



## Certificate of Analysis

**Productname:** Propylenglycolum

**Inspection No:** K08126/1223/536  
**Batchnumber:** 23H04-T11-108994  
**Expiration date:** 21.02.2025  
**Analysed according to:** ČL 2017, Ph.Eur.11.0  
**Original Manuf. Date:** 22.2.2023

**Sample Unit:** 1 x 50 ml  
**Batch Size:** 285 x 250 ml

**Identification of producer:** V01648  
**Batch no. of vendor:** 21640336W0

	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	1,039		Relative density	Fagron CZ
Identification B	1,431 - 1,433	1,432		Refraction index	Fagron CZ
Identification C	184 - 189	188	°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	1,039			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 Na2S2O3	Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Water (Karl Fischer)	<=0,2	0,05	%		Fagron CZ
Sulfated ash	<=0,01	0,00	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
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**Performed by:** Ludmila Stochlebová

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

**Date:** 07.11.2023

**Conclusion:** **APPROVED**

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