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SANOFI

CERTIFICATE OF ANALYSIS

CYANOCOBALAMINE VITAMIN B12 CRYSTALLINE

F6746

Batch number : 1402061418
 Purchase: 1000130975 / June 13, 2014

Delivery: 1080159217

Lote: 0170914

Manufacturing date : May 29, 2014
 Expiry date : May 29, 2019
 Analytical method : CYANOCOBALAMINE PHARMACEUTIQUE
 Storage conditions : Storage: room temperature.
 Inspection lot number : 6586044
 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)	5.6	4.2 to 7.0 pH
Loss on drying	2.0	≤ 3.0 %
Pseudo cyanocobalamin test	Complies	Complies
Absorbance ratio 361/278 nm	1.85	1.70 to 1.90
Absorbance ratio 361/550 nm	3.27	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	3.27	3.15 to 3.45
Assay by spectrophotometry (on dried basis)	99.7	97.0 to 100.5 %
Acetone (GC)	≤ 0.0010	≤ 0.1000 %
Total impurities HPLC (PE)	1.2	≤ 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 %

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

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 July 01, 2014 at 10:28:19 by Emmanuel SENECA

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