



## Certificate of Analysis

**Productname:** Dexpanthenolum

**Inspection No:** J07655/0922/536  
**Batchnumber:** 22G22-T04-097546  
**Expiration date:** 27.01.2025  
**Analysed according to:** Ph.Eur.10.6  
**Original Manuf. Date:** 28.1.2022

**Sample Unit:** 1 x 30 g  
**Batch Size:** 19 x 25 g

**Identification of producer:** V00709  
**Batch no. of vendor:** 66885924U0

	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	+31,0		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	9,73		5% <i>m/V</i>	Fagron CZ
Specific optical rotation	+29,0 - +32,0	+31,0		anhydrous	Fagron CZ
Impurity A and amino compounds	<=1,0	0,3	%		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	0,12	%	Karl Fischer	Fagron CZ
Sulfated ash	<=0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	< 10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	< 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	98,7	%	Anhydrous	Contract Lab

Quality: API

<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:** Pavla Šlězarová

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

**Date:** 31.08.2022

**Conclusion:** **APPROVED**

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