



## Certificate of Analysis

**Productname:** Glycerolum 99,5%

**Inspection No:** J02756/0322/536

**Batchnumber:** 22B25-T04-093451

**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:** 263 x 100 ml

**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 hydroskopic.	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% <i>m/V</i>	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**

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