



Certificate of Analysis

Productname: Sorbitolum liquidum non crist.

Inspection No: J08038/1022/536

Sample Unit: 1 x 50 ml

Batchnumber: 22H12-T06-098687

Batch Size: 391 x 5 l

Expiration date: 01.07.2027

Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0

Original Manuf. Date: 1.7.2022

Identification of producer: V01603

Batch no. of vendor: E893W

	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	+2,1	°	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	0,5	$\mu S.cm^{-1}$		Fagron CZ
Reducing sugars	$\leq 0,2$	$< 0,2$	%	Glucose equivalent	Fagron CZ
Reducing sugars after hydrolysis	$\leq 9,3$	$< 9,3$	%	Glucose equivalent	Fagron CZ
Water (Karl Fischer)	28,0 - 32,0	31,2	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	$\leq 2 \times 10^3$	< 10	CFU/g		Contract Lab
TYMC	$\leq 2 \times 10^2$	< 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	68,8	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	77,8	%	Anhydrous, HPLC	Contract Lab

Quality: Excipient

Performed by: Ludmila Stochlebová

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

Date: 14.09.2022

Conclusion: **APPROVED**

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