

SPECIFICATION

Product : HEPARIN LITHIUM

Quality : ex porcine mucosa

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Product-no. : 5011000900

Version : 3

Valid from : 02/09

CAS-no. : 9045-22-1

Mol.-weight : 3.000-30.000 da

Controls	Specification	Method
Description	white hygroscopic powder	visual
Loss on drying	≤ 8.0 %	Ph. Eur. 2.2.32
pH	5.5-8.0	Ph. Eur. 2.2.3
Sulphated Ashes	20-35 %	Ph. Eur. 2.4.14
Heavy metals	≤30 ppm	Ph. Eur. 2.4.8 (ICP-MS)
Nitrogen	≤2.5 %	Ph. Eur. 2.5.9
Sulfur	≥10 %	Ph. Eur. 2.5.10
Optical rotation	≥ + 35°	Ph. Eur. 2.2.7
Proteins	no precipitate or turbidity	USP 26 <641>
Pb	≤10 ppm	Ph. Eur. 2.4.8 (ICP-MS)
Zinc	≤5 ppm	Ph. Eur. 2.2.23 (ICP-MS)
Potassium	≤0.5 %	Ph. Eur. 2.2.23 (ICP-MS)
Calcium	≤0.4 %	Ph. Eur. 2.2.23 (ICP-MS)
Lithium	3,0-4,5 %	Ph. Eur. 2.2.23 (ICP-MS)
Chlorides	≤0.75 %	titrimetical
Appearance of solution	clear, not more than degree 5	Ph. Eur. 2.2.1 + 2.2.2 (Method II)
Protein and nucleitidic impurities	280 nm = 0.4 in H ₂ O = ≤0.150 260 nm = 0.4 in H ₂ O = ≤0.200	Ph. Eur. 2.2.25
Extinction	400 nm/25.000 iu/ml = ≤0.150	Ph. Eur. 2.2.25
Solvents	≤1.0 %	Ph. Eur. 2.4.24
Microbiological impurities	≤100 CFU/g substance	Ph. Eur. 2.6.12
Germs after enrichment	negative	Ph. Eur. 2.6.13
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