



Certificate of Analysis

Productname: Dimeticonum 350

Inspection No: J08236/1022/536
Batchnumber: 22B25-T02-098671
Expiration date: 28.10.2027
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 29.10.2021

Sample Unit: 1 x 100 ml
Batch Size: 5 x 100 ml

Identification of producer: V01085
Batch no. of vendor: B097527

	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	0,09	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	0,0	%	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

Density: 0,9729 g/cm³

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: Ing. Petra Drábková

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

Date: 16.09.2022

Conclusion: **APPROVED**

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