SCIENTIFIC PROTEIN LABORATORIES
a Hepalink Company

Technical Data Sheet

HEPARIN SODIUM

Description

Heparin Sodium USP is the sodium salt of a sulfated glycosaminoglycan of mixed mucopolysaccharides varying in molecular weights. It is a high purity lyophilized powder purified from porcine intestinal mucosa. Heparin Sodium USP is manufactured in conformity with FDA Current Good Manufacturing Practice regulations and meets all declared standards, assays, and other specifications of the current version of the United States Pharmacopeia Monograph for Heparin Sodium USP.

Uses

Heparin Sodium USP is an anticoagulant that is used to prevent certain blood clotting disorders and to prevent clotting during surgeries, dialysis, and blood transfusions. There are also some topical applications.

Specifications

Appearance	White to off-white powder
Identification A: H NMR Spectrum	No Unidentified signals greater than 4% of the mean of signal height of 1 and 2 are present in the following ranges: 0.10-2.00, 2.10-3.20 and 5.70-8.00 ppm. No signals greater than 200% signal height of the mean of the signal height of 1 and 2 are present in the 3.75-4.55 ppm for porcine heparin.
Identification B: Chromatographic Identity	The retention time of the major peak from the Sample solution corresponds to that from the Standard solution.
Identification C: Anti-Factor Xa- Anti-Factor IIa Ratio	NLT 0.9 and NMT 1.1
Identification D: Molecular Weight Determinations	M_{24000} is NMT 20%
	Mw is between 15,000 Da and 19,000 Da
	Ratio $M_{8000\text{-}16000}$ to $M_{16000\text{-}24000}$ is NLT 1.0
Identification E: Sodium	Pass
Anti-Factor IIa Potency	NLT 180 USP U/mg
Residue On Ignition (USP)	28.0 to 41.0%
Nitrogen Content	1.3 to 2.5%
Organic Impurities Limit of Galactosamine	NMT 1%
Nucleotidic Impurities	NMT 0.1%
Absence of Oversulfated Chondroitin Sulfate A	No features associated with Oversulfated chondroitin sulfate are found between 2.12 and 3.00 ppm in NMR Spectrum.
Absence of Oversulfated Chondroitin Sulfate B	No peaks corresponding to Oversulfated chondroitin sulfate should be detected eluting after the heparin peak in the chromatographic identity test.
Protein Impurities	NMT 0.1%
pH	5.0 – 7.5
Loss on Drying	NMT 5.0%
Bacterial Endotoxin	NMT 0.03 EU/USP Heparin Unit
Total Aerobic Microbial Count	NMT 100 CFU/g

Certification

Each lot is analyzed at the time of manufacture in accordance with the USP monograph for Heparin Sodium USP. Testing and release per the EP and JP monographs is also available. Other test results, customized specifications, and compliance documentation may be available upon request. Minimally, a Certificate of Analysis and Material Safety Data Sheet accompany each order.

Packaging

Routinely packaged in poly-liners inside heat-sealed foil pouches inside a fiber or poly drum.

Storage

Preserved in airtight containers. Store up to 25°C (77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).