

Certificate of Analysis

Productname: DIMETHYLSULFOXIDE

Inspection No: I01739/0321/536
Batchnumber: 21A12-T06-084735
Expiration date: 21.01.2024
Analysed according to: Ph.Eur.10.3
Original Manuf. Date: 21.1.2020

Sample Unit: 1 x 5 ml
Batch Size: 197 x 100 ml

Identification of producer: V01458
Batch no. of vendor: USP200117

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless liquid or colourless crystals, hygroscopic.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification C	Conform	Conform		IR-spectrum	Contract Lab
TESTS					
Acidity	<= 5,0	1,6	ml	0,01 M NaOH	Contract Lab
Relative density	1,100 - 1,104	1,102			Contract Lab
Refractive index	1,478 - 1,480	1,479			Contract Lab
Freezing point	>=18,3	18,4	°C		Contract Lab
Absorbance 275 nm	<= 0,30	0,18			Contract Lab
Absorbance 285 nm	<= 0,20	0,10			Contract Lab
Absorbance 295 nm	<= 0,20	0,07			Contract Lab
Absorbance at 270-350 nm	No absorption max. observed	Conform			Contract Lab
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	0,1	%		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

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

Performed by: External/Ekocentrum

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

Date: 17.03.2021

Conclusion: **APPROVED**

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