

Certificate of Analysis

Productname: DIMETHYLSULFOXIDE

Inspection No: I07922/1021/536
Batchnumber: 21106-T01-090252
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: 605 x 100 ml

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

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Performed by: Ekocentrum

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

Date: 15.10.2021

Conclusion: APPROVED

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

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