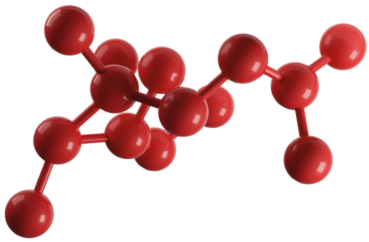
Heparin Sodium



EP SPECIFICATION

EP Parameter	Limit
Description	White or almost white hygroscopic powder. Freely soluble in water
Heparin identification	It complies with the requirements described under assay
Anti-factor Xa/anti-factor IIa ratio	0.9 — 1.1
Identification by H-NMR	The large heparin sodium signals must be present: 2.04 ppm, 3.27 ppm (doublet), 4.34 ppm, 5.22 ppm and 5.42 ppm, all within ± 0.03 ppm. No unidentified signals larger than 4 % compared to the height of the heparin signal at 5.42 ppm are present in the ranges 0.10-2.00 ppm, 2.10-3.10 ppm and 5.70-8.00 ppm.
Identification by SAX-HPLC	The principal peak in the chromatogram obtained with the test solution (a) is similar in retention time and shape to the principal peak in the chromatogram obtained with reference solution (c).
Sodium identification	It complies with the test for sodium
Clarity in solution (5000 IU/mL)	Not more than 2.5 NTU
Color of solution (5000 IU/mL)	Not more than Y5
pH	5.5 — 8.0
Nucleotidic impurities	Not more than 0.15
Protein (odb)	Not more than 0.5 %
Related substances • Sum of dermatan sulfate and chondroitin sulfate • Any other impurity	 Not more than 2.0 % No peaks other than the peak due to dermatan sulfate + chondroitin sulfate are detected
Nitrogen (odb)	1.5 — 2.5 %
Sodium (odb)	10.5 — 13.5 %
Loss on drying	Not more than 8.0 %
Methanol	Not more than 3000 ppm
Bacterial endotoxins	Less than 0.01 IU/IU Heparin Unit
Anti-factor IIa activity (odb)	Not less than 180 UI/mg
Anti-factor IIa activity (as is)	No limit

ADDITIONAL INFORMATION

- The shelflife is 5 years
- Source: from Europe, North and South America
- Animal origin: 100% porcine origin (rtPCR certified)
- Certification: GMP approved
- The average biological activity (APTT) is 200 MIU/KG
- No special storage requirements

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