

CIANOCOBALAMINA (VITAMINA B12) (EUR. PH.)			
PRODUCT CODE: 1894		CAS Nº: 68-19-9	ANALYSIS Nº: 058/23
MANUFACTURER BATCH:	C220520A	CERTIFICATE ID:	37.607
SUPPLIER BATCH:	----	MANUFACTURING DATE:	07/06/2022
METAPH BATCH:	0040323	EXPIRY DATE:	06/06/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	Dark red, crystalline powder or dark red crystals	Dark red, crystalline powder
Solubility	Sparingly soluble in water and in ethanol (96 %), practically insoluble in acetone	Complies (*)
Absorption maxima	Complies	Complies
Ratio Abs (361/547-559)	3.15 - 3.45	3.28
Ratio Abs (361/278)	1.70 - 1.90	1.86
Identification B	Complies	Complies
Related substances		
Impurity C	=< 1.5 %	Not Detected
Impurity A	=< 0.7 %	Not Detected
Impurity B	=< 0.5 %	Not Detected
Impurity D	=< 0.5 %	Not Detected
Impurity E	=< 0.5 %	Not Detected
Impurity F	=< 0.5 %	Not Detected
Unspecified impurities	=< 0.2 %	< 0.05 %
Total of impurities	=< 3.0 %	< 0.05 %
Loss on drying	=< 12.0 %	0.60 %
Assay	96.0 - 102.0 %	96.0 %

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.

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.

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


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.

Release date: 08/06/2023
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies



Manufacturer: 40000943
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Original certificate available upon request

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