

**VITAMINA D3 40000000 UI/mg (EUR. PH.)**

PRODUCT CODE: 0020351		CAS Nº: 67-97-0	ANALYSIS Nº: 211/24
MANUFACTURER BATCH:		CERTIFICATE ID:	43.212
SUPPLIER BATCH:	02202007	MANUFACTURING DATE:	03/02/2022
METAPH BATCH:	0050824	RETEST DATE:	02/02/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystals	White crystals
Identification	Complies	Complies
Specific optical rotation	+105 / +112	+109
Related substances		(*)
Impurity A	=< 0.1 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	< 0.05 %
Assay	97.0 - 102.0 %	101.1%

**COMPLIES WITH**

European Pharmacopoeia 11.3

**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".

(\*) Data adapted from the supplier's certificate of analysis.

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

Analysis date: 11/11/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies

Manufacturer: 40000872