

TECHNICAL DATA SHEET

1894-TDS-ENG-2025

CIANOCOBALAMINA (VITAMINA B12) (EUR. PH.)		
DESCRIPTION DCI: CYANOCOBALAMIN		DESCRIPTION DOE: CIANOCOBALAMINA
CAS Nº: 68-19-9	EC Nº: 200-680-0	AEMPS CODE: 56A
MOL. WEIGHT: 1355,38	MOL. FORMULA: C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P	ARTICLE CODE: 1894

ATTRIBUTES	SHOULD BE
Appearance	Dark red, crystalline powder or dark red crystals
Solubility	Sparingly soluble in water and in ethanol (96 %), practically insoluble in acetone
Identification A	Complies
Absorption maxima	Complies
Ratio Abs (361/547-559)	3.15 - 3.45
Ratio Abs (361/278)	1.70 - 1.90
Identification B	Complies
Related substances	
Impurity C	=< 1.5 %
Impurity A	=< 0.7 %
Impurity B	=< 0.5 %
Impurity D	=< 0.5 %
Impurity E	=< 0.5 %
Impurity F	=< 0.5 %
Unspecified impurities	=< 0.2 %
Total of impurities	=< 3.0 %
Loss on drying	=< 12.0 %
Assay	96.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

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

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.