

## Certificate of Analysis

**Productname:** Sorbitolum liquidum non crist.

**Inspection No:** I01923/0321/536  
**Batchnumber:** 21B04-T02-085427  
**Expiration date:** 22.08.2025  
**Analysed according to:** ČL 2017-Dopl.2019,Ph.Eur.10.0  
**Original Manuf. Date:** 22.8.2020

**Sample Unit:** 1 x 50 ml  
**Batch Size:** 417 x 1 l

**Identification of producer:** V00792  
**Batch no. of vendor:** E899T

	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	+2,6	°	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>	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 <sup>2</sup>	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	70,2	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	74,5	%	Anhydrous, HPLC	Contract Lab

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**Performed by:** Lucie Kubáňová DiS.

**Responsible:** Ing. Mgr. Kateřina Jokešová, QC  
PharmDr. Ivana Urbánková, QA

**Date:** 09.04.2021

**Conclusion:** **APPROVED**

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