



## Certificate of Analysis

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

**Inspection No:** J02341/0422/536  
**Batchnumber:** **21K08-T12-093716**  
**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:** 122 x 100 ml

**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 <sup>2</sup> .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 <sup>2</sup> .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 <sup>3</sup>                                  | Conform | CFU/g                |                   | Contract Lab  |
| TYMC                   | <=2 x 10 <sup>2</sup>                                  | 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

|             |                            |                  |                           |                  |                  |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| <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:** Lucie Kubáňová DiS.

**Responsible:** Ing. Pavel Mišák, QC  
PharmDr. Ivana Urbánková, QA

**Date:** 22.04.2022

**Conclusion:** **APPROVED**

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