



## Certificate of Analysis

**Productname:** Sorbitolum liquidum non crist.

**Inspection No:** K10028/0124/536

**Sample Unit:** 1 x 50 ml

**Batchnumber:** 23I20-T06-106558

**Batch Size:** 1,500 x 1 l

**Expiration date:** 26.06.2028

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

**Original Manuf. Date:** 27.6.2023

**Identification of producer:** V01603

**Batch no. of vendor:** 683824

	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	+2,4	°	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	0,3	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	29,5	%		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	70,5	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	77,1	%	Anhydrous, HPLC	Contract Lab

Quality: Excipient

**Performed by:** Ludmila Burianová

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

**Date:** 16.01.2024

**Conclusion:** **APPROVED**

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