



Certificate of Analysis

Productname: Glycerolum 99,5%

Inspection No: J07576/0922/536
Batchnumber: 22H01-T03-097552
Expiration date: 18.07.2024
Analysed according to: Ph.Eur.10.8
Original Manuf. Date: 18.7.2022

Sample Unit: 1 x 10 ml
Batch Size: 375 x 5 l

Identification of producer: V01457
Batch no. of vendor: GLY_20220718_0720

| | 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 | 1,472 | | 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 | 1,472 | | | Fagron CZ |
| Aldehydes | <=10 | <10 | ppm | | Fagron CZ |
| Esters | >=8,0 | 9,1 | ml | 0,1 mol/l HCl | Fagron CZ |
| Impurity A and related substances | Conform | Conform | | GC | Contract Lab |
| Impurity A | <=0,1 | <0,1 | % | | Contract Lab |
| Any other impurities tR<tR glycerol | <=0,1 | <0,1 | % | | Contract Lab |
| Total impurit. tR>tR glycerol | <=0,5 | <0,5 | % | | Contract Lab |
| Halogens | <=35 | <35 | ppm | | Fagron CZ |
| Sugars | Conform | Conform | | | Fagron CZ |
| Chlorides | <=10 | <10 | ppm | | Fagron CZ |
| Water (Karl Fischer) | <=2,0 | 0,2 | % | | Fagron CZ |
| Sulfated ash | <=0,01 | 0,00 | % | | 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 | ICH Q3C | Conform | | | Data Producer |
| Metallic residues | ICH Q3D | Conform | | | Data Producer |
| ASSAY | | | | | |
| Assay Propane-1, 2, 3-triol | 98,0 - 101,0 | 98,5 | % | Anhydrous subst. | Fagron CZ |

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 Stochlebová

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

Date: 31.08.2022

Conclusion: **APPROVED**

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