



## Certificate of Analysis

**Productname:** Propylenglycolum

**Inspection No:** J02918/0622/536  
**Batchnumber:** 22C14-T01-095482  
**Expiration date:** 17.01.2024  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 17.1.2022

**Sample Unit:** 1 x 50 ml  
**Batch Size:** 35 x 5 l

**Identification of producer:** V00709  
**Batch no. of vendor:** 54630775L0

	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	1,036		Relative density	Fagron CZ
Identification B	1,431 - 1,433	1,432		Refraction index	Fagron CZ
Identification C	184 - 189	187	°C	Boiling point	Fagron CZ
Identification D	121 - 128	125	°C	Melting temperature of crystals	Fagron CZ
TESTS					
Appearance	Clear / colourless	Conform			Fagron CZ
Relative density	1,035 - 1,040	1,036			Fagron CZ
Refractive index	1,431 - 1,433	1,432			Fagron CZ
Acidity	<=0,05	0,04	ml	0,1 mol/l NaOH	Fagron CZ
Oxidising substances	<=0,2	0,1	ml	0,05 mol/l Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub>	Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Water (Karl Fischer)	<=0,2	0,03	%		Fagron CZ
Sulfated ash	<=0,01	0,00	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

Quality: Excipient

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**Performed by:** Ludmila Stochlebová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QA

**Date:** 07.04.2022

**Conclusion:** **APPROVED**

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