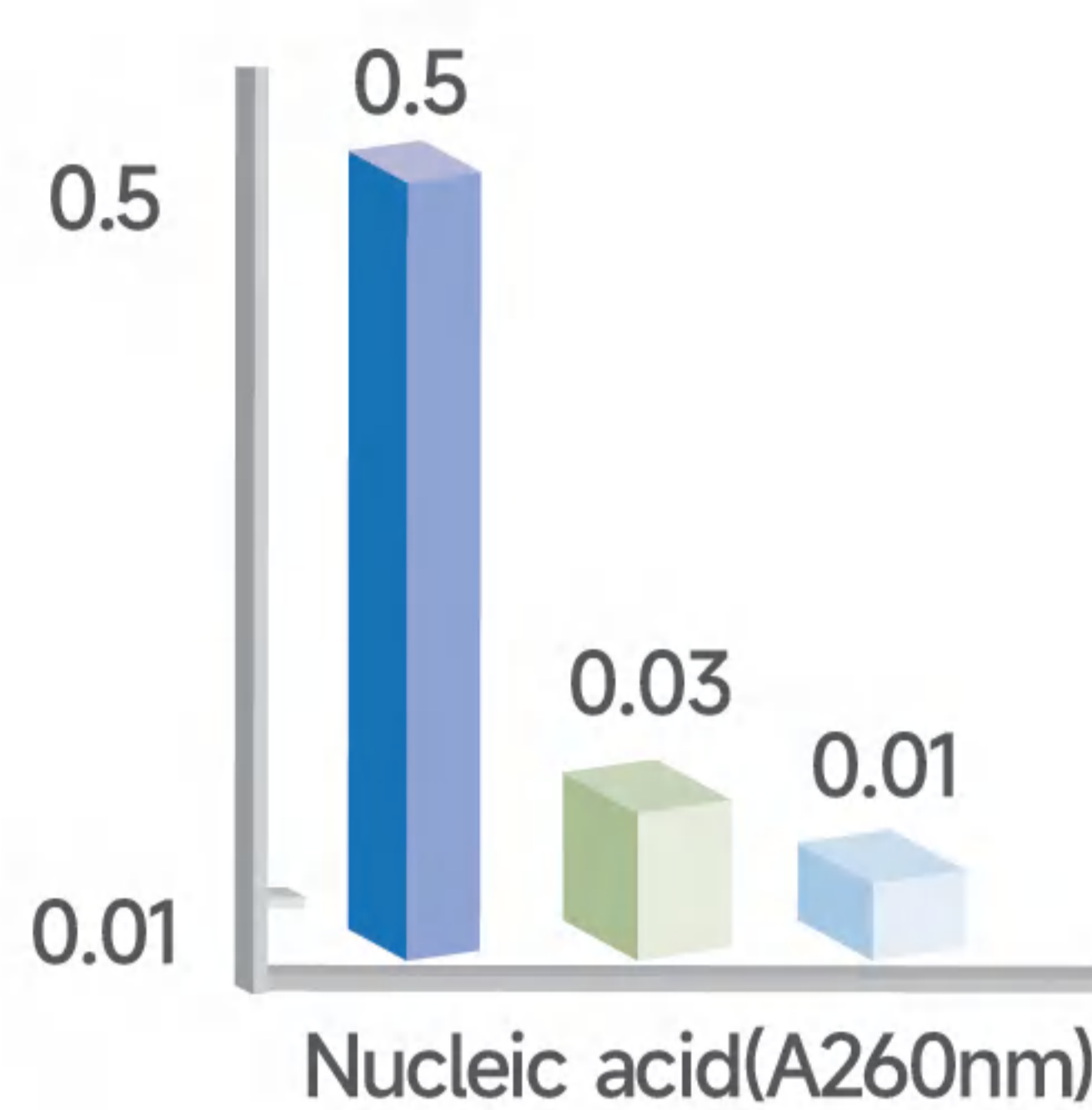
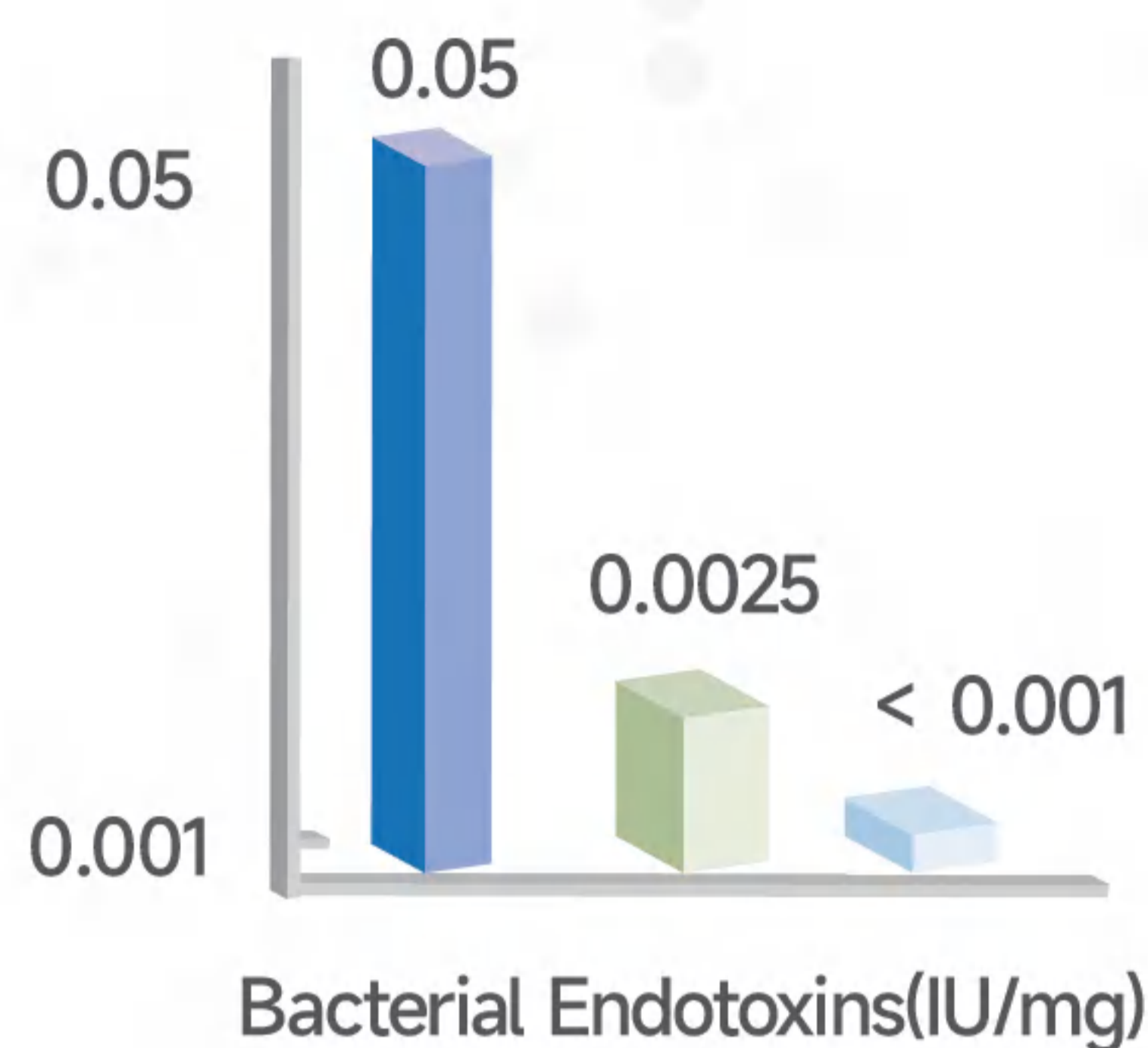
MEDIHYA Medical Grade Sodium Hyaluronate

