



January 23, 2024

CERTIFICATE OF ANALYSIS

CYANOCOBALAMINE VITAMIN B12 CRYSTALLINE ✓

F6719

Batch number: 2311922379 ✓

Manufacturing date : November 26, 2023 ✓
 Expiry date : November 24, 2028 ✓
 Analytical method : CYANOCOBALAMINE PHARMACEUTIQUE
 Storage conditions : Storage: room temperature.
 Inspection lot number : 28096298
 Compliance : This batch is accepted and complies with the specifications.

Tests	Analytical results	Specifications
Identity UV spectrum (EP, USP, JP, IP)	Complies	Complies
Absorbance ratio 361/278 nm (EP, USP, IP)	1.86	1.70 to 1.90
Absorbance ratio 361/550nm (USP)	3.28	3.15 to 3.40
Absorbance ratio 277-279/360-362nm	0.54	0.53 to 0.59
Absorbance ratio 548-552/360-362nm	0.31	0.29 to 0.32
Absorbance ratio 361/547-559 nm (EP, IP)	3.28	3.15 to 3.45
Identity Infra red spectrum	Complies	Complies
Identity HPLC	Complies	Complies
Identity UHPLC (EP)	Complies	Complies
Appearance	Crystalline powder	Crystalline powder or small crystals
Coloration	Dark red	Red to purplish red
Appearance of aqueous solution	Standard I	Reference suspension standard I maximum
Coloration of aqueous solution	Red	Red
pH of aqueous solution (JP)	5.7	4.2 to 7.0
Loss on drying (EP, USP, JP, IP) * %	2.2	≤ 3.0 %
Assay UV (EP, USP, JP, IP) ** %	100.4	97.0 to 100.5 %
Acetone CC ppm	< 10	≤ 1000 ppm
Total impurities HPLC (EP 10.2, IP) %	1.3	≤ 3.0 %

Page 1 out of 3



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Total impurities HPLC (JP) $\leq 3.0\%$	Complies	Complies
Total impurities HPLC (USP) %	1.4	$\leq 3.0\%$
34-Methylcyanocobalamin HPLC (USP) %	0.3	$\leq 2.0\%$
7B, 8B-Lactocyanocobalamin HPLC (USP) %	0.4	$\leq 1.0\%$
32-Carboxycyanocobalamin HPLC (USP) %	0.1	$\leq 1.0\%$
8-Epi-Cyanocobalamin HPLC (USP) %	0.1	$\leq 1.0\%$
50-Carboxycyanocobalamin HPLC (USP) %	0.0	$\leq 0.5\%$
Any other impurity, each HPLC (USP) $\leq 0.5\%$	Complies	Complies
Total impurities UHPLC (EP) %	1.3	$\leq 3.0\%$
34-Methylcyanocobalamin UHPLC (EP) %	0.2	$\leq 1.5\%$
7B, 8B-Lactocyanocobalamin UHPLC (EP) %	0.2	$\leq 0.7\%$
50-Carboxycyanocobalamin UHPLC (EP) %	0.0	$\leq 0.5\%$
32-Carboxycyanocobalamin UHPLC (EP) %	0.0	$\leq 0.5\%$
8-Epi-cyanocobalamin UHPLC (EP) %	0.1	$\leq 0.5\%$
Impurity F UHPLC (EP) %	0.3	$\leq 0.5\%$
Any other impurity, each UHPLC (EP) $\leq 0.2\%$	Complies	Complies
Bacterial endotoxins $\leq 0.45\text{UE/mg}$	Complies	Complies

EUROAPI

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This product is « non pyrogenic » and complies with the current US, European, Indian and Japanese pharmacopoeia specifications. This batch has been manufactured in compliance with the current Good Manufacturing Practice requirements and complies with the specifications of the relevant marketing authorization.

* Loss on drying in compliance with EP, USP, JP, IP with more restrictive limit at release 3.0% as EUROAPI internal specification and equal with Pharmacopoeia limits at expiry date 12.0%

** Acceptance criteria defined in EP, USP, JP, IP is "assay result between 96.0% and 102.0%"

Product manufactured at Saint-Aubin-lès-Elbeuf
EUROAPI France
Rue de Verdun
76410 Saint-Aubin-lès-Elbeuf
France

EUROAPI France, formerly Sanofi Chimie

Data entered by Caroline FEUGRAY, Quality Assurance, January 23, 2024

Data verified and approved by: *[Signature]* Date: *[Date]* Signature: *[Signature]*