

Certificate of Analysis

Productname: Dimeticonum 350

Inspection No: H01314/0420/536
Batchnumber: 19L30-T04-074244
Expiration date: 09.07.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 11.7.2019

Sample Unit: 1 x 100 ml
Batch Size: 101 x 100 ml

Identification of producer: V01085
Batch no. of vendor: B067181

	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	356	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	0,12	ml	0,01 mol/l NaOH	Fagron CZ
Kinematic viscosity	315 - 385	356	mm2.s-1	25°C	Fagron CZ
Mineral oils	Conform	Conform			Fagron CZ
Phenylated compounds	Conform	Conform			Fagron CZ
Volatile matter	≤0,3	0,07	%	2 h 150 °C	Fagron CZ
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

Density: 0,9767 g/cm³
 Excipient

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Kateřina Jokešová, QC
 PharmDr. Ivana Urbánková, QA

Date: 30.04.2020

Conclusion: APPROVED

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