

## Certificate of Analysis

**Productname:** Polysorbatum 80  
**Inspection No:** J09992/0223/536 **Sample Unit:** 1 x 10 ml  
**Batchnumber:** 22C07-T01-101027 **Batch Size:** 98 x 250 ml  
**Expiration date:** 30.11.2023  
**Analysed according to:** ČL 2017-Dopl.2020,Ph.Eur.10.0  
**Original Manuf. Date:** 18.11.2021  
**Identification of producer:** V01687  
**Batch no. of vendor:** 1/2531129

|                            | Requirement  | Result  | Unit  | Standard remark            | Insp. Site    |
|----------------------------|--|---------|-------|----------------------------|---------------|
| <b>CHARACTERS</b>          |  |         |       |                            |               |
| Appearance                 | Oily, colourless or brownish-yellow, clear. or slightly opalescent liquid. | Conform |       |                            | Contract Lab  |
| Solubility                 | Conform  | Conform |       |                            | Contract Lab  |
| Relative density           | About 1,10   | 1,08    |       |                            | Contract Lab  |
| Viscosity                  | About 400  | 483     | mPa.s | 25 °C                      | Contract Lab  |
| <b>IDENTIFICATION</b>      |  |         |       |                            |               |
| Identification A           | Conform  | Conform |       | IR-spectrum                | Contract Lab  |
| Identification D           | Conform  | Conform |       | Composition of fatty acids | Contract Lab  |
| <b>TESTS</b>               |  |         |       |                            |               |
| Acid value                 | <=2,0  | 0,3     |       |                            | Contract Lab  |
| Hydroxyl value             | 65 - 80  | 75      |       |                            | Contract Lab  |
| Peroxide value             | <=10,0   | 0,8     |       |                            | Contract Lab  |
| Saponification value       | 45 - 55  | 47      |       |                            | Contract Lab  |
| Composition of fatty acids | Conform  | Conform |       | GC                         | Contract Lab  |
| Myristic acid              | <=5,0  | 0,1     | %     |                            | Contract Lab  |
| Palmitic acid              | <=16,0   | 16,0    | %     |                            | Contract Lab  |
| Palmitoleic acid           | <=8,0  | 0,9     | %     |                            | Contract Lab  |
| Stearic acid               | <=6,0  | 3,8     | %     |                            | Contract Lab  |
| Oleic acid                 | >=58,0   | 75,7    | %     |                            | Contract Lab  |
| Linoleic acid              | <=18,0   | <0,1    | %     |                            | Contract Lab  |
| Linolenic acid             | <=4,0  | <0,1    | %     |                            | 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               | Contract Lab  |
| Total ash                  | <=0,25   | 0,05    | %     |                            | Contract Lab  |
| 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 |

Quality: Excipient

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

**Performed by:** Ekocentrum

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

**Date:** 23.11.2022

**Conclusion:** **APPROVED**

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|-------------|--|------------------|---------------------------|------------------|------------------|
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