



Certificate of Analysis

Productname: Polysorbatum 80

Inspection No: K05689/0823/536
Batchnumber: 22L16-T01-104769
Expiration date: 30.06.2025
Analysed according to: Ph.Eur.11.2
Original Manuf. Date: 29.6.2022

Sample Unit: 1 x 10 ml
Batch Size: 192 x 250 ml

Identification of producer: V01687
Batch no. of vendor: 1/2544304

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------------|---|---------|-------|----------------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Oily, colourless or brownish-yellow, clear. or slightly opalescent liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| Relative density | About 1,10 | 1,10 | | | Fagron CZ |
| Viscosity | About 400 | Asi 400 | mPa.s | 25 °C | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | IR-spectrum | Fagron CZ |
| Identification D | Conform | Conform | | Composition of fatty acids | Contract Lab |
| TESTS | | | | | |
| Acid value | <=2,0 | 0,21 | | | Fagron CZ |
| Hydroxyl value | 65 - 80 | 70 | | | Fagron CZ |
| Peroxide value | <=10,0 | 0,456 | | | Fagron CZ |
| Saponification value | 45 - 55 | 49 | | | Fagron CZ |
| Composition of fatty acids | Conform | Conform | | GC | Contract Lab |
| Myristic acid | <=5,0 | 0,1 | % | | Contract Lab |
| Palmitic acid | <=16,0 | 14,0 | % | | Contract Lab |
| Palmitoleic acid | <=8,0 | 0,8 | % | | Contract Lab |
| Stearic acid | <=6,0 | 3,7 | % | | Contract Lab |
| Oleic acid | >=58,0 | 75,6 | % | | Contract Lab |
| Linoleic acid | <=18,0 | 0,5 | % | | Contract Lab |
| Linolenic acid | <=4,0 | <0,05 | % | | Contract Lab |
| Ethylene oxide | <=1 | <0,3 | ppm | GC | Contract Lab |
| Dioxane | <=10 | <3,5 | ppm | GC | Contract Lab |
| Water | <=3,0 | 2,5 | % | Karl Fischer | Fagron CZ |
| Total ash | <=0,25 | 0,11 | % | | 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 |

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. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 23.08.2023

Conclusion: **APPROVED**

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