



## Certificate of Analysis

**Productname:** DIMETHYLSULFOXIDE

**Inspection No:** K09960/0124/536

**Batchnumber:** 23F27-T05-110154

**Expiration date:** 30.06.2026

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

**Original Manuf. Date:** 1.6.2023

**Sample Unit:** 1 x 5 ml

**Batch Size:** 112 x 100 ml

**Identification of producer:** V01106

**Batch no. of vendor:** 101289

	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	0,6	ml	0,01 M NaOH	Fagron CZ
Relative density	1,100 - 1,104	1,103			Fagron CZ
Refractive index	1,478 - 1,480	1,478			Fagron CZ
Freezing point	>=18,3	19,3	°C		Fagron CZ
Absorbance 275 nm	<= 0,30	0,25			Fagron CZ
Absorbance 285 nm	<= 0,20	0,15			Fagron CZ
Absorbance 295 nm	<= 0,20	0,096			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	0,02	%		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

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

**Performed by:** Ludmila Burianová

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

**Date:** 10.01.2024

**Conclusion:** **APPROVED**

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