



## Certificate of Analysis

**Productname:** Propylenglycolum

**Inspection No:** L01298/0124/536

**Batchnumber:** 24B02-T03-109507

**Expiration date:** 02.02.2025

**Analysed according to:** ČL 2023, Ph. Eur. 11.0

**Original Manuf. Date:** 3.2.2023

**Sample Unit:** 1 x 50 ml

**Batch Size:** 13 x 5 l

**Identification of producer:** V01648

**Batch no. of vendor:** 63518756P0

	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	185	°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	0,02	ml	0,1 mol/l NaOH	Fagron CZ
Oxidising substances	<=0,2	0,0	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	0,0	%		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

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
	Kontrolní laboratoř č. 536	<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** QC Fagron a.s. (CZ)

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

**Date:** 05.03.2024

**Conclusion:** **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.