

Certificate of Analysis

Productname: Glycerolum 99,5%

Inspection No: I07812/0921/536
Batchnumber: 21107-T02-089559
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: 900 x 100 ml

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 hygroscopic.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,470 - 1,475	1,474		Refractive index	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Clear / colourless	Conform		10% m/V	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 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		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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