

Gojira Fine Chemicals, LLC

Quality Products & Services Meeting Customer Needs 5386 Majestic Parkway, Suite 7, Bedford Heights, OH 44146 www.gojirafc.com • sales@gojirafc.com

Certificate of Analysis

Heparin Sodium USP

Catalog Number: HS1003 Lot Number: 1026801 **CAS Number:** 9041-08-1

Origin: Healthy porcine mucosa

15°C - 30°C Storage: **Date of Manufacture:** August 14, 2018 **Retest Date:** August 13, 2021

Test	Specification	Result
Appearance	White or almost white powder, hygroscopic	Conforms
Identification		
A: ¹ H-NMR	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	Conforms
B: Chromatographic identity	The retention time of the major peak from sample solution corresponds to that from the RS	Conforms
C: Anti-factor Xa to anti- factor II a ratio	0.9 – 1.1	1.0
D: Molecular weight	$M_{24,000} \le 20\%$	12%
determinations	Mw range 15,000 – 19,000Da	16,412Da
	$M_{8,000-16,000}/M_{16,000-24,000} \ge 1.0$	1.6
E: Sodium Reaction	Positive	Conforms
Assay (anti-factor II a potency, Dried Basis)	> 180 USP-U/mg	193.3 USP-U/mg
Solubility	Freely soluble in water	Conforms
pH (1% solution)	5.0 - 7.5	6.4
Moisture (LOD)	≤ 5.0% (in vacuum at 60°C for 3 hours)	1.7%
Residue on Ignition	28.0 – 41.0%	37.7%
Nitrogen (Dried Basis)	1.3 - 2.5%	2.0%
Nucleotide Impurities (0.4% solution)	260 nm: ≤ 0.10%	< 0.1%
Limit of galactosamine	≤ 1.0%	0.1%
Absence of OSCS	A: (1H-NMR) – no OSCS features between	Conforms
	2.12- 3.00	Conforms
	B: (SAX-HPLC) – no OSCS peaks after heparin	
	peak	
Protein Impurities	≤ 0.1%	0.08%
Bacterial Endotoxins	≤ 0.03 EU/USP Heparin Unit	< 0.03 EU/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



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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 by:

Date: October 26, 2018

John Grubb, PhD

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Quality Manager

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