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

PHARMAHYA Pharmaceutical Sodium Hyaluronate

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

Quality & Speciality

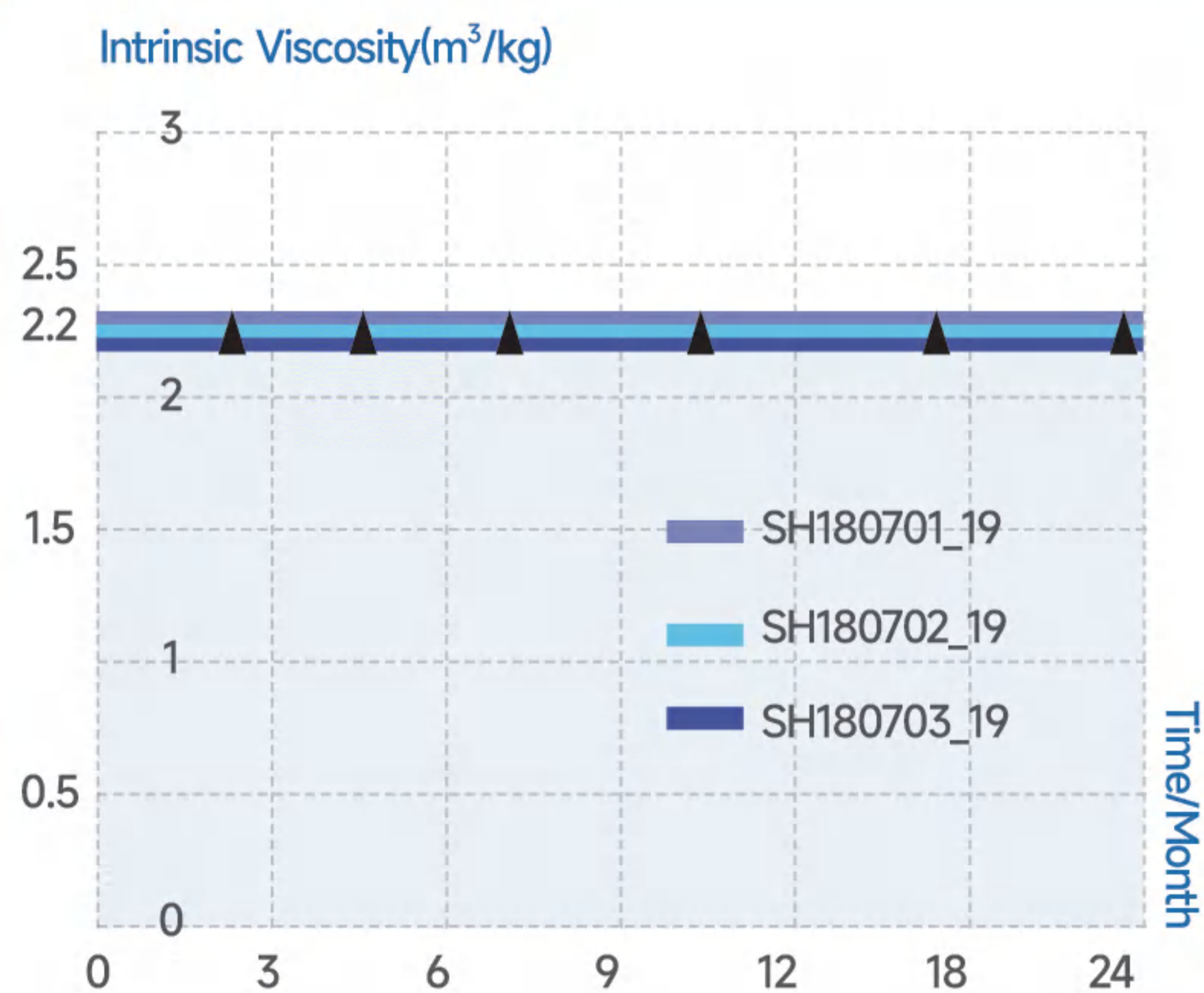


■ Ph.Eur.10.0

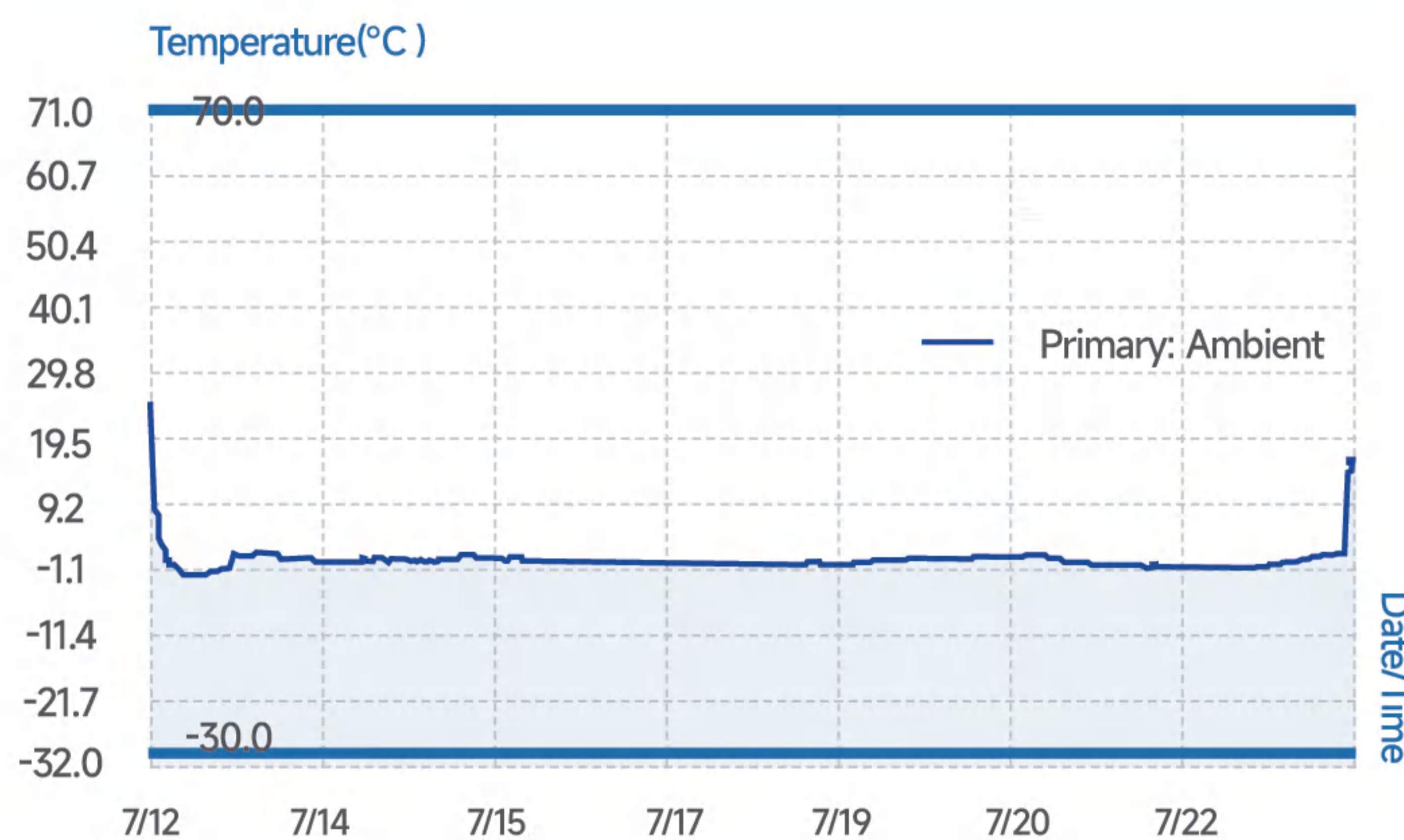
■ Other Producers

■ PHARMAHYA-INJ

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 < 0.001IU/mg, which are 1/50 of the value specified in the standard of Ph.Eur. At the same time, the content of protein is lower than detection limit(0.03%), which is in the leading position in the industry.



According to the stability test of PHARMAHYA-INJ Sodium Hyaluronate (Injection Grade), Topscience Biotech's products have the characteristics of "excellent stability".



According to the temperature-controlled transportation records of PHARMAHYA-INJ Sodium Hyaluronate (Injection Grade), the temperature-controlled transportation protocol of Topscience Biotech is safe and effective.

Safety Test

Test project	Pyrogen test	Cytotoxicity test
Conclusion	No pyrogenicity	No potential cytotoxicity
Test project	Skin sensitization test	Acute systemic toxicity test
Conclusion	No obvious sensitization reaction observed	No obvious acute systemic toxicity observed

Efficacy Test

Topscience Biotech has also completed efficacy experiments on "Product Impermeability Absorption Effect Experiment" and "Wound Impermeability Effect Experiment", which fully comply with the requirements of the "Announcement on the Categories Management of Medical Sodium Hyaluronate Products(No. 103 of 2022)" that when Sodium Hyaluronate is applied as medical dressings, it cannot be absorbed by the human body and used for non-chronic wounds. Medical dressings are managed according to Medical Device Class II.

Application



Suitable for aquatic product, dermal filler, viscoelastic agent, etc.



Suitable for wound dressing, eyewash, contact lens care solution, cold compress, liquid dressing, gynecologic gel and other fields.



Suitable for joint surgical filling, reproductive medicine, tissue culture, etc.



Suitable for eye drops and artificial tears, etc.



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