



Certificate of Analysis

Productname: Propylenglycolum

Inspection No: K05670/0923/536

Batchnumber: 22J26-T06-107560

Expiration date: 05.06.2024

Analysed according to: ČL 2017, Ph.Eur.10.0

Original Manuf. Date: 6.6.2022

Sample Unit: 1 x 50 ml

Batch Size: 17 x 5 l

Identification of producer: V01648

Batch no. of vendor: 37825709T0

	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	1,432		Refraction index	Fagron CZ
Identification C	184 - 189	186	°C	Boiling point	Fagron CZ
Identification D	121 - 128	126	°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	1,432			Fagron CZ
Acidity	<=0,05	0,04	ml	0,1 mol/l NaOH	Fagron CZ
Oxidising substances	<=0,2	0,0	ml	0,05 mol/l Na ₂ S ₂ O ₃	Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Water (Karl Fischer)	<=0,2	0,02	%		Fagron CZ
Sulfated ash	<=0,01	0,00	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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

Performed by: Ing. Petra Drábková

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

Date: 11.10.2023

Conclusion: **APPROVED**

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