



## Certificate of Analysis

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

**Inspection No:** J08912/1022/536  
**Batchnumber:** **22I02-T06-098692**  
**Expiration date:** 22.08.2024  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 22.8.2022

**Sample Unit:** 1 x 50 ml  
**Batch Size:** 55 x 100 ml

**Identification of producer:** V01621  
**Batch no. of vendor:** 02223701

|                        | 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   | 97      | mm <sup>2</sup> .s <sup>-1</sup> |                   | Fagron CZ     |
| dynamic                | 105 - 130  | 109     | 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  | 0,06    | ml                               | 0,1 mol/l NaOH    | Fagron CZ     |
| Viscosity              | Conform  | Conform |                                  |                   | Fagron CZ     |
| kinematic              | 94 - 116   | 97      | mm <sup>2</sup> .s <sup>-1</sup> |                   | Fagron CZ     |
| dynamic                | 105 - 130  | 109     | mPa.s                            | 20°C              | Fagron CZ     |
| Hydroxyl value         | 264 - 300  | 290     |                                  |                   | 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  | 0,11    | %                                |                   | 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:** Ing. Petra Drábková

**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QP

**Date:** 11.10.2022

**Conclusion:** **APPROVED**

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