

# SODIUM HYALURONATE

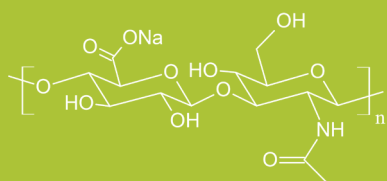
ULTRA PURE

NATRII HYALURONAS

MOLECULAR WEIGHT 7–250 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

(7–250 kDa, short – cca 7–50 kDa, long – cca 50–250 kDa)

### MEDICAL DEVICES

- eye drops for dry eye (eg. artificial tears; long molecules)
- topical preparations for wound and burns healing

### REMEDIES/DRUGS

Sodium hyaluronate on its own as active substance

- anti-cancer drugs (short molecules)
- wound and burns healing preparations
- healing preparations for corneal injuries (long molecules)
- treatment of age- and drug-related atrophy of skin
- immune potentiator against bacterial infections

### 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)
- immune potentiator against bacterial infections
- anti-inflammatory dermatological composition (with corticosteroids)

### TISSUE ENGINEERING

- replacement of injured cartilage, artificial cartilage grafts (long molecules)
- tissue regeneration as differentiation guidance materials of stem cells
- support for nerve regeneration after spinal cord injury (with growth factors)

### APPLICATION IN BIOTECHNOLOGY AND MOLECULAR BIOLOGY

- component of special cell culture medium
- supporting material for gene transfer
- biotinylated for detection of hyaluronan binding proteins

### OTHER BIOLOGICAL APPLICATION

- medium for in vitro ovum fertilization (short molecules)

# PRODUCT SPECIFICATION

Appearance	odourless white to almost white powder or granules
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	≤ 0.016 %
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 %
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 7–250 kDa.

## SOURCE

- Sodium hyaluronate of high molecular weight produced by fermentation (Streptococcus 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 (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.



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