



## Certificate of Analysis

**Productname:** Dexpanthenolum

**Inspection No:** L02402/0524/536  
**Batchnumber:** 23E11-T01-112106  
**Expiration date:** 08.01.2026  
**Analysed according to:** Ph.Eur.11.1

**Customer:** FAGRON a.s.  
**Sample Unit:** 1 x 30 g  
**Batch Size:** 10 x 25 g

**Batch no. of vendor:** 45484209T0

	Requirement	Result	Unit	Standard remark
<b>CHARACTERS</b>				
Appearance	A colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder.	Conform		
Solubility	Conform	Conform		
<b>IDENTIFICATION</b>				
Identification A	+29,0 - +32,0	+29,7		Specific optical rotation (anhydrous)
Identification B	Conform	Conform		IR-spectrum
<b>TESTS</b>				
Appearance of solution	Clear / <=B6	Conform		5% <i>m/V</i>
pH	<=10,5	8,81		5% <i>m/V</i>
Specific optical rotation	+29,0 - +32,0	+29,7		anhydrous
Impurity A and amino compounds	<=1,0	0,30	%	
Related substances	Conform	Conform		HPLC
Impurity C	<= 1,0	0,46	%	
Impurity B	<= 0,5	0,08	%	
Unspecified impurities	<= 0,10	<0,05	%	
Total impurities	<=2,0	0,54	%	
Water	<=1,0	0,090	%	Karl Fischer
Sulfated ash	<=0,1	0,0	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g	
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	CPMP/ICH/82 260/2006	Conform		
Metallic residues	ICH Q3D on elemental impurities	Conform		
<b>ASSAY</b>				
Dexpanthenol	98,0 - 101,0	98,80	%	Anhydrous

Quality: API

<b>Name</b>	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
		<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** QC Fagron a.s. (CZ)  
**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QA/ QP  
**Date:** 17.04.2024

**Conclusion:** **APPROVED**

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

<b>Name</b>	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
		<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521