

Certificate of Analysis

Productname: Sorbitolum liquidum non crist.

Inspection No: I03891/0521/536
Batchnumber: 21D12-T09-086804
Expiration date: 11.02.2026
Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0
Original Manuf. Date: 11.2.2021

Sample Unit: 1 x 50 ml
Batch Size: 96 x 1 l

Identification of producer: V00792
Batch no. of vendor: E529V

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless, syrupy liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Assay, HPLC	Contract Lab
Identification B	+1,5 - +3,5	+2,5	°	Optical rotation	Fagron CZ
Identification C	Conform	Conform		Clear syrupy liquid	Fagron CZ
TESTS					
Appearance of solution	Clear, colourless	Conform		14% <i>m/V</i>	Fagron CZ
Conductivity	≤10	0,2	μS.cm ⁻¹		Fagron CZ
Reducing sugars	≤0,2	<0,2	%	Glucose equivalent	Fagron CZ
Reducing sugars after hydrolysis	≤9,3	<9,3	%	Glucose equivalent	Fagron CZ
Water (Karl Fischer)	28,0 - 32,0	29,1	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Anhydrous substance	68,0 - 72,0	70,9	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	77,6	%	Anhydrous, HPLC	Contract Lab

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Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 25.05.2021

Conclusion: **APPROVED**

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