



Certificate of Analysis

Productname: Glycerolum 99,5%

Inspection No: J11653/0223/536
Batchnumber: 22L12-T07-100391
Expiration date: 25.11.2024
Analysed according to: Ph.Eur.11.0
Original Manuf. Date: 25.11.2022

Sample Unit: 1 x 10 ml
Batch Size: 100 x 300 ml

Identification of producer: V01457
Batch no. of vendor: GLY_20221125_0730

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless or almost colourless, very hygroscopic, syrupy liquid, unctuous to the touch.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,470 - 1,475	1,473		Refractive index	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Clear / colourless	Conform		10% <i>m/V</i>	Fagron CZ
Acidity or alkalinity	≤0,2	0,1	ml	0,1 mol/l NaOH	Fagron CZ
Refractive index	1,470 - 1,475	1,473			Fagron CZ
Aldehydes	≤10	<10	ppm		Fagron CZ
Esters	≥8,0	9,6	ml	0,1 mol/l HCl	Fagron CZ
Impurity A and related substances	Conform	Conform		GC	Contract Lab
Impurity A	≤0,1	<0,05	%		Contract Lab
Any other impurities <i>tR</i> < <i>tR</i> glycerol	≤0,1	<0,05	%		Contract Lab
Total impurit. <i>tR</i> > <i>tR</i> glycerol	≤0,5	<0,05	%		Contract Lab
Halogens	≤35	<35	ppm		Fagron CZ
Sugars	Conform	Conform			Fagron CZ
Chlorides	≤10	<10	ppm		Fagron CZ
Water (Karl Fischer)	≤2,0	0,11	%		Fagron CZ
Sulfated ash	≤0,01	0,006	%		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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
ASSAY					
Assay Propane-1, 2, 3-triol	98,0 - 101,0	99,1	%	Anhydrous subst.	Fagron CZ

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: Ludmila Stochlebová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 17.01.2023

Conclusion: **APPROVED**

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