

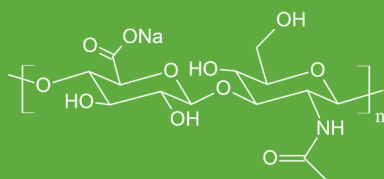
# SODIUM ULTRA PURE NATRII HYALURONAS

# HYALURONATE

## MOLECULAR WEIGHT 250–2300 kDa

### GENERAL INFORMATION

Sodium hyaluronate (hyaluronan, sodium salt of hyaluronic acid) is a non-sulfated glycosaminoglycan, a naturally occurring polysaccharide.



Structural formula

Molecular mass of disaccharide unit is 401,3 Da  
CAS number 9067–32–7

### MEDICAL APPLICATIONS

#### MEDICAL DEVICES

- ophthalmic surgery (viscosupplementation)
- eye drops for dry eye (eg. artificial tears)
- intra-articular injections
- topical preparations for wound and burns healing
- intradermal injections for aesthetic correction
- anti-adhesive and shape keeping products for thoracic and abdominal surgery
- anti-adhesive wound healing products
- bandages with exudates absorbing capacity

#### REMEDIES/DRUGS

Sodium hyaluronate on its own as active substance

- cartilage (joint) and tendon disorders (i.a., i.v. and local application)
- wound and burns healing preparations

#### REMEDIES/DRUGS

Sodium hyaluronate (in combination with other active substances)

- anti-cancer preparations (together with anti-neoplastic drugs)
- wound and burns healing preparations (cytokines, chemokins, factors)
- preparations for reduction of scar formation (cytokines, chemokins, factors)
- eye drops (antibiotics, anti-inflammatory substances)

- topical anti-inflammatory and analgesics preparations
- cartilage (joint) and tendon disorders (injection or topical application)
- nutraceuticals supporting the treatment of skeleton or prevention of skeleton disorders
- preparations for liver regeneration

#### TISSUE ENGINEERING

- artificial skin grafts for plastic and reconstruction surgery
- artificial skin for test of cosmetic raw material
- replacement of injured cartilage, artificial cartilage grafts
- artificial bone grafts
- adipose tissue replacement (mammary replacement)
- support for growing of soft tissue grafts
- aorta and large venous grafts industry

#### APPLICATION IN BIOTECHNOLOGY AND MOLECULAR BIOLOGY

- component of special cell culture medium
- supporting material for gene transfer

#### OTHER BIOLOGICAL APPLICATION

- sperm separation according to their mobility
- medium for in vitro ovum fertilization

# PRODUCT SPECIFICATION

Appearance	white or almost white powder, granules or fibrous aggregate
Identification - test A (Infrared spectrum)	complies with the Ph. Eur. reference spectrum
Identification - test B (Sodium)	pass
Appearance of solution - Appearance	clear
Appearance of solution - Absorbance	≤ 0.010
pH	5.0–8.5
Intrinsic viscosity	≥ 0.65 m <sup>3</sup> /kg
Nucleic acids	≤ 0.03
Protein	≤ 0.035
Chlorides	< 0.3 %
Iron	< 4.0 ppm
Loss on drying	< 10.0 %
Microbial contamination	< 5 CFU/g
Bacterial endotoxins	< 0.005 IU/mg
Sodium hyaluronate	95.0–105.0 %
Residual isopropanol	≤ 0.50 %
Ca <sup>2+</sup> , Mg <sup>2+</sup>	≤ 80.0 ppm

THIS GRADE OF SODIUM HYALURONATE CAN BE SUPPLIED WITH ANY MOLECULAR WEIGHT WITHIN THE RANGE 250–2300 kDa.

## SOURCE

- Fermentation, *Streptococcus equi*, subsp. *zooepidemicus* bacterial strain, non-haemolytic
- Non-GMO
- Non-animal materials used during the manufacturing process

## TOXICOLOGY

Sodium hyaluronate has been proven to be a non-toxic substance. Toxicological data available upon request.

## QUALITY

- Within the limits of Ph. Eur. latest edition
- ISO EN 9001 : 2008
- GMP facility according to ICH Q7
- In-house quality management measures
- FDA-audited facility

## CERTIFICATES AND REGISTRATIONS

- GMP certificate - State Institute for Drug Control, Prague, Czech Republic
- CoS certificate (Certificate of Suitability to Ph.Eur.) – EDQM, Strasbourg, France
- DMF submitted to FDA, USA
- DMF (ASMF) - available upon request

## STABILITY & STORAGE

- The stability and quality of sodium hyaluronate powder is guaranteed for 36 months when stored in originally sealed packaging at the temperature 2–8 °C.
- Sodium hyaluronate is delivered in polyethylene bag and three-layer aluminium foil. Packaging size according to customer's demand.

