



TECHNICAL DATA SHEET

0020351-TDS-ENG-2024

VITAMINA D3 40000000 UI/mg (EUR. PH.)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS N°: 67-97-0	EC N°: 200-673-2	AEMPS CODE: ---
MOL. WEIGHT: 384,60	MOL. FORMULA: C ₂₇ H ₄₄ O	ARTICLE CODE: 0020351

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystals
Solubility	Practically insoluble in water, freely soluble in ethanol (96 per cent), soluble in trimethylpentane and in fatty oils.
Identification	Complies
Specific optical rotation	+105 / +112
Related substances	
Impurity A	= < 0.1 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 1.0 %
Assay	97.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.3

STORAGE

Store in tightly closed containers under nitrogen, protected from the light and at a temperature of 2 to 8 °C.

REMARKS

Vitamin D3 is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.