Fagron personalizing medicine

Certificate of Analysis

Productname: **Sorbitolum liquidum non crist.**

Inspection No: I09367/1221/536
Batchnumber: **21J21-T19-092601**
Expiration date: 07.01.2026
Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0
Original Manuf. Date: 7.1.2021

Identification of producer: V00792
Batch no. of vendor: E455V

Sample Unit: 0 x
Batch Size: 2 x 5 l

	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	0,30	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	29,4	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<10	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	70,6	%	HPLC	Contract Lab
D-glucitol	72,0 - 92,0	78,8	%	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: 08.12.2021

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.

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