

Certificate of Analysis

Productname: **Glycerolum**
Number of analysis/Inspection Code: 1 / KEUR-186872B
Batchnumber: **20I15-F02-374247**
Reference code / No.: 3635 / GLY_20200804_1515
Analysed according to: **PHEUR10.2+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Clear, (almost) colourless, unctuous to the touch,	Conform		Very hygroscopic !
Appearance	sirupy liquid	Conform		
Identification A	1,470 - 1,475	Conform		Refraction index
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		50% <i>m/V</i> / 25% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Refractive index	1,470 - 1,475	1,474		
Aldehydes	<=10	Conform	ppm	
Esters	Conform	Conform		
Impurity A and related substances	Conform	Conform		GC
Impurity A	<=0,1	0,0	%	
Any other impurity <i>Rt</i> < <i>Rt</i> glycerol	<=0,1	<0,05	%	
Total of all imp. <i>Rt</i> > <i>Rt</i> glycerol	<=0,5	0,0	%	
Halogenated compounds	<= 35	Conform	ppm	
Sugars	Conform	Conform		
Chlorides	<= 10	Conform	ppm	
Water (Karl Fischer)	<=2,0	0,2	%	
Sulphated ash	<= 0,01	0,00	%	
Absorbance	<=0,2	Conform		20% <i>m/V</i> ; house standard
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Propane-1, 2, 3-triol	98,0 - 101,0	100,4	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer



Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

Paul Hofman

Pharmacist - Qualified Person

11/09/20

Expiration: 08-2022

Conclusion: APPROVED

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