

neoFroxx GmbH

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Certificate of Analysis

Product	D(-)-Sorbitol	
Brand	Labochem	
Quality	pure EP, NF	
Product number	LC-6666	
Lot number	5A8C3C43	
Synonyms	D-Glucitol, Nivitin, D-Sorbitol, Sorbol	
Formula	C ₆ H ₁₄ O ₆	
Molecular weight	182.18 g/mol	
CAS number	50-70-4	
Solubility (water, 25°C)	2350 g/l	
Melting point	94 - 96°C	
Storage	RT	
Manufacturing date	September 2017	
Retest date	September 2022	
<p>We herewith confirm that this product meets the requirements of the European Pharmacopoeia (EP 9.0) and the US Pharmacopoeia (USP 40).</p> <p>TSE/BSE declaration: The product is manufactured wholly from synthetic and plant materials and does not contain any raw materials produced from or substances derived of animal origin. Moreover this product is not derived from specific risk materials as defined in Guideline EMEA/410/01 final Rev. 03/2004.</p> <p>All packaging materials are not of animal origin. The product does not come in contact with animal products during storage or transportation. Depending on the quantity we either use PE-Flascs with original lids or PE-cans with original lid with PE-bags inside or card boxes with PE-bags inside.</p>		
Parameter	Specification	Result
Assay (HPLC, dried substance)	97.0 - 100.5 %	99.4 %

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Identity (USP)	passes test	complies
	<p>A. Dissolve 0.5 g with heating in a mixture of 0.5 ml of pyridine R and 5 ml of acetic anhydride R. After 10 min, pour the solution into 25 ml of water R and allow to stand in iced water for 2 h. The precipitate, recrystallised from a small volume of alcohol R and dried in vacuo, melts (2.2.14) at 98°C to 104°C.</p> <p>B. Examine by thin-layer chromatography (2.2.27), using a TLC silicagel G plate R.</p> <p>Test solution: Dissolve 25 mg of the substance to be examined in water R and dilute to 10 ml with the same solvent</p> <p>Reference solution (a): Dissolve 25 mg of sorbitol CRS in water R and dilute to 10 ml with the same solvent.</p> <p>Reference solution (b): Dissolve 25 mg of mannitol CRS and 25 mg of sorbitol CRS in water R and dilute to 10 ml with the same solvent.</p> <p>Apply to the plate 2 ml of each solution. Develop over a path of 17 cm using a mixture of 10 volumes of water R, 20 volumes of ethyl acetate R and 70 volumes of propanol R. Allow the plate to dry in air and spray with 4-aminobenzoic acid solution R. Dry the plate in a current of cold air until the acetone is removed. Heat the plate at 100°C for 15 min. Allow to cool and spray with a 2 g/l solution of sodium periodate R. Dry the plate in a current of cold air. Heat the plate at 100°C for 15 min. The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a). The test is not valid unless the chromatogram obtained with reference solution (b) shows 2 clearly separated spots.</p>	
Appearance of solution	passes test	complies
Identity	passes test	complies
Conductivity (20 % in water dest.)	max. 20 µS/cm	complies
Microbiological test	passes test	complies
pH (10 % in water)	3.5 - 7.0	complies
Reducing sugars	max. 0.2 %	complies
Sulfated ash	max. 0.1 %	complies
Related substances	passes test	complies
Water (K.F.)	max. 1.5 %	0.16 %
Ni	max. 0.0001 %	complies
Pb	max. 0.00005 %	complies

Einhausen, 02.06.2017	Quality control: M.F.
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