

TECHNICAL DATA SHEET

151894-TDS-ENG-2025

METIL COBALAMINA Farma		
DESCRIPTION DCI: METHYLCOBALAMIN		DESCRIPTION DOE: METILCOBALAMINA
CAS Nº: 13422-55-4	EC Nº: 236-535-4	AEMPS CODE: 104B
MOL. WEIGHT: 1344,4	MOL. FORMULA: C ₆₃ H ₉₁ CoN ₁₃ O ₁₄ P	ARTICLE CODE: 151894

ATTRIBUTES	SHOULD BE
Appearance	Dark red crystalls or crystalline powder
Solubility	Sparingly soluble in water, slightly soluble in ethanol (99.5), and practically insoluble in acetonitrile
Identification A	Complies
Identification B	Complies
Identification C	Complies
Clarity and colour of solution	Clear, red color
Related substances	
Any impurity	=< 0.5 %
Sum of impurities	=< 2.0 %
Impurezas	
Agua (K.F.)	=< 6.0 %
Assay	98.0 - 101.0 %
Residual solvents	
Acetone	=< 2000 ppm
Methanol	=< 1000 ppm
Methylethylketone	=< 1000 ppm
Microbiological control	
TAMC	=< 100 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/1g
Salmonella	Absence/10g
Staphylococcus aureus	Absence/g
Pseudomonas aeruginosa	Absence/1g
Bacterial endotoxines	=< 0.4 %

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

REMARKS

Methylcobalamine 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".

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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.