



## Certificate of Analysis

**Productname:** Glycerolum 99,5%

**Inspection No:** J02755/0322/536

**Batchnumber:** 22B25-T04-093437

**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:** 92 x 5 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 <sup>3</sup>	< 10	CFU/g		Contract Lab
TYMC	≤ 2 x 10 <sup>2</sup>	< 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

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
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**Performed by:** Ekocentrum

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

**Date:** 30.03.2022

**Conclusion:** **APPROVED**

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