



## Certificate of Analysis

**Productname:** Sorbitolum liquidum non crist.

**Inspection No:** K08405/1023/536

**Sample Unit:** 1 x 50 ml

**Batchnumber:** 23J02-T04-106557

**Batch Size:** 504 x 5 l

**Expiration date:** 08.11.2027

**Analysed according to:** ČL 2017-Dopl.2019, Ph.Eur. 11.0

**Original Manuf. Date:** 8.11.2022

**Identification of producer:** V01603

**Batch no. of vendor:** E521X

	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% m/V	Fagron CZ
Conductivity	≤10	0,3	μS.cm <sup>-1</sup>		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	29,8	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	≤2 x 10 <sup>2</sup>	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
ASSAY					
Anhydrous substance	68,0 - 72,0	70,2	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	75,2	%	Anhydrous, HPLC	Contract Lab

Quality: Excipient

**Performed by:** Ludmila Burianová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 16.11.2023

**Conclusion:** **APPROVED**

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