



Certificate of Analysis

Productname: DIMETHYLSULFOXIDE

Inspection No: K03959/0823/536

Batchnumber: 23A16-T06-104756

Expiration date: 31.12.2025

Analysed according to: ČL 2017-Dopl.2021, Ph.Eur. 11.0

Original Manuf. Date: 16.12.2022

Sample Unit: 1 x 5 ml

Batch Size: 14 x 100 ml

Identification of producer: V01106

Batch no. of vendor: 98970

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless liquid or colourless crystals, hygroscopic.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification C	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Acidity	<= 5,0	1,1	ml	0,01 M NaOH	Fagron CZ
Relative density	1,100 - 1,104	1,102			Fagron CZ
Refractive index	1,478 - 1,480	1,479			Fagron CZ
Freezing point	>=18,3	18,3	°C		Fagron CZ
Absorbance 275 nm	<= 0,30	0,16			Fagron CZ
Absorbance 285 nm	<= 0,20	0,10			Fagron CZ
Absorbance 295 nm	<= 0,20	0,083			Fagron CZ
Absorbance at 270-350 nm	No absorption max. observed	Conform			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
Unspecified impurities	<= 0,10	<0,05	%		Contract Lab
Total impurities	<=0,15	<0,05	%		Contract Lab
Water	<=0,2	0,04	%		Contract Lab
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

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: Ludmila Stochlebová

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

Date: 30.08.2023

Conclusion: **APPROVED**

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