






坤联产业
SHEELIAN INDUSTRY PARK

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CERTIFICATE OF ANALYSIS

Product Name	Heparin Sodium	Batch Number	01220404	Code	CP00103
Specifications	API	Batch size	68.5448kg	Sampling quantity	27.0g
Origin	Porcine intestinal mucosa	Production Date	2022.04.29	Inspection Date	2022.05.13
Acceptance Criteria	USP 43	Report Date	2022.06.29	Expiry Date	2025.04.28

Inspection Items	Specifications	Test Result
Character		
Exterior	white or almost white, hygroscopic powder, freely soluble in water	Complies
Identification		
¹ H NMR Spectrum	Conforms	Complies
Chromatography	Conforms	Complies
Anti FXa/Anti FIIa	0.9~1.1	1.0
Molecular Weight Determinations	M24000≤20%	13%
	Mw between 15000Da and 19000Da	16700
	The ratio between M8000-16,000 and M16,000-24000≥1.0	1.6
Sodium	Conforms	Complies
Test		
Coagulant-Anti Factor IIa	≥180 UspU/mg(dried substance)	212UspU/mg(dried) 208UspU/mg(wet)
Nitrogen	1.3%~2.5%(dried substance)	2.0%
Residue on ignition	28.0%~41.0%	38.4%
Nucleotidic Impurities	≤0.1%	Absent
Limit of Galactosamine in total Hexosamine	≤1%	Absent
Absence of Oversulfated Chondroitin Sulfate	Polysulfuric acid chondroitin cannot be detected	Absent
Protein	≤ 0.1%(dried substance)	0.09%
Residual Solvents	Methanol≤0.3%	Absent
	Ethanol≤0.5%	0.06%
	Acetone≤0.5%	Absent
Loss on Drying	≤5.0%	2.0%
pH	5.0~7.5	6.6
Micro Organisms		
Bacterial Endotoxins	<0.03 UspEU/UspU	<0.03 UspEU/UspU
Aerobic Bacteria Count	<10 ³ cfu/g	<10 cfu/g
Fungi/Yeast	<10 ² cfu/g	<10 cfu/g
Conclusion	This product has been tested in accordance with the USP 43	

Analyzed by:  2022.06.29 Checked by:  2022.06.29 Signature: 

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