

## DEXPANTENOL (EUR. PH.)

PRODUCT CODE: 009673	CAS Nº: 81-13-0	ANALYSIS Nº: 070/23
MANUFACTURER BATCH: TL02210099	CERTIFICATE ID: 37.770	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 16/10/2022	
METAPH BATCH: 0120323	EXPIRY DATE: 15/10/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder	Colourless viscous hygroscopic liquid (*)
Solubility	Very soluble in water, freely soluble in ethanol (96 %) and practically insoluble in heptane	Complies
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	9.8
Specific optical rotation	+29.0 / +32.0	+29.8 (*)
Impurity A and other amino compounds	=< 1.0 %	0.40 %
Related substances		
Impurity C	=< 1.0 %	0.79 %
Impurity B	=< 0.5 %	0.30 %
Unspecified impurities	=< 0.10 %	0.07 %
Total impurities	=< 2.0 %	1.2 %
Water	=< 1.0 %	0.10 %
Sulfated ash	=< 0.1 %	< 0.10 % (**)
Assay	98.0 - 101.0 %	99.2 % (*)

### COMPLIES WITH

European Pharmacopoeia 11.0

### 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.

(\*\*) Checked at regular intervals.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

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: 23/03/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Manufacturer: 40000334

