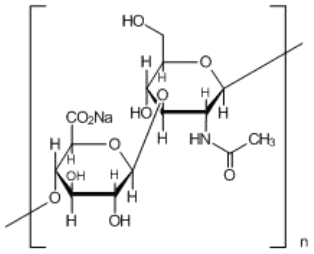
TECHNICAL DATA SHEET

HyaPoly™ Sodium Hyaluronate

Injection Grade

Chemical Properties

CAS No: 9067-32-7;
EINECS No.: 232-678-0
INCI name: Sodium Hyaluronate
Chemical Formula: $(C_{14}H_{20}NO_{11}Na)n$
Molecular Weight: (403.31)n



Description

Sodium hyaluronate is used to be called as hyaluronic acid.It is a water-soluble salt form of hyaluronic acid to increase stability and lessen the likelihood of oxidization. It is a glycosaminoglycan and long-chain polymer of disaccharide units of Na-glucuronate-N-acetylglucosamine.

Solubility

It is soluble in water, diluted acids, but insoluble in ethanol, chloroform and ether.

Specification

Item	Specification	Test Method
Appearance	White or almost white powder	Visual
Odor	Odorless	Organoleptic
Identification	Complies with the Ph. Eur. Reference	
A: Infrared absorption	spectrum of sodium hyaluronate	EP
B: Reaction of sodium	Positive	
Glucuronic Acid	Min 46.0%	In-house
Sodium hyaluronate	Min 95.0%	In-house
Molecular Weight	1.3~2.4 MDa	EP
pH	5.0 ~ 8.5	EP
Nucleic acids	$A_{260nm} \leqslant 0.5$	EP
Appearance of solution (0.1% water solution)	$A_{600nm} \leqslant 0.01$	EP
Protein	Max 0.05%	EP
Residue on ignition	Max 20.0%	In-house
Loss on drying	Max 10.0%	EP
Chlorides	Max 0.5%	EP
Iron	Max 80ppm	EP
Heavy Metals	Max 10ppm	EP

Arsenic	Max 2ppm	In-house
Hemolysis	Negative	In-house
Bacterial endotoxins	Max 0.05 IU/mg	EP
Total plate count	Max 100 CFU/g	EP
Total yeast &mold	Max 50 CFU/g	In-house
Pseudomonas aeruginosa	Negative	In-house
Staphylococcus aureus	Negative	In-house
Viable hemolytic streptococcus	Negative	In-house

Ingredients

Sodium Hyaluronate 95.0%~105.0%

Labeling

In the United States and the European Union: HyaPoly^{TM} Sodium Hyaluronate
Injection Grade

Applications

Sodium hyaluronate is used as a viscosupplement, administered through a series of injections into the knee, increasing the viscosity of the synovial fluid, which helps lubricate, cushion and reduce pain in the joint. It is generally used as a last resort before surgery and provides symptomatic relief, by recovering the viscoelasticity of the articular fluid, and by stimulating new production from synovial fluid. Use of sodium hyaluronate may reduce the need for joint replacement. Injections appear to increase in effectiveness over the course of four weeks, reaching a peak at eight weeks and retaining some effectiveness at six months, with greater benefit for osteoarthritis than oral analgesics. It may also be effective when used with other joints.

Safety

This product is safe for the intended use. Avoid ingestion, inhalation of dust or direct contact by applying suitable protective measures and personal hygiene. See Material Safety Data Sheet for full safety information.

Handling recommendations

Wash thoroughly after handling. Use only in a well-ventilated area.Avoid contact with skin and eyes. Avoid ingestion and inhalation.

Packaging, Storage &Shelf Life

Package	1kg/Aluminum foil bag;or according to customers' requirements.
Storage	Store in cool temperature (2°C~10°C) away from moisture and direct sunlight.
Shelf Life	2 years if sealed and stored properly.