



## Certificate of Analysis

**Productname:** Dexpanthenolum

**Inspection No:** K08057/1123/536  
**Batchnumber:** 23E11-T01-108942  
**Expiration date:** 08.01.2026  
**Analysed according to:** Ph.Eur.11.1  
**Original Manuf. Date:** 9.1.2023

**Sample Unit:** 1 x 30 g  
**Batch Size:** 4 x 100 g

**Identification of producer:** V01648  
**Batch no. of vendor:** 45484209T0

	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	+29,7		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	8,81		5% <i>m/V</i>	Fagron CZ
Specific optical rotation	+29,0 - +32,0	+29,7		anhydrous	Fagron CZ
Impurity A and amino compounds	<=1,0	0,30	%		Fagron PL
Related substances	Conform	Conform		HPLC	Fagron PL
Impurity C	<= 1,0	0,46	%		Fagron PL
Impurity B	<= 0,5	0,08	%		Fagron PL
Unspecified impurities	<= 0,10	<0,05	%		Fagron PL
Total impurities	<=2,0	0,54	%		Fagron PL
Water	<=1,0	0,090	%	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	98,80	%	Anhydrous	Fagron PL

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:** Ludmila Burianová

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

**Date:** 09.11.2023

**Conclusion:** **APPROVED**

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