

Certificate of Analysis

Productname: **Macrogolum 400**

Inspection No: I06952/0821/536
Batchnumber: **21C22-B06-085758**
Expiration date: 25.02.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 25.2.2021

Sample Unit: 0 x
Batch Size: 60 x 100 ml

Identification of producer: V01621
Batch no. of vendor: 02106001

	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	108	mm ² .s ⁻¹		Fagron CZ
dynamic	105 - 130	121	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 PL
Acidity or alkalinity	<=0,1	<0,1	ml	0,1 mol/l NaOH	Fagron PL
Viscosity	Conform	Conform			Fagron CZ
kinematic	94 - 116	108	mm ² .s ⁻¹		Fagron CZ
dynamic	105 - 130	121	mPa.s	20°C	Fagron CZ
Hydroxyl value	264 - 300	275			Fagron PL
Reducing substances	<=R3	Conform			Fagron PL
Formaldehyde	<=30	10,7	ppm		Fagron PL
(Di-)ethyleneglycol	<=0,4	<0,4	%		Fagron PL
Ethylene oxide	<=1	<1	ppm		Fagron PL
Dioxan	<=10	<10	ppm		Fagron PL
Water (Karl Fischer)	<=2,0	0,11	%		Fagron PL
Sulfated ash	<=0,2	0,06	%		Fagron PL
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

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

Performed by: Lenka Morávková

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 03.09.2021 

Conclusion: **APPROVED**

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