Gojira Fine Chemicals, LLC

Quality Products & Services Meeting Customer Needs

5386 Majestic Parkway, Suite 7, Bedford Heights, OH 44146

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Specification

Heparin Sodium USP

Catalog Number: HS1003
CAS Number: 9041-08-1
Origin: Healthy porcine mucosa
Storage: 15ºC – 30ºC
Retest Period: Three years from the date of manufacture

Test	Specification
Appearance	White or almost white powder, hygroscopic
Identification A: ^{1}H-NMR B: Chromatographic identity C: Anti-factor Xa to anti-factor II a ratio D: Molecular weight determinations E: Sodium Reaction	 No unidentified signals greater than 4 % of main signal height of 1 and 2 at 0.10-2.00, 2.10-3.20, 5.70-8.00; no signal >200% signal height mean signal height of 1 and 2 present at 3.75-4.55 The retention time of the major peak from sample solution corresponds to that from the RS 0.9 – 1.1 $M_{24,000}$ ≤ 20% Mw range 15,000 – 19,000Da $M_{8,000\text{-}16,000}/M_{16,000\text{-}24,000}$ ≥ 1.0 Positive
Assay (anti-factor II a potency, Dried Basis)	> 180 USP-U/mg
Solubility	Freely soluble in water
pH (1% solution)	5.0 - 7.5
Moisture (LOD)	≤ 5.0% (in vacuum at 60ºC for 3 hours)
Residue on Ignition	28.0 – 41.0%
Nitrogen (Dried Basis)	1.3 - 2.5%
Nucleotide Impurities (0.4% solution)	260 nm: ≤ 0.10%
Limit of galactosamine	≤ 1.0%
Absence of OSCS	A: (^{1}H-NMR) – no OSCS features between 2.12- 3.00 B: (SAX-HPLC) – no OSCS peaks after heparin peak
Protein Impurities	≤ 0.1%
Bacterial Endotoxins	≤ 0.03 EU/USP Heparin Unit
This batch meets the specifications for USP41. The country of origin is China.	
Heparin Sodium is a highly-sulfated glycosaminoglycan carbohydrate polymer derived from porcine intestinal mucosa. Heparin is most often used as an anticoagulant based upon its ability to bind to antithrombin III, a naturally occurring plasma protease inhibitor, and accelerates the rate at which ATIII inhibits the coagulation proteases factor Xa and thrombin. **Heparin Sodium is intended for manufacturing, development or technical purposes only and must not be administered to humans or used for any drug purpose.**	

Approved: Date: November 27, 2018

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