



Certificate of Analysis

Productname: Glycerolum 99,5%

Inspection No: J02754/0322/536

Batchnumber: 22B25-T04-093436

Expiration date: 14.02.2024

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

Original Manuf. Date: 14.2.2022

Sample Unit: 1 x 10 ml

Batch Size: 360 x 1 l

Identification of producer: V01457

Batch no. of vendor: GLY_20220214_0800

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Syrupy liquid, unctuous to the touch, colourless or almost colourless, clear, very hygroscopic.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification A	1,470 - 1,475	1,473		Refractive index	Contract Lab
Identification B	Conform	Conform		IR-spectrum	Contract Lab
TESTS					
Appearance of solution	Clear / colourless	Conform		10% m/V	Contract Lab
Acidity or alkalinity	≤ 0,2	0,1	ml	0,1 mol/l NaOH	Contract Lab
Refractive index	1,470 - 1,475	1,473			Contract Lab
Aldehydes	≤ 10	< 10	µg/g		Contract Lab
Esters	≥ 8,0	9,3	ml	0,1 mol/l HCl	Contract Lab
Impurity A and related substances	Conform	Conform		GC	Contract Lab
Impurity A	≤ 0,1	< 0,1	%		Contract Lab
Any other impurities tR < tR glycerol	≤ 0,1	< 0,1	%		Contract Lab
Total impurit. tR > tR glycerol	≤ 0,5	< 0,5	%		Contract Lab
Halogens	≤ 35	< 35	µg/g		Contract Lab
Sugars	Conform	Conform			Contract Lab
Chlorides	≤ 10	< 10	µg/g		Contract Lab
Water (Karl Fischer)	≤ 2,0	0,2	%		Contract Lab
Sulfated ash	≤ 0,01	< 0,01	%		Contract Lab
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					
Assay Propane-1, 2, 3-triol	98,0 - 101,0	99,0	%	Anhydrous subst.	Contract Lab

Quality: Excipient

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

Performed by: Ekocentrum

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

Date: 30.03.2022

Conclusion: **APPROVED**

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