



Certificate of Analysis

Productname: Dexpanthenolum

Inspection No: J09289/1222/536
Batchnumber: 22G22-T05-099537
Expiration date: 07.12.2024
Analysed according to: Ph.Eur.10.6
Original Manuf. Date: 8.12.2021

Sample Unit: 1 x 30 g
Batch Size: 88 x 25 g

Identification of producer: V00709
Batch no. of vendor: 96412309T0

	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	+29,3		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	9,32		5% <i>m/V</i>	Fagron CZ
Specific optical rotation	+29,0 - +32,0	+29,3		anhydrous	Fagron CZ
Impurity A and amino compounds	<=1,0	0,4	%		Contract Lab
Related substances	Conform	Conform		HPLC	Contract Lab
Impurity C	<= 1,0	< 0,05	%		Contract Lab
Impurity B	<= 0,5	0,5	%		Contract Lab
Unspecified impurities	<= 0,10	< 0,05	%		Contract Lab
Total impurities	<=2,0	0,5	%		Contract Lab
Water	<=1,0	0,45	%	Karl Fischer	Fagron CZ
Sulfated ash	<=0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	< 10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	< 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
ASSAY					
Dexpanthenol	98,0 - 101,0	99,9	%	Anhydrous	Contract Lab

Quality: API

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: Pavla Šlězarová

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QP

Date: 23.11.2022

Conclusion: **APPROVED**

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