

Certificate of Analysis

Productname: Glycerolum 99,5%

Inspection No: I07808/0921/536
Batchnumber: 21107-T02-089557
Expiration date: 30.08.2023
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 30.8.2021

Sample Unit: 1 x 10 ml
Batch Size: 1 142 x 1 l

Identification of producer: V01457
Batch no. of vendor: GLY_20210830_0814

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Syrupy liquid,unctuous to the touch,colourless or almost colourless,clear,very hydroskopic.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,470 - 1,475	1,474		Rafractive 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	1,474			Fagron CZ
Aldehydes	<=10	<10	µg/g		Fagron CZ
Esters	>=8,0	9,2	ml	0,1 mol/l HCl	Fagron CZ
Impurity A and related substances	Conform	Conform		GC	Contract Lab
Impurity A	<=0,1	<0,1	%		Contract Lab
Any other impurities <i>tR</i> < <i>tR</i> glycerol	<=0,1	<0,1	%		Contract Lab
Total impurit. <i>tR</i> > <i>tR</i> glycerol	<=0,5	<0,5	%		Contract Lab
Halogens	<=35	<35	µg/g		Fagron CZ
Sugars	Conform	Conform			Fagron CZ
Chlorides	<=10	<10	µg/g		Fagron CZ
Water (Karl Fischer)	<=2,0	0,31	%		Fagron CZ
Sulfated ash	<=0,01	0	%		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	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	99,1	%	Anhydrous subst.	Fagron CZ

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 15.10.2021
Conclusion: **APPROVED**

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