Heparin Sodium Salt

1. Why use Akron's Heparin Sodium Salt?

Akron's Heparin Sodium Salt is manufactured, tested, and released following relevant cGMP guidelines and is supported by a Type II Master File (MF) with the FDA. 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.

2. What are the recommended storage conditions for Akron's Heparin Sodium Salt?

We recommend storing these products at or below 40 °C in a closed, dry container; protect from light and humidity.

3. What are the shipping conditions for Akron's Heparin Sodium Salt?

These products ship ambient.

4. What is the shelf-life for Akron's Heparin Sodium Salt?

These products have a shelf life of 5 years after the date of manufacture under recommended controlled storage conditions.

5. How do you dissolve Akron's Heparin Sodium Salt?

Heparin is soluble in water, saline solution, and aqueous buffers. Heparin sodium salt has a typical solubility of around 50 mg/mL.

6. How long can I store Akron's Heparin Sodium Salt after dissolution?

We do not suggest an ideal storage medium or storage conditions for reconstituted aliquots, as this product is intended for direct use within cGMP manufacturing protocols. Storage after reconstitution is affected by many factors such as benchtop methodology, concentration, diluent, storage temperature, etc.

7. Do you have available for this product?

Yes, our Heparin Sodium Salt has a Type II eCTD MF (#026153) on file with the FDA. We can provide you a Letter of Authorization that will permit the FDA to refer to the information on file in support of your submissions.

8. What organism is used as the source for Akron's Heparin Sodium Salt?

Akron's Heparin Sodium Salt is manufactured using porcine intestinal mucosa. The raw material used for his product is certified to have been collected from animals that were deemed wholesome and fit for technical and pharmaceutical use, were handled under hygienic conditions, received veterinary inspection ante-mortem and post-mortem, and were found to be free from parasitic and contagious diseases.

9. What country does the raw material originate from?

The porcine-derived raw material originates from Brazil. All slaughterhouses are inspected by the Brazilian Inspection Federal Service (SIF), and the raw material is certified by the Brazilian Ministry of Agriculture, Livestock, and Supply (MAPA). Each load of porcine mucosa raw material is supported with a Sanitary Certificate from the SIF attesting its origin and within the regulations required for use in the manufacture of APIs of animal origin.

10. Does this product have a TSE/BSE statement?

Yes, a TSE/BSE statement is available upon request for this product. Each batch of porcine-derived raw material used in the manufacture of Akon's Heparin Sodium Salt comes from inspected and registered animal facilities and is supported with a Sanitary Certificate. All applicable health certificates and relevant documents are maintained under Akron Biotech's quality systems.

11. Is virus and pathogen inactivation included in the manufacturing process?

Yes, there are two critical controlled steps in the production of Akron's Heparin Sodium Salt. This product undergoes a validated virus reduction step using strong alkaline conditions and raised temperature for an extended period and another validated step consisting of extended treatment with potassium permanganate at high temperatures.

12. What safety testing is done on this product?

Every lot of product is tested and released, with specifications and methods per EP, for Bacterial Endotoxin (EP 2.6.14).

13. Do you have an SDS for this product?

Yes, an SDS is available upon request.

14. How does Akron measure activity for Heparin Sodium Salt?

Akron's Heparin Sodium Salt is tested for activity with validated chromogenic assays that use the USP reference standard for heparin and a parallel line statistical analysis resulting in reported IU values which directly correspond to USP units. Lot-specific activity is reported on every Certificate of Analysis (CoA) as the two following values in IU/mg: "Potency Anti-factor IIa" and "Potency Anti-factor Xa."

15. Why are two different activity values reported and what is the difference between Anti-factor IIa and Anti-factor Xa?

Prothrombin (also known as factor II) gets activated into thrombin (also known as factor IIa) via factor Xa. Anti-factor IIa activity (anti-thrombin activity) shows how strongly this product binds to and inhibits thrombin. Anti-factor Xa activity shows how strongly this product binds to and inhibits factor Xa. Heparin inhibits a number of coagulant proteins, but factors IIa and Xa are the most clinically relevant and are used to standardize heparin products. If only one value is reported, it is normally Anti-factor IIa.

16. Is this product unfractionated or fractionated heparin?

Akron's Heparin Sodium Salt is unfractionated heparin. It is the salt of sulfated glycosaminoglycans present 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.

17. What is the molecular weight of Akron's Heparin Sodium Salt?

Because Akron's Heparin Sodium Salt is unfractionated, it is present as a mixture of heterogeneous molecules varying in molecular weight. High performance size exclusion chromatography was paired with a triple detector array (HP-SEC/TDA) to determine the molecular weight distribution of these polymer fragments. This product has a weight average molecular weight (Mw) of about 18-19 kDa and a number average molecular weight (Mn) of about 14-15 kDa.

18. What is the intended use for the product?

For research 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.

For more information on our available products or for technical assistance, see contact info below.
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