

## Certificate of Analysis

**Productname:** Propylenglycolum

**Inspection No:** I05649/0821/536  
**Batchnumber:** 21E25-T03-088477  
**Expiration date:** 12.04.2023  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 12.4.2021

**Sample Unit:** 0 x  
**Batch Size:** 2 147 x 250 ml

**Identification of producer:** V00709  
**Batch no. of vendor:** 24014556P0

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	A viscous, clear, colourless, hygroscopic liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,035 - 1,040	1,037		Relative density	Fagron CZ
Identification B	1,431 - 1,433	1,433		Refraction index	Fagron CZ
Identification C	184 - 189	186	°C	Boiling point	Fagron CZ
Identification D	121 - 128	124	°C	Melting temperature of crystals	Fagron CZ
TESTS					
Appearance	Clear / colourless	Conform			Fagron CZ
Relative density	1,035 - 1,040	1,037			Fagron CZ
Refractive index	1,431 - 1,433	1,433			Fagron CZ
Acidity	<=0,05	0,03	ml	0,1 mol/l NaOH	Fagron CZ
Oxidising substances	<=0,2	0,1	ml	0,05 mol/l Na2S2O3	Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Water (Karl Fischer)	<=0,2	0,2	%		Fagron CZ
Sulfated ash	<=0,01	0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	Conform	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

**Performed by:** Lucie Kubáňová DiS.  
**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QA  
**Date:** 23.08.2021  
**Conclusion:** **APPROVED**

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