

CERTIFICATE OF ANALYSIS

**Cyanocobalamin (VIT B12)
EP**
Quantity

15 Kg

Product name	Vitamin B12 (Cyanocobalamin)		
Characters	Dark-red crystalline powder or dark red crystals	Complies	Monograph: 0547 Visual Method
Identification A			
UV: A361nm/A278nm	1.70~1.90	1.85	Ph. Eur. monograph/Ph. Eur. <2.2.25>
UV: A361nm/A547-559nm	3.15~3.45	3.22	Ph. Eur. monograph/Ph. Eur. <2.2.25>
Identification B	TCL: Meets Ph. Eur. monograph requirements	Complies	Ph. Eur. monograph/Ph. Eur. <2.2.27>
Loss on drying	≤10.0%	2.95%	Ph. Eur monograph/PH. Eur. <2.2.32>
Assay	97.0% - 102.0%	99.10%	Ph. Eur monograph
Related substances			
Total impurities	≤3.0%	0.87%	Ph. Eur monograph/PH. Eur. <2.2.29> (HPLC)
7β, 8β - Lactocyanocobalamin	≤1.0%	0.52%	Ph. Eur monograph/PH. Eur. <2.2.29> (HPLC)
34-Methylcyanocobalamin	≤0.5%	<0.1%	Ph. Eur monograph/PH. Eur. <2.2.29> (HPLC)
8-Epi-cyanocobalamin	≤0.32%	0.23%	Ph. Eur monograph/PH. Eur. <2.2.29> (HPLC)
Any unspecified impurity	≤0.2%	<0.2%	Ph. Eur monograph/PH. Eur. <2.2.29> (HPLC)
Residual solvents Acetone	≤0.5%	0.01%	In house (GC)
Total plate count	≤800 cfu/g	20cfu/g	Ph. Eur <2.6.12>
Yeasts and Molds	≤80 cfu/g	<10cfu/g	Ph. Eur <2.6.12>
E. coli	Negative	Complies	Ph. Eur <2.6.13>
Lead	≤3(mg/kg)	Complies	Atomic absorption spectrometry
Arsenic	≤1(mg/kg)	Complies	Ch.P.Appendix VIII J
Cadmium	≤1(mg/kg)	Complies	Atomic absorption spectrometry
Mercury	≤0.1(mg/kg)	Complies	ICP-MS

Conclusion: The product complies with the specification of Ph.Eur.8.2 and in house standard
Packing: 0.1kg/tin

