



Certificate of Analysis

Productname: Dimeticonum 350

Inspection No: K01737/0523/536
Batchnumber: 21I21-T08-102642
Expiration date: 05.07.2027
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 6.7.2021

Sample Unit: 1 x 100 ml
Batch Size: 13 x 100 ml

Identification of producer: V01085
Batch no. of vendor: B093005

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------|---|---------|---------|---------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Clear, colourless viscous liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | 315 - 385 | 362 | mm2.s-1 | Kinematic viscosity | Fagron CZ |
| Identification B | Conform | Conform | | IR-spectrum | Fagron CZ |
| Identification C | Violet | Conform | | | Fagron CZ |
| Identification D | White | Conform | | Silicates | Fagron CZ |
| TESTS | | | | | |
| Acidity | <=0,15 | 0,10 | ml | 0,01 mol/l NaOH | Fagron CZ |
| Kinematic viscosity | 315 - 385 | 362 | mm2.s-1 | 25°C | Fagron CZ |
| Mineral oils | Conform | Conform | | | Fagron CZ |
| Phenylated compounds | Conform | Conform | | | Fagron CZ |
| Volatile matter | <=0,3 | 0,03 | % | 2 h 150 °C | 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 |

Densitiv:0,9734

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| 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, QP

Date: 26.05.2023

Conclusion: **APPROVED**

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