

Introduction

Sodium hyaluronate, also known as hyaluronan, or HA, is a natural polysaccharide existing in human and animal bodies, mainly in the soft connective tissues such as the skin, vitreous humor of eyes and synovial fluid of joints. HA is a high molecular weight mucopolysaccharide composed of repeating disaccharide units of *D*-glucuronic acid and *N*-acetyl-*D*-glucosamine. Its random coiled configuration and fluid kinetics characteristic in solutions gives it some important physical characters like moisturizing and lubricating properties, viscoelasticity and pseudo-plasticity and also because of its good biocompatibility, it is widely used in pharmaceuticals and medical devices.





Pharmaceutical Grade Sodium Hyaluronate

Hyatru® – Pharmaceutical Grade Sodium Hyaluronate

Hyatru® is a pharmaceutical grade sodium hyaluronate which can be used as an API or excipient for drugs and medical devices in ophthalmic preparations, intra-articular injections, anti-adhesive preparations, topical preparations for wound healing and soft tissue filler, etc. Hyatru® sodium hyaluronate is divided into two categories based on the applications, medical grade and injection grade.

Hyatru® – Functions And Its Applications

Product Category	Functions	Applications
 Medical Grade Sodium Hyaluronate	Lubricating, moisturizing, improving efficacy of drugs, relieving dry eye syndrome, and promote healing of corneal and conjunctival injury	Eye drops, eye lotions, contact lens solutions, medical lubricants, etc.
	Wound healing	Topical preparations (formulations of gel, film, etc.)
	Drug or cell carrier/matrix	Eye drops, cell culture, etc.
	Repairing damaged mucous membrane or cartilage, etc.	Oral pharmaceutical preparations
 Injection Grade Sodium Hyaluronate	Viscoelasticity, protecting corneal endothelium	Ophthalmic viscosurgical devices (OVD)
	Lubricating, viscoelasticity, repairing damage cartilage, inhibition of inflammation, pain relief, etc.	Intra-articular injections
	Good biocompatibility and bio-degradability of HA and its derivatives	Anti-adhesive products, dermal filler, scaffold materials in tissue engineering, etc.

We could provide research grade sodium hyaluronate oligosaccharides, including tetrasaccharide(HA4), hexasaccharide (HA6), octasaccharide (HA8) and decasacchride (HA10).

1 Natural and Safe

Bacteria and raw materials for fermentation are safe.

- It is produced by bacterial fermentation.
- Non GMO: The strain is widely accepted as safe and is included in EP, JP, and China National Standard.

Products are safe

- Hyatrue® has been tested and proven safe and non-toxic.
- Regulatory Compliance:
GMP Certificate, ICH Q7, ISO 9001, ISO 14001, and pass on-site audit by US FDA and Korea MFDS.
- Registration

DMFs filed in the main countries & areas, including US DMF, CEP, Japan MF, etc..

Approved by the SFDA for sodium hyaluronate pharmaceutical excipient (Registration No.: F20040001, CDE Procedure Documents: F20180001497), sodium hyaluronate API (Registration No.: H20113379, CDE Procedure Documents: Y20180001650; Registration No.: H20133147, CDE Procedure Documents: Y20180001413).

2 High Purity

Quality of Hyatrue® is much higher than European Pharmacopoeia standard. Impurity control is much more strict compared to EP 9.0 as shown in chart1&2.

The endotoxin of Hyatrue® tested is less than 0.0025IU/mg (by Charles River).

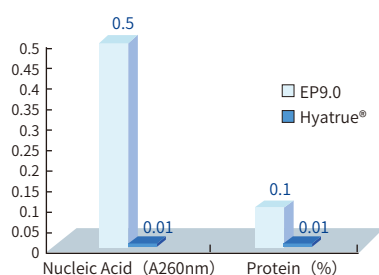


Chart 1. Impurity level of Hyatrue® (Medical Grade)

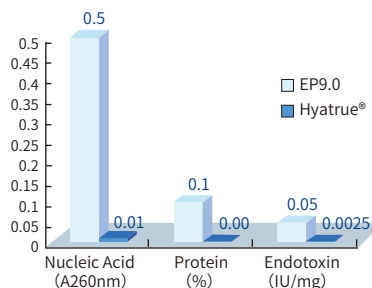


Chart 2. Impurity level of Hyatrue® (Injection Grade)

3 High Stability

Hyatrue® is stable under its recommended storage and transportation conditions.

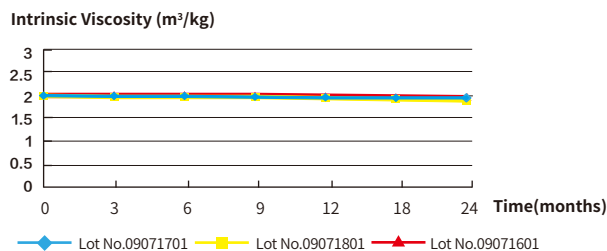


Chart 3. Long-term stability test for Hyatrue® (2~8°C)

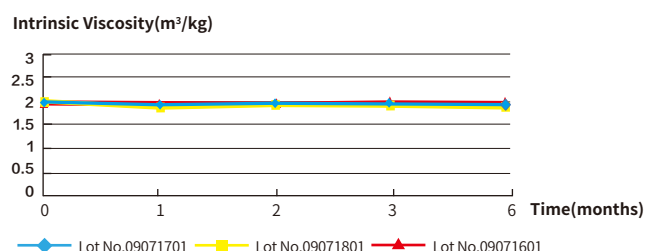


Chart 4. Accelerated stability test for Hyatrue® (25°C)

