

**DEXPANTENOL (EUR. PH.)**

PRODUCT CODE: 009673	CAS Nº: 81-13-0	ANALYSIS Nº: 302/24
MANUFACTURER BATCH: TL02407064	CERTIFICATE ID: 44.285	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 27/07/2024	
METAPH BATCH: 0271124	EXPIRY DATE: 27/07/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder	Colourless viscous hygroscopic liquid (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6	Complies (*)
pH	=< 10.5	9.7
Specific optical rotation	+29.0 / +32.0	+30.8 (*)
Impurity A and other amino compounds	=< 1.0 %	0.4 %
Related substances		
Impurity C	=< 1.0 %	0.9 %
Impurity B	=< 0.5 %	0.3 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 2.0 %	1.2 %
Water	=< 1.0 %	0.3 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	98.0 - 101.0 %	99.5 % (*)

**COMPLIES WITH**

European Pharmacopoeia 11.1

**REMARKS**

Dexpanthenol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(\*) Data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

**STORAGE**

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Analysis date: 27/02/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Manufacturer: 40000334