



## Certificate of Analysis

**Productname:** Glycerolum 99,5%

**Inspection No:** K06228/1023/536

**Batchnumber:** 23E09-T03-106106

**Expiration date:** 11.04.2025

**Analysed according to:** ČL 2017-Dopl.2022, Ph.Eur. 11.0

**Original Manuf. Date:** 11.4.2023

**Sample Unit:** 1 x 10 ml

**Batch Size:** 31 x 300 ml

**Identification of producer:** V01457

**Batch no. of vendor:** GLY\_20230411\_0930

|                                     | Requirement   | Result  | Unit  | Standard remark  | Insp. Site    |
|-------------------------------------|---|---------|-------|------------------|---------------|
| CHARACTERS                          |   |         |       |                  |               |
| Appearance                          | Clear, colourless or almost colourless, very hygroscopic, syrupy liquid, unctuous to the touch. | Conform |       |                  | Fagron CZ     |
| Solubility                          | Conform   | Conform |       |                  | Fagron CZ     |
| IDENTIFICATION                      |   |         |       |                  |               |
| Identification A                    | 1,470 - 1,475   | 1,473   |       | Refractive index | Fagron CZ     |
| Identification B                    | Conform   | Conform |       | IR-spectrum      | Fagron CZ     |
| TESTS                               |   |         |       |                  |               |
| Appearance of solution              | Clear / colourless  | Conform |       | 10% <i>m/V</i>   | Fagron CZ     |
| Acidity or alkalinity               | <=0,2   | 0,1     | ml    | 0,1 mol/l NaOH   | Fagron CZ     |
| Refractive index                    | 1,470 - 1,475   | 1,473   |       |                  | Fagron CZ     |
| Aldehydes                           | <=10  | <10     | ppm   |                  | Fagron CZ     |
| Esters                              | >=8,0   | 8,8     | ml    | 0,1 mol/l HCl    | Fagron CZ     |
| Impurity A and related substances   | Conform   | Conform |       | GC               | Contract Lab  |
| Impurity A                          | <=0,1   | <0,05   | %     |                  | Contract Lab  |
| Any other impurities tR<tR glycerol | <=0,1   | <0,05   | %     |                  | Contract Lab  |
| Total impurit. tR>tR glycerol       | <=0,5   | <0,05   | %     |                  | Contract Lab  |
| Halogens                            | <=35  | <35     | ppm   |                  | Fagron CZ     |
| Sugars                              | Conform   | Conform |       |                  | Fagron CZ     |
| Chlorides                           | <=10  | <10     | ppm   |                  | Fagron CZ     |
| Water (Karl Fischer)                | <=2,0   | 0,18    | %     |                  | Fagron CZ     |
| Sulfated ash                        | <=0,01  | 0,00    | %     |                  | 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                   | ICH Q3C   | Conform |       |                  | Data Producer |
| Metallic residues                   | ICH Q3D   | Conform |       |                  | Data Producer |
| ASSAY                               |   |         |       |                  |               |
| Assay Propane-1, 2, 3-triol         | 98,0 - 101,0  | 98,2    | %     | Anhydrous subst. | Fagron CZ     |

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:** Ludmila Stochlebová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 17.10.2023

**Conclusion:** **APPROVED**

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