



## Certificate of Analysis

**Productname:** Dexpanthenolum

**Inspection No:** K06312/1023/536

**Batchnumber:** 23B02-T02-107998

**Expiration date:** 11.09.2025

**Analysed according to:** ČL 2017-Dopl.2022, Ph.Eur. 11.0

**Original Manuf. Date:** 12.9.2022

**Sample Unit:** 1 x 30 g

**Batch Size:** 72 x 25 g

**Identification of producer:** V01648

**Batch no. of vendor:** 01617129U0

	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	+29,5		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	10,0		5% <i>m/V</i>	Fagron CZ
Specific optical rotation	+29,0 - +32,0	+29,5		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	0,1	%		Contract Lab
Impurity B	<= 0,5	<0,1	%		Contract Lab
Unspecified impurities	<= 0,10	<0,05	%		Contract Lab
Total impurities	<=2,0	0,1	%		Contract Lab
Water	<=1,0	0,077	%	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	100,2	%	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:** Ing. Petra Drábková

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

**Date:** 13.09.2023

**Conclusion:** **APPROVED**

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