TOPSCIENCE众山

Topscience Biotech

Sodium Hyaluronate Expert

Shandong Topscience Biotech Co., Ltd.

http://www.topscience.cn/

COMPANY PROFILE

Shandong Topscience Biotech Co., Ltd., manufacturing site covering an area of 100,000m^2, is located in Rizhao of Shandong. Topscience has established 10 APl and preparation workshops in compliance with GMP, 3 standard laboratories in compliance with GLP and 1 SPF animal laboratory. Topscience has set up the complete quality system in compliance with ICH and GMP, equipped with advanced analytical instruments and professional technicians, product quality can be guaranteed by the strict and effective management from starting materials to product release.

Topscience has successfully passed the on-site inspections by drug regulatory administrations for many times, as well as the on-site audits by many well known enterprises worldwide.

Sodium Hyaluronate API in Topscience includes Injection grade, Eye-Drop grade, Pharmaceutical Excipients grade and many other specifications, with a wide range of intrinsic viscosity, which can meet various medical uses. Sodium Hyaluronate is produced by microbial fermentation with non-animal origin, and has the advantages of ultra-low impurity level, ultra-low bacterial endotoxins level, ultra-low heavy metal impurity residue and ultra-low microbial pollution.

TOPSCIENCE 众山
山东众山生物科技
SHANDONG TOPSCIENCE BIOTECH CO LTD.

QUALITY & SPECIALITY

① **GMP** Certificate issued by National Medical Products Administration of China.

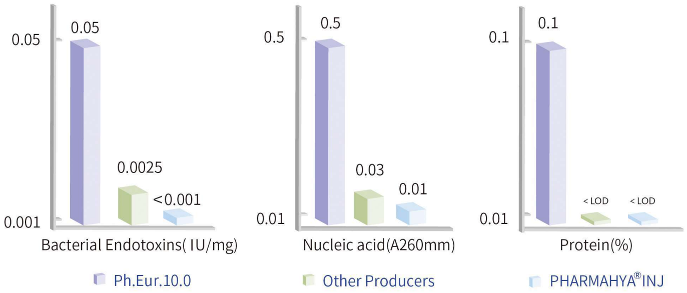
② Patented **Fermentation Technology**, non-animal origin used in the manufacturing process.

③ **Worldwide registrations** including COS, KDMF, Form 41, etc.

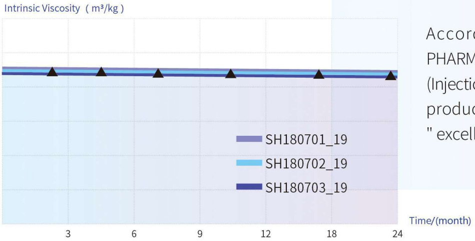
④ High **purity**, excellent **stability**.

⑤ The bacterial endotoxins level is only **1/50** of the value specified in the Ph. Eur.

⑥ **Tailor-made** service, **temperature-controlled** transportation.

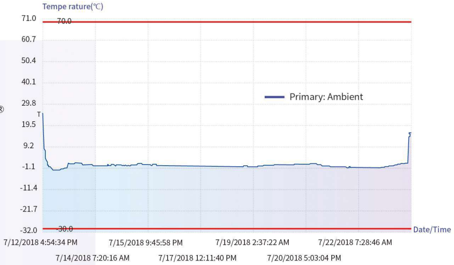


According to the continuous batch test results of PHARMAHYA®INJ Sodium Hyaluronate (Injection Grade) of Topscience Biotech, the nucleic acid level is 0.01 (A260nm) and bacterial endotoxins is <0.001 IU/mg, which are **1/50** of the value specified in the standard of Ph. Eur. At the same time, the content of protein is lower than the 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.



CERTIFICATION

Drug-Manufacturing-License

CEP Certificates

Written confirmation for active substances exported to EU

KDMF Registration

Japan GMP

India Form 41 Registration

China GMP

Accreditation certificate of foreign drug manufacturer

PRODUCT LIST

- **PHARMAHYA® INJ** Sodium Hyaluronate(Injection Grade)
- **PHARMAHYA® OPH** Sodium Hyaluronate(Eye-drop Grade)
- **PHARMAHYA® PHA** Sodium Hyaluronate(Pharmaceutical Grade)
- **PHARMAHYA® EXC** Sodium Hyaluronate(Pharma Excipient Grade)
- **MEDIHYA® I** Sodium Hyaluronate(Medical Injection Grade)
- **MEDIHYA® S** Sodium Hyaluronate(Medical Device Grade)
- **MEDIHYA® T** Sodium Hyaluronate(Topical Grade)

APPLICATIONS

Sodium Hyaluronate is the main component of connective tissue such as human intercellular substance, eye vitreous body and synovial fluid. It plays an important physiological role in water retention, maintaining the extracellular space, osmotic pressure regulation, lubrication and promotion of cell repair.

Sodium Hyaluronate can be used as a viscoelastic substance in ophthalmic intraocular lens implantation, dermal filler in medical cosmetology, filling agent in osteoarthritis and rheumatoid arthritis and other joint operations, a medium in moisturizing eye drops, prevention postoperative adhesion and promotion of skin wound healing.

The compound formed by the reaction of Sodium Hyaluronate with other drugs exerts a sustained release effect on the drug, which can achieve the purpose of targeted and timed release.

Sodium Hyaluronate has unique physical& chemical properties and physiological functions, with the development of medical science and technology, the medical applications of Sodium Hyaluronate will become more and more extensive.

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