



Certificate of Analysis

Productname: **Macrogolum 400**

Inspection No: K07327/1123/536
Batchnumber: **23H17-T02-107305**
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: 108 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 ² .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 ² .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 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

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| 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: Ludmila Burianová

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

Date: 23.10.2023

Conclusion: **APPROVED**

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