

Certificate of Analysis

Commodity	Heparin Sodium	Grade	Injectable grade	Batch No.	RBHB171103-5
Quantity	140g	Manufacturing Date	2017.12.06	Expiry Date	2020.11
Test Date	2017.12.08	Report Date	2017.12.16	Acceptance Criteria	EP 6.0
Origin	Bovine Intestinal Mucosa				

TESTS	SPECIFICATIONS	RESULTS
Appearance	White or almost white hygroscopic powder	Complies
Optical rotation	$\geq 50^\circ$	56°
Solubility	Freely soluble in water	Complies
Identification A	The sample solution to be examined should inhibit the formation of clot of the citrated ovine plasma after recalcification.	Complies
Identification D	Complies with the sodium test	Complies
Molecular weight distribution	Mw 15000~19000; M24000 \leq 20%; M8000~16000/M16000~24000 \geq 1.0.	15875 12.6 2.23
PH	5.5 to 8.0	7.0
Loss on Drying	$\leq 8.0\%$	1.6%
Heavy Metals	$\leq 0.003\%$ (30ppm)	Complies
Nitrogen Content	1.5 to 2.5% (Anhydrous Basis)	1.9%
Sodium	Potency \geq 150 IU/mg (Anhydrous basis)	157.5
Nucleotides	9.5 to 12.5% (Anhydrous Basis)	11.6%
Protein	≤ 0.150	0.034
Related Substances	$\leq 0.5\%$ (Anhydrous Basis) Dermatan Sulphated + Chondroitin Sulphated $< 2.0\%$ Any other impurities: should not be detected others peaks, beside the peak of the Dermatan Sulphate + Chondroitin Sulphate.	0.32% 0.10% Complies
Residual Solvents	Ethanol ≤ 5000 ppm	300ppm

Welcome to contact us for latest and more COA by contact method below :



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