

Certificate of analysis



Article	4060	Dexpanthenol, API	
Synonym		Alcohol pantothenylicus, Dexpanthenolum	
Synonym		Dexpanthenol, API	
Batch	24001962		
Specification	Ph.Eur. 11.1		
Production date	06.2023	Retest date	06.2026

Test	Specification	Result	
Characters	According to specification	Complies	
Appearance	According to specification	Complies	
Solubility	According to specification	Complies	
Identification	According to specification	Complies	
A	According to specification	Complies	
IR spectrophotometry	According to specification	Complies	
Raman spectrophotometry	According to specification	Complies	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
pH-Value	Max. 10.5	10.0	
Specific optical rotation	29.0 ... 32.0	31.4	
Impurity A and other amino compounds	Max. 1.0 %	0.4 %	#
Related substances	According to specification	Complies	
Impurity C	Max. 1.0 %	0.5 %	
Impurity B	Max. 0.5 %	0.1 %	
Each unspecified impurity	Max. 0.10 %	< 0.05 %	
Total of all impurities	Max. 2.0 %	< 0.1 %	
Water	Max. 1.0 %	0.3 %	
Sulphated ash	Max. 0.1 %	< 0.1 %	#
Assay	98.0 ... 101.0 %	99.2 %	#
Correction factor weighing (f, NRF)	1,000	1,011	
Complies specification		Yes	

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Production date	06.2023	Retest date	06.2026

Release date	24.10.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	BASF SE		
Manufacturer batch	93924577L0		
Manufacturer street	Carl-Bosch-Straße 38		
Manufacturer city	67056 Ludwigshafen		
Manufacturer country	Deutschland		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 24001962 complies specification.

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