

Certificate of Analysis

Productname: Polysorbatum 80

Inspection No: I08910/1121/536
Batchnumber: 21J07-T03-090745
Expiration date: 31.08.2023
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 5.8.2021

Sample Unit: 1 x 10 ml
Batch Size: 410 x 100 ml

Identification of producer: V01687
Batch no. of vendor: 2525731

| | 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 | 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 | 0,05 | | | Fagron CZ |
| Hydroxyl value | 65 - 80 | 73 | | | Fagron CZ |
| Peroxide value | <=10,0 | 0,356 | | | 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 | 15,3 | % | | Contract Lab |
| Palmitoleic acid | <=8,0 | 0,8 | % | | Contract Lab |
| Stearic acid | <=6,0 | 3,8 | % | | Contract Lab |
| Oleic acid | >=58,0 | 78,4 | % | | Contract Lab |
| Linoleic acid | <=18,0 | 0,1 | % | | Contract Lab |
| Linolenic acid | <=4,0 | <0,1 | % | | Contract Lab |
| Ethylene oxide | <=1 | <0,2 | µg/g | GC | Contract Lab |
| Dioxane | <=10 | <2,5 | µg/g | GC | Contract Lab |
| Water | <=3,0 | 2,7 | % | Karl Fischer | Fagron CZ |
| Total ash | <=0,25 | 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 | CPMP/ICH/82 260/2006 | Conform | | | Data Producer |
| Metallic residues | ICH Q3D on elemental impurities | Conform | | | Data Producer |

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| 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: Lucie Kubáňová DIS.

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

Date: 19.11.2021

Conclusion: **APPROVED**

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

| | | | | | |
|-------------|--|------------------|---------------------------|------------------|------------------|
| Name | Fagron a.s. (CZ) Kontrolní laboratoř č. 536 | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
| | | Post Code | 779 00 | Fax No. | +420 585 226 521 |