

CIANOCOBALAMINA (VITAMINA B12) (EUR. PH.)

PRODUCT CODE: 1894	CAS Nº: 68-19-9	ANALYSIS Nº: 043/24
MANUFACTURER BATCH: C230402G	CERTIFICATE ID: 41.264	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 03/04/2023	
METAPH BATCH: 0300224	EXPIRY DATE: 02/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Dark red, crystalline powder or dark red crystals, anhydrous substance very hygroscopic	Dark red crystalline powder, anhydrous substance very hygroscopic
Solubility	Sparingly soluble in water and in ethanol (96 %), practically insoluble in acetone	
Absorption maxima	Complies	Complies
Ratio Abs (361/547-559)	3.15 - 3.45	3.28
Ratio Abs (361/278)	1.70 - 1.90	1.85
Identification B	Complies	Complies
Related substances		
Impurity C	=< 1.5 %	< 0.10 %
Impurity A	=< 0.7 %	< 0.10 %
Impurity B	=< 0.5 %	Not Detected
Impurity D	=< 0.5 %	Not Detected
Impurity E	=< 0.5 %	0.4 %
Impurity F	=< 0.5 %	< 0.10 %
Unspecified impurities	=< 0.2 %	< 0.10 %
Total of impurities	=< 3.0 %	0.4 %
Loss on drying	=< 12.0 %	5.9 %
Assay	96.0 - 102.0 %	99.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

All data controlled by Metapharmaceutical Industrial SL.

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

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

Analysis date: 17/04/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000943
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