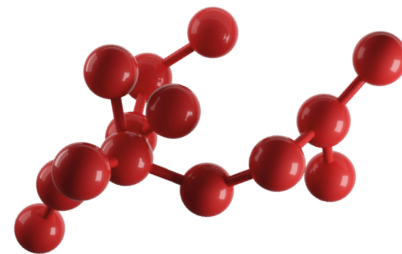


Heparin Sodium ^b



USP SPECIFICATION

Organoleptic characteristics

Appearance White or almost white powder, moderately hygroscopic

Identification tests

Identification A: ¹H-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} NMT 20 %
Mw 15,000 - 19,000 Da
Ratio $M_{8000-16000} / M_{16000-24000}$ 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 1.0 %

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 ¹H-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 NMT 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