



## Certificate of Analysis

**Productname:** **Macrogolum 400**

**Inspection No:** L01185/0524/536  
**Batchnumber:** **23H17-T02-110743**  
**Expiration date:** 13.06.2025  
**Analysed according to:** Ph.Eur.11.0  
**Original Manuf. Date:** 13.6.2023

**Sample Unit:** 1 x 50 ml  
**Batch Size:** 116 x 250 ml

**Identification of producer:** V01621  
**Batch no. of vendor:** 02317403

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, viscous, (almost) colorless hygroscopic liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Viscosity	Fagron CZ
kinematic	94 - 116	100	mm <sup>2</sup> .s-1		Fagron CZ
dynamic	105 - 130	112	mPa.s	20°C	Fagron CZ
Identification B	Conform	Conform		White precipitate	Fagron CZ
Identification C	Conform	Conform		Blue liquid phase	Fagron CZ
TESTS					
Appearance of solution	Clear/ <=BY6	Conform			Fagron CZ
Acidity or alkalinity	<=0,1	0,07	ml	0,1 mol/l NaOH	Fagron CZ
Viscosity	Conform	Conform			Fagron CZ
kinematic	94 - 116	100	mm <sup>2</sup> .s-1		Fagron CZ
dynamic	105 - 130	112	mPa.s	20°C	Fagron CZ
Hydroxyl value	264 - 300	277			Fagron CZ
Reducing substances	<=R3	Conform			Fagron CZ
Formaldehyde	<=30	<30	ppm		Fagron CZ
(Di-)ethyleneglycol	<=0,4	<0,4	%		Contract Lab
Ethylene oxide	<=1	0,3	ppm		Contract Lab
Dioxan	<=10	<4	ppm		Contract Lab
Water (Karl Fischer)	<=2,0	0,2	%		Fagron CZ
Sulfated ash	<=0,2	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:** Ludmila Burianová

**Responsible:** Mgr. Barbora Vránová, QC  
MVDr. Zdenka Borská, QP

**Date:** 27.02.2024

**Conclusion:** **APPROVED**

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