Heparin Sodium

JP SPECIFICATION

Description	
Appearance	White to grayish brown powder or grains

Identification tests	
WAX-HPLC	The retention time for the major peak from the sample solution and the standard solution are identical

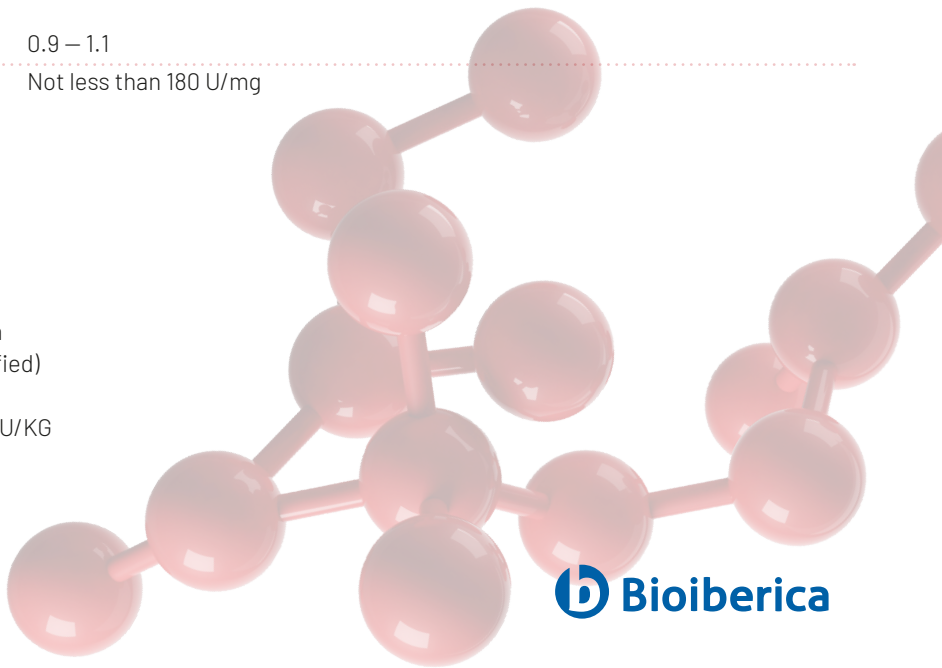
Physico-Chemical and Chemical Parameters	
pH (1%, H2O)	6.0 – 8.0
Clarity and color of solution (2.5%, H_2O)	The solution is clear and colorless to light yellow
Barium	No turbidity is produced
Nitrogen (odb)	Not more than 3.0 %
Protein	The absorbance of the solution obtained from the sample solution is not larger than that of the solution obtained from the standard solution
Nucleotidic impurities (Abs 260 nm)	Not more than 0.15
Oversulfated chondroitin sulfate	The H-NMR spectrum exhibits no signal corresponding to N-acetyl proton of oversulfated chondroitin sulfate at ∂ 2.13 – 2.17 ppm
Related substances (WAX-HPLC)	No peaks are eluted after the heparin peak
Galactosamine	The peak area ratio of galactosamine to glucosamine of the sample solution is not larger than that of the standard solution
Loss on drying	Not more than 10 %
Residue on ignition (odb)	Not more than 40 %

Microbiological Test	
Bacterial endotoxins	Not more than 0.0030 EU/Heparin Unit No limit

Assay	
Anti-factor Xa activity to anti-factor IIa activity ratio	0.9 – 1.1
Anti-factor IIa activity (odb)	Not less than 180 U/mg

ADDITIONAL INFORMATION

- The shelflife is 4 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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