



CERTIFICATE OF ANALYSIS
CYANOCOBALAMINE VITAMIN B12 CRYSTALLINE

F6719

Batch number : **1200722201**

Purchase: 1000120824 / September 03, 2012

Delivery: 1080148781

Lote: 0061212

Manufacturing date : October 29, 2012

Expiry date : October 29, 2017

Analytical method : CYANOCOBALAMINE PHARMACEUTIQUE

Storage conditions : Storage: room temperature.

Inspection lot number : 6517718

Compliance : This batch is accepted and complies with the specifications.

Tests	Analytical results	Specifications
Identity	Complies	Complies
Infrared spectrum	Complies	Complies
Appearance	Crystalline powder	Crystalline powder or small crystals
Coloration	Dark red	Red to purplish red
Appearance of aqueous solution (0.650g + 25ml)	Standard I	Reference suspension standard 1 maximum
Coloration of aqueous solution (0.650g + 25ml)	Red	Red
pH of aqueous solution (0.10g + 25ml)	5.9	4.2 to 7.0 pH
Loss on drying	1.3	$\leq 3.0 \%$
Pseudo cyanocobalamin test	Complies	Complies
Absorbance ratio 361/278 nm	1.87	1.70 to 1.90
Absorbance ratio 361/550 nm	3.29	3.15 to 3.40
Absorbance ratio 277-279/360-362 nm	0.53	0.53 to 0.59
Absorbance ratio 548-552/360-362 nm	0.30	0.29 to 0.32
Absorbance ratio 361/547-559 nm	3.29	3.15 to 3.45
Assay by spectrophotometry (on dried basis)	99.6	97.0 to 100.5 %
Related substances (HPLC)	1.0	$\leq 3.0 \%$
Averone (GC)	≤ 0.0010	$\leq 0.0005 \%$
Bacterial endotoxins ≤ 0.45 UE/mg	Complies	Complies
Total aerobic microbial count	≤ 1	≤ 100 cfu/g
Yeasts and molds	≤ 1	≤ 10 cfu/g



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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

This product is non pyrogenic and complies with the current microbiological and US, European, Indian and Japanese pharmacopoeia specifications.

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