

## CIANOCOBALAMINA (VITAMINA B12) (EUR. PH.)

PRODUCT CODE: 1894	CAS Nº: 68-19-9	ANALYSIS Nº: 132/22
MANUFACTURER BATCH: C211007D	CERTIFICATE ID: 34.949	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 15/10/2021	
METAPH BATCH: 0150522	EXPIRY DATE: 14/10/2026	

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 (*)
Identification A	Complies	Complies
Absorption maxima	Complies	Complies
Ratio Abs (361/547-559)	3.15 - 3.45	3.30
Ratio Abs (361/278)	1.70 - 1.90	1.84
Identification B	Complies	Complies
Related substances		
Impurity C	=< 1.5 %	0.53 %
Impurity A	=< 0.7 %	0.18 %
Impurity B	=< 0.5 %	Not Detected
Impurity D	=< 0.5 %	Not Detected
Impurity E	=< 0.5 %	< 0.10 %
Impurity F	=< 0.5 %	0.11 %
Unspecified impurities	=< 0.2 %	< 0.20 % (#)
Total of impurities	=< 3.0 %	1.1 %
Loss on drying	=< 12.0 %	2.0 %
Assay	96.0 - 102.0 %	98.2 %
Residual solvents [In-house]		(*) (**)
Acetone	=< 5000 ppm	300 ppm
Microbiological control		(*)
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g

### COMPLIES WITH

European Pharmacopoeia 10.7

### REMARKS

(#) Unspecified impurities detailed underneath:

RT (20.59 min) = 0.17 %

RT (20.79 min) = 0.10 %

Cyanocobalamin is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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 certificate of analysis of the manufacturer.

(\*\*) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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,

Analysis date: 23/06/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000943

HEBEI YUXING BIO-ENGINEERING CO., LTD

XICHENG DISTRICT, NINGJIN COUNTY

055550 XING TAI CITY

HEBEI PROVINCE(China)





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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.

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