



sanofi aventis

CERTIFICATE OF ANALYSIS
CYANOCOBALAMINE VITAMIN B12 CRYSTALLINE
F6719

Batch number : 1011000023
 Purchase: 1000103144 / February 02, 2010 Delivery: 1080127790

Manufacturing date : February 01, 2010
 Expiry date : February 01, 2015
 Analytical method : CYANOCOBALAMINE PHARMACEUTIQUE
 Storage conditions : Storage: room temperature.
 Inspection lot number : 6372564

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)	6.0	4.2 to 7.0 pH
Loss on drying	1.6	≤ 3.0 %
Pseudo cyanocobalamin test	Complies	Complies
Absorbance ratio 361/278 nm	1.8E	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)	99.6	97.0 to 100.5 %
Related substances (HPLC)	1.0	≤ 3.0 %
Acetone (GC)	0.0012	≤ 0.1000 %
Bacterial endotoxins <0.64 UE/mg	Complies	Complies
Total aerobic microbial count	11	≤ 100 cfu/g
Yeasts and moulds	< 1	≤ 10 cfu/g
Staphylococcus aureus in 10 g	Absence	Absence



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<i>Pseudomonas aeruginosa</i> in 10 g	Absence	Absence
<i>Escherichia coli</i> in 10 g	Absence	Absence
<i>Salmonellae</i> in 10 g	Absence	Absence

This product is non pyrogenic and complies with the current microbiological and US, European 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 March 11, 2010 at 10:18:19 by Stéphane BIGER
Quality assurance