

Lot: 0101015

Registro: Z7164



CERTIFICATE OF ANALYSIS

CYANOCOBALAMINE VITAMIN B12 CRYSTALLINE

F6746

Batch number : 1502730530

Purchase: 1000134489 / February 19, 2015

Delivery: 1080163251

Manufacturing date : February 12, 2015
 Expiry date : February 12, 2020
 Analytical method : CYANOCOBALAMINE PHARMACEUTIQUE
 Storage conditions : Storage: room temperature.
 Inspection lot number : 6611110
 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	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)	5.8	4.2 to 7.0 pH
Loss on drying	1.2	<= 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)	100.3	97.0 to 100.5 %
Acetone (GC)	0.0388	<= 0.1000 %
Total impurities HPLC (PE)	0.9	<= 3.0 %
Total impurities HPLC (JP) <=3.0%	Complies	Complies
Total impurities HPLC (USP)	1.4	<= 3.0 %
7B, 8B-Lactocyanocobalamin	0.2	<= 1.0 %



March 13, 2015

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50-Carboxycyanocobalamin	0.0	$\leq 0.5 \%$
34-Methylcyanocobalamin	0.1	$\leq 2.0 \%$
32-Carboxycyanocobalamin	0.1	$\leq 1.0 \%$
8-Epi-Cyanocobalamin	0.2	$\leq 1.0 \%$
Any other unidentified impurity $\leq 0.5 \%$	Complies	Complies
Total aerobic microbial count	2	≤ 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.