

Certificate of Analysis

Productname: Glycerolum 85% Bag In Box

Inspection No: I07650/1021/536

Batchnumber: 21I07-T01-090063

Expiration date: 27.08.2023

Analysed according to: ČL 2017-Dopl.2020, Ph.Eur. 10.0

Original Manuf. Date: 27.8.2021

Sample Unit:

0 x

Batch Size:

100 x 5 l

Identification of producer: V01457

Batch no. of vendor: GLYD_20210827_1425

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Syrupy liquid, unctuous to the touch,(almost) colourless, clear, very hygroscopic.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,449 - 1,455	1,454		Refractive index	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Clear, colourless	Conform			Fagron CZ
Acidity or alkalinity	<=0,2	0,1	ml	0,1 mol/l NaOH	Fagron CZ
Refractive index	1,449 - 1,455	1,454			Fagron CZ
Aldehydes	<=10	<10	µg/g		Fagron CZ
Esters	>=8,0	9,3	ml	0,1 mol/l HCl	Fagron CZ
Impurity A and related substances	Conform	Conform			Contract Lab
Impurity A	<=0,1	<0,1	%		Contract Lab
Any other impurities tR<tR glycerol	<=0,1	<0,1	%		Contract Lab
Tot. all imp. tR>tR glycerol	<=0,5	<0,5	%		Contract Lab
Halogenated compounds	<=30	<30	µg/g		Fagron CZ
Sugars	Conform	Conform			Fagron CZ
Chlorides	<=10	<10	µg/g		Fagron CZ
Water (Karl Fischer)	12,0 - 16,0	12,6	%		Fagron CZ
Sulfated ash	<=0,01	0	%		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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Propane-1,2,3-triol	83,5 - 88,5	86,6	%		Fagron CZ

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

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The product conforms to ČL 2017-Dopl.2020, Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

Responsible: Lenka Morávková, QC
MVDr. Zdenka Borská, QA

Date: 03.11.2021



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.

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