

Certificate of Analysis

Productname: DIMETHYLSULFOXIDE

Inspection No: I07956/1121/536
 Batchnumber: **21106-T01-090764**
 Expiration date: 31.03.2025
 Analysed according to: Ph.Eur.10.3
 Original Manuf. Date: 16.3.2021

Sample Unit: 1 x 5 ml
 Batch Size: 20 x 1 l

Identification of producer: V01458
 Batch no. of vendor: USP210312

	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	$\leq 5,0$	0,7	ml	0,01 M NaOH	Contract Lab
Relative density	1,100 - 1,104	1,102			Contract Lab
Refractive index	1,478 - 1,480	1,478			Contract Lab
Freezing point	$\geq 18,3$	18,4	°C		Contract Lab
Absorbance 275 nm	$\leq 0,30$	0,11			Contract Lab
Absorbance 285 nm	$\leq 0,20$	0,05			Contract Lab
Absorbance 295 nm	$\leq 0,20$	0,03			Contract Lab
Absorbance at 270-350 nm	No absorption max. observed	Conform			Contract Lab
Related substances	Conform	Conform		GC	Contract Lab
Unspecified impurities	$\leq 0,10$	$<0,05$	%		Contract Lab
Total impurities	$\leq 0,15$	$<0,05$	%		Contract Lab
Water	$\leq 0,2$	$<0,1$	%		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: Ekocentrum

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 27.10.2021

Conclusion: **APPROVED**

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