



Certificate of Analysis

Productname: Sorbitolum liquidum non crist.

Inspection No: K05691/0823/536

Sample Unit: 1 x 50 ml

Batchnumber: 23G04-T12-107037

Batch Size: 150 x 5 l

Expiration date: 16.08.2027

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

Original Manuf. Date: 16.8.2022

Identification of producer: V01603

Batch no. of vendor: E311X

	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	0,2	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	30,6	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	<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	69,4	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	75,4	%	Anhydrous, HPLC	Contract Lab

Quality: Excipient

Performed by: Ludmila Burianová

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

Date: 05.09.2023

Conclusion: **APPROVED**

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