

CIANOCOBALAMINA (VITAMINA B12) (EUR. PH.)			
PRODUCT CODE: 1894		CAS Nº: 68-19-9	ANALYSIS Nº: 109/25
MANUFACTURER BATCH:	C241022A	CERTIFICATE ID:	46.275
SUPPLIER BATCH:	----	MANUFACTURING DATE:	05/11/2024
METAPH BATCH:	0270425	EXPIRY DATE:	04/11/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	Dark red, crystalline powder or dark red crystals	Dark red, crystalline powder
Identification A	Complies	Complies
Absorption maxima	Complies	Complies
Ratio Abs (361/547-559)	3.15 - 3.45	3.3
Ratio Abs (361/278)	1.70 - 1.90	1.9
Identification B	Complies	Complies
Related substances		
Impurity C	=< 1.5 %	0.4 %
Impurity A	=< 0.7 %	< 0.10 %
Impurity B	=< 0.5 %	< 0.10 %
Impurity D	=< 0.5 %	< 0.10 %
Impurity E	=< 0.5 %	< 0.10 %
Impurity F	=< 0.5 %	< 0.10 %
Unspecified impurities	=< 0.2 %	0.1 %
Total of impurities	=< 3.0 %	0.5 %
Loss on drying	=< 12.0 %	1.5 %
Assay	96.0 - 102.0 %	99.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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.

Release date: 18/12/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40000943
HEBEI YUXING BIO-ENGINEERING CO., LTD
XICHENG DISTRICT, NINGJIN COUNTY
055550 XING TAI CITY
HEBEI PROVINCE(China)

Original certificate available upon request

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