



Certificate of Analysis

Productname: **Macrogolum 400**

Inspection No: I09857/1221/536
Batchnumber: **21K08-T12-090290**
Expiration date: 02.07.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 2.7.2021

Sample Unit: 1 x 50 ml
Batch Size: 127 x 1 l

Identification of producer: V01621
Batch no. of vendor: 02119501

	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	104	mm ² .s ⁻¹		Fagron CZ
dynamic	105 - 130	117	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	0,05	ml	0,1 mol/l NaOH	Fagron CZ
Viscosity	Conform	Conform			Fagron CZ
kinematic	94 - 116	104	mm ² .s ⁻¹		Fagron CZ
dynamic	105 - 130	117	mPa.s	20°C	Fagron CZ
Hydroxyl value	264 - 300	285			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	<0,2	ppm		Contract Lab
Dioxan	<=10	<2,5	ppm		Contract Lab
Water (Karl Fischer)	<=2,0	0,12	%		Fagron CZ
Sulfated ash	<=0,2	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	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: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA
Date: 10.12.2021
Conclusion: **APPROVED**

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