

Certificate of Analysis

Productname: Sorbitolum liquidum non crist.

Inspection No: I07781/1021/536

Batchnumber: 21D12-T09-090062

Expiration date: 11.02.2026

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

Original Manuf. Date: 11.2.2021

Sample Unit: 0 x

Batch Size: 8 x 5 l

Identification of producer: V00792

Batch no. of vendor: E529V

	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	+2,5	°	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	0,2	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	29,1	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	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	70,9	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	77,6	%	Anhydrous, HPLC	Contract Lab

Name Fagron a.s. (CZ)
Kontrolní laboratoř č. 536

Address Holická 1098/31m, Olomouc
Post Code 779 00

Phone No. +420585222590
Fax No. +420 585 226 521

The product conforms to ČL 2017-Dopl.2019,Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 10.11.2021



Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

This document has been produced electronically from our quality system and is valid without signature.

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521