



Certificate of Analysis

Productname: Sorbitolum liquidum non crist.

Inspection No: K04356/0823/536

Sample Unit: 1 x 50 ml

Batchnumber: 23C21-T07-106021

Batch Size: 167 x 5 l

Expiration date: 23.01.2028

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

Original Manuf. Date: 22.1.2023

Identification of producer: V01603

Batch no. of vendor: 562483

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless, syrupy liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification A	Conform	Conform		Assay, HPLC	Contract Lab
Identification B	+1,5 - +3,5	2,3	°	Optical rotation	Contract Lab
Identification C	Conform	Conform		Clear syrupy liquid	Contract Lab
TESTS					
Appearance of solution	Clear, colourless	Conform		14% m/V	Contract Lab
Conductivity	<=10	2	µS.cm-1		Contract Lab
Reducing sugars	<=0,2	<0,2	%	Glucose equivalent	Contract Lab
Reducing sugars after hydrolysis	<=9,3	<9,3	%	Glucose equivalent	Contract Lab
Water (Karl Fischer)	28,0 - 32,0	28,9	%		Contract Lab
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	71,1	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	77,8	%	Anhydrous, HPLC	Contract Lab

Quality: Excipient

Performed by: Ekocentrum

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

Date: 30.08.2023

Conclusion: **APPROVED**

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