

SPECIFICATION

Product : HEPARIN AMMONIUM

Quality : ex porcine mucosa, for technical use

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Product-no. : 5012000900

Version : 4

Valid from : 01/10

CAS-no. : 60800-63-7

Mol.-weight : 3.000-30.000 da

Controls	Specification	Method
Description	white hygroscopic powder, watersoluble	visual
Loss on drying	≤8.0 %	Ph. Eur. 2.2.32
Optical rotation	≥+ 35°	Ph. Eur. 2.2.7
Ammonium-N	≥6,0 %	Ph. Eur. 2.2.23
Sodium	≤0,5 %	Ph. Eur. 2.2.23
pH in 1 % solution	5.5-8.0	Ph. Eur. 2.2.3
Nitrogen	≤2,5 %	Ph. Eur. 2.5.9
Sulphur	≥10 %	Ph. Eur. 2.5.10
Proteins	no precipitate or turbidity	Ph. Eur. 2.2.25
Heavy metals	≤30 ppm	Ph. Eur. 2.4.8 (ICP-MS)
Appearance of solution	clear, not more than 5 degree	Ph. Eur. 2.2.1 + 2.2.2 (Method II)
Protein and nucleotide impurities (0.4 % in H ₂ O)	280 nm ≤ 0.150 260 nm ≤ 0.200	Ph. Eur. 2.2.25
Total bacterial count	≤100 CFU/g substance	Ph. Eur. 2.6.12
Activity	≥150 I.U./mg in dried substance	Ph. Eur. 2.7.5
NMR spectrum	free of OSCS	¹ H-NMR spectroscopy according to BfArM

Primary packing : security tubs

Storage : well closed

Shelf life : 36 months