

Certificate of Analysis

Productname: **Dexpanthenolum**

Inspection No: H04500/0520/536
 Batchnumber: **20D16-T16-080049**
 Expiration date: 22.01.2023
 Analysed according to: ČL 2017, Ph.Eur.10.0
 Original Manuf. Date: 23.1.2020

Sample Unit: 0 x
 Batch Size: 500 x 250 g

Identification of producer: V01538
 Batch no. of vendor: TL02001009

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	A colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	+29,0 - +32,0	+30,1		Specific optical rotation (anhydrous)	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Clear / ≤B6	Conform		5% <i>m/V</i>	Fagron CZ
pH	≤10,5	9,92		5% <i>m/V</i>	Fagron CZ
Specific optical rotation	+29,0 - +32,0	+30,1		anhydrous	Fagron CZ
3-Aminopropanol	≤0,5	<0,5	%	TLC	Fagron CZ
Water	≤1,0	0,29	%	Karl Fischer	Fagron CZ
Sulfated ash	≤0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	≤2 x 10 ²	Conform	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
ASSAY					
Dexpanthenol	98,0 - 101,0	98,9	%	Anhydrous	Fagron CZ

Performed by: Lucie Kubáňová

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

Date: 23.06.2020

Conclusion: **APPROVED**

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