



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			
МЕТАРН ВАТСН:	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.

- $(\ensuremath{^*})$  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)

Page 1 of 2

A073.03.ENG





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			
МЕТАРН ВАТСН:	0150522		EXPIRY DATE:	14/10/2026			

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: 23/06/2022

Signature: Ferran Gonzalez de Rivera Rier

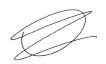
Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000943

HEBEI YUXING BIO-ENGINEERING CO., LTD XICHENG DISTRICT, NINGJIN COUNTY

055550 XING TAI CITY HEBEI PROVINCE(China)



Page 2 of 2 A073.03.ENG