

Certificate of Analysis

Product Name	Heparin sodium salt, Ph. Eur. grade
Glentham Code	GC9695
CAS Number	9041-08-1
MDL Number	MFCD00081689
Additional CAS	9005-49-6
Batch Number	427PAY
Molecular Weight	1090.86
Molecular Formula	$C_{24}H_{38}N_2O_{36}S_5$
Storage Temp.	+4°C

Property	Specification	Batch 427PAY
Physical Description	White or almost white, hygroscopic powder	Conforms
Identification	A, B, C, D, E: According to EP	Conforms
Appearance of Solution	Clear, and colour ≤ Y5	Clear, and colour ≤ Y5
pH	5.5 - 8.0	6.9
Nucleotidic impurities	≤ 0.15 (at 260nm)	0.01
Protein	≤ 0.5% (anhydrous)	< 0.1%
Related Substances	Sum of Dermatan Sulfate and Chondroitin Sulfate: ≤ 2.0%	< 0.1
	Any other impurity: According to EP	Conforms
Nitrogen	1.5 - 2.5 % (anhydrous)	2.1%
Sodium	10.5 - 13.5 % (anhydrous)	12.4%
Loss on Drying	≤ 8.0%	2.6%
Bacterial Endotoxins	0.01 IU max per IU Heparin	Conforms
Total Aerobic Microbial Count	≤ 10CFU/g	≤ 10CFU/g
Total Mould / Yeast Count	≤ 10CFU/g	≤ 10CFU/g
Potency	≥ 180IU/mg (wet)	223IU/mg
Pharmacopoeia Specification(s)	EP	EP

Specification Version	v1.1
Manufacture Date	2024-03-15
Re-Test Date	2028-07-29

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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