

USP SPECIFICATION

ORGANOLEPTIC CHARACTERISTICS	
Appearance	White or almost white powder, moderately hygroscopic
IDENTIFICATION TESTS	
Identification A: ¹ H-NMR spectrum	No unidentified signals greater than 4% of the mean of signal height of 1 and 2 are present in the following ranges: 0.10-2.00, 2.10-3.20, and 5.70-8.00 ppm. No signals greater than 200% signal height of the mean of the signal height of 1 and 2 are present in the 3.75-4.55 ppm for porcine heparin
Identification B: Chromatographic identity	The retention time of the major peak from the Sample solution corresponds to that from the Standard solution
Identification C: Anti-Factor Xa to anti-Factor IIa ratio	NLT 0.9 and NMT 1.1
Identification D: Molecular weight determinations Nitrogen (odb) M ₂₄₀₀₀ Mw Ratio M ₈₀₀₀₋₁₆₀₀₀ /M ₁₆₀₀₀₋₂₄₀₀₀	NMT 20 % 15,000 – 19,000 Da NLT 1.0
Identification E: Sodium	A solution of Heparin Sodium imparts an intense yellow color to a nonluminous flame
PHYSICO-CHEMICAL and CHEMICAL TESTS	
Residue on ignition	28.0 - 41.0 %
Nitrogen (odb)	1.3 - 2.5 %
Limit of galactosamine in total hexosamine	NMT 1 %
Nucleotidic impurities	NMT 0.1 %
Absence of oversulfated chondroitin sulfate-test A	No features associated with oversulfated chondroitin sulfate are found between 2.12 and 3.00 ppm in ¹ H-NMR Spectrum.
Absence of oversulfated chondroitin sulfate-test B	No peaks corresponding to oversulfated chondroitin sulfate detected eluting after the heparin peak in the chromatographic identity.
Protein impurities	NMT 0.1 %
pH	5.0 – 7.5
Loss on drying	NMT 5.0 %
MICROBIOLOGICAL TEST	
Bacterial endotoxins	MT 0.03 EU/USP U
ASSAY	
Anti-Factor IIa Potency (odb)	NLT 180 USP U/mg

ADDITIONAL INFORMATION

- The shelflife is 4 years
- Source: from Europe, North and South America
- Animal origin: 100% porcine origin (rtPCR certified)
- Certification: FDA, GMP approved
- The average biological activity (APTT) is 200 MIU/KG
- No special storage requirements