



Certificate of Analysis

Productname: Glycerolum 85%

Inspection No: J10081/1222/536

Batchnumber: 100837

Expiration date: 14.07.2024

Analysed according to: Ph.Eur.10.8

Customer: FAGRON a.s.

Sample Unit: 1 x 250 g

Batch Size: 600 x 250 g

Batch no. of vendor: GLYD_20220714_0800

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear, colourless or almost colourless, very hygroscopic, syrupy liquid, unctuous to the touch.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	1,449 - 1,455	1,454		Refractive index
Identification B	Conform	Conform		IR-spectrum
TESTS				
Appearance of solution	Clear, colourless	Conform		
Acidity or alkalinity	<=0,2	0,1	ml	0,1 mol/l NaOH
Refractive index	1,449 - 1,455	1,454		
Aldehydes	<=10	<10	ppm	
Esters	>=8,0	9,5	ml	0,1 mol/l HCl
Impurity A and related substances	Conform	Conform		
Impurity A	<=0,1	<0,1	%	
Any other impurities tR<tR glycerol	<=0,1	<0,1	%	
Tot. all imp. tR>tR glycerol	<=0,5	<0,5	%	
Halogenated compounds	<=30	<30	ppm	
Sugars	Conform	Conform		
Chlorides	<=10	<10	ppm	
Water (Karl Fischer)	12,0 - 16,0	13,0	%	
Sulfated ash	<=0,01	0,00	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		
ASSAY				
Propane-1,2,3-triol	83,5 - 88,5	85,7	%	

Quality: Excipient

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

Performed by: Ludmila Stochlebová
Responsible: Ing. Pavel Mišák, QC
Mgr. Barbora Agatha Halouzková, QP
Date: 07.12.2022

Conclusion: **APPROVED**

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