



Certificate of Analysis

Productname: DIMETHYLSULFOXIDE

Inspection No: J03395/0322/536

Batchnumber: 22C14-T02-093456

Expiration date: 31.10.2025

Analysed according to: ČL 2017-Dopl.2021, Ph.Eur. 10.3

Original Manuf. Date: 26.10.2021

Sample Unit: 1 x 5 ml

Batch Size: 56 x 250 ml

Identification of producer: V01458

Batch no. of vendor: USP211019

	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	5,0	ml	0,01 M NaOH	Fagron CZ
Relative density	1,100 - 1,104	1,102			Fagron CZ
Refractive index	1,478 - 1,480	1,478			Fagron CZ
Freezing point	>=18,3	18,5	°C		Fagron CZ
Absorbance 275 nm	<= 0,30	0,090			Fagron CZ
Absorbance 285 nm	<= 0,20	0,038			Fagron CZ
Absorbance 295 nm	<= 0,20	0,030			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	<0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 20.04.2022

Conclusion: **APPROVED**

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