

I6700-3 - I EN



Lot: 0180618

April 24, 2018 UTC+01

CERTIFICATE OF ANALYSIS
CYANOCOBALAMIN VITAMIN B12 CRYSTALLINE
F6719

Batch number : 1806100897

Purchase: 1000149267 / January 15, 2018

Delivery: 1080181337

Manufacturing date : March 29, 2018
 Expiry date : March 29, 2023
 Analytical method : CYANOCOBALAMINE PHARMACEUTIQUE
 Storage conditions : Storage: room temperature.
 Inspection lot number : 6733882
 Compliance : This batch is accepted and complies with the specifications.

Tests	Analytical results	Specifications
Identity	Complies	Complies
Infra red spectrum	Complies	Complies
Appearance	Crystalline powder	Crystalline powder or small crystals
Coloration	Dark red	Red to purplish red
Appearance of aqueous solution (0.050g + 25ml)	Standard I	Reference suspension standard 1 maximum
Coloration of aqueous solution (0.050g + 25ml)	Red	Red
pH of aqueous solution (0.10g + 20ml)	5.7	4.2 to 7.0 pH
Loss on drying	2.0	<= 3.0 %
Pseudo cyanocobalamin test	Complies	Complies
Absorbance ratio 361/278 nm	1.86	1.70 to 1.90
Absorbance ratio 361/550 nm	3.28	3.15 to 3.40
Absorbance ratio 277-279/360-362 nm	0.54	0.53 to 0.59
Absorbance ratio 548-552/360-362 nm	0.31	0.29 to 0.32
Absorbance ratio 361/547-559 nm	3.28	3.15 to 3.45
Assay by spectrophotometry (on dried basis)	99.6	97.0 to 100.5 %
Acetone (GC)	< 0.0010	<= 0.1000 %
Total impurities HPLC (PE)	0.7	<= 3.0 %
Total impurities HPLC (JP) <=3.0%	Complies	Complies
Total impurities HPLC (USP)	0.9	<= 3.0 %
7B, 8B-Lactocyanocobalamin	0.3	<= 1.0 %

I6700-3 - I EN



April 24, 2018 UTC+01

CERTIFICATE OF ANALYSIS
CYANOCOBALAMIN VITAMIN B12 CRYSTALLINE
F6719

Batch number: 1806100897

Purchase: 1000149267 / January 15, 2018

Delivery: 1080181337

Tests	Analytical results	Specifications
50-Carboxycyanocobalamin	0.0	<= 0.5 %
34-Methylcyanocobalamin	0.2	<= 2.0 %
32-Carboxycyanocobalamin	0.0	<= 1.0 %
8-Epi-Cyanocobalamin	0.1	<= 1.0 %
Any other unidentified impurity <=0.5%	Complies	Complies
Total aerobic microbial count	< 1	<= 100 cfu/g
Yeasts and moulds	< 1	<= 10 cfu/g
Staphylococcus aureus in 10 g	Absence	Absence
Pseudomonas aeruginosa in 10 g	Absence	Absence
Escherichia coli in 10 g	Absence	Absence
Salmonellae in 10 g	Absence	Absence
Entérobactéries in 10 g	Absence	Absence
Candida Albicans in 1 g	Absence	Absence
Bacterial endotoxins <0.45 UE/mg	Complies	Complies

This product is non pyrogenic and complies with the current microbiological and 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.

Product manufactured at Saint Aubin lès Elbeuf
 BP 80125
 76410 Saint Aubin lès Elbeuf
 France

The certificate of analysis has been produced by a validated Laboratory Information Management System and signed electronically the April 20, 2018 at 14:03:51 UTC+01 by Thierry CHAPERON Technicien supérieur qualité