Heparin Sodium Salt

Product Description:

Akron's Heparin Sodium Salt is manufactured, tested, and released following relevant cGMP guidelines and is supported by a Type II Master File (MF) which the FDA can reference during your drug or biologic application process. It is a non-sterile bulk active pharmaceutical ingredient (API) and an intermediary for the final formulation of pharmaceutical heparin. This product is tested to meet EP standards for Heparin Sodium Salt and is suitable for cell and gene therapy manufacturing applications. Heparin is used as an anti-coagulant in cell culture media, inactivating several key clotting factors. Akron's Heparin Sodium Salt is an unfractionated hygroscopic powder extracted from porcine intestinal mucosa and is freely soluble in water. The multi-step purification process results in a salt of sulfated glycosaminoglycans presented as a mixture of heterogeneous molecules varying in molecular weight. It is composed of polymers of alternating derivatives of D-glucosamine (N-sulfated, O-sulfated, or N-acetylated) and uronic acid (O-sulfated) joined by glycosidic linkages. The chemical composition of Akron's Heparin Sodium Salt has been characterized by H-NMR spectroscopy, heteronuclear correlation analyses (HSQC), and IR spectroscopy.

Advantages:

Raw Material

- Country of Origin: Brazil
- Inspected and registered animal facilities
- Sanitary Certificate supporting each batch of raw material

Manufacturing

- Type II eCTD MF (#026153) on file with FDA
- Validated alkaline and heat treatment for inactivation of conventional viruses
- Validated removal of protein impurities and pigments
- Sterile microfiltration before dry milling and homogenization

Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- Meets Heparin Sodium EP monograph specifications
- USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- ISO 13485:2016, Medical devices - Quality Management Systems - Requirements for Regulatory Purposes
- ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products

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Release Testing:

- Appearance
- pH
- ^{1}H-NMR (see spectrum below)
- Chromatographic Identity
- Anti-Factor Xa / Anti-Factor IIa Ratio
- Sodium
- Potency Anti-Factor IIa
- Potency Anti-Factor Xa
- Ethanol
- Nitrogen Determination
- Residue on Ignition
- Limit of Glactosamine in Total Hexosamine
- Nucleotidic Impurities (A_{260})
- Absence of Oversulfated Chondroitin Sulfate
- Protein Impurities
- Loss on Drying
- Methanol
- Bacterial Endotoxins

Stability:

- 5-year shelf life
- Store at or below 40 °C
- Protect from light and humidity
- Transport ambient

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

Related Products:

Catalog Number	Product Name	Size
AK8946-0100	Bovine Serum Albumin, Fraction V (Cohn Method)	100 g
AR1010-0100	Human AB Serum (Converted from Plasma), Xeno-Free, Virus Inactivated	100 mL
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)	100 mL
AK8228-0100	Human Serum Albumin (HSA) 25% Solution	100 mL

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^{1}H-NMR Characterization:

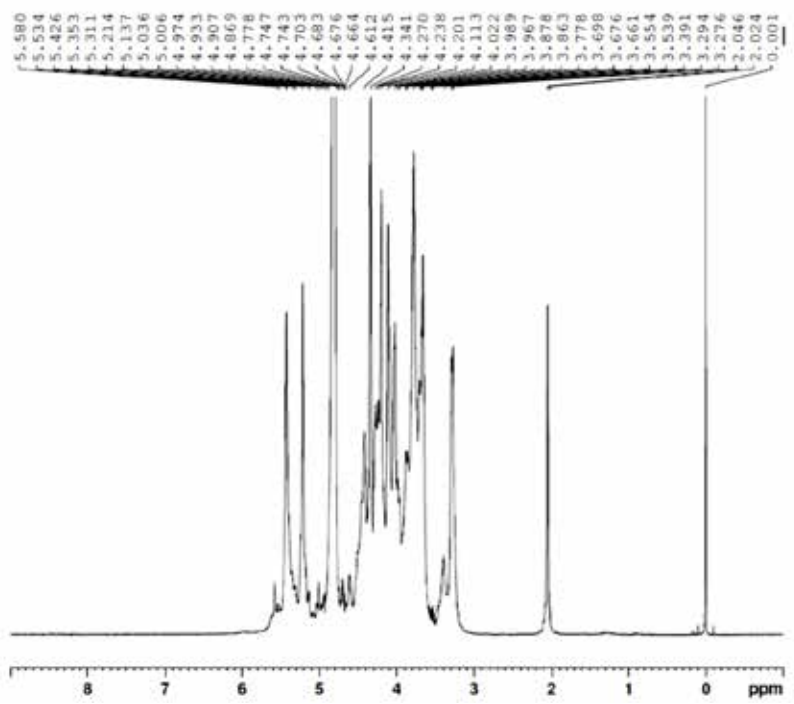

Fig.1 Representative H-NMR Spectrum showing large heparin sodium signals at: 2.04 ppm, 3.27 ppm (doublet), 4.34 ppm, 5.22 ppm and 5.42 ppm with no unidentified signals larger than 4% compared to the height of the heparin signal at 5.42 ppm present in the ranges: 0.10 – 2.00 ppm, 2.10 - 3.10 ppm and 5.70 – 8.00 ppm.

For more information on our available products or for technical assistance, see contact info below.
For contract orders under master supply agreement, please inquire.