

Cyanocobalamin(Vitamin B₁₂)

Certificate of Analysis

Manufacturing Date	Batch No.
2021-07-02	C210701D

Items	Specifications	Results	Test methods
Characters	Dark red,crystalline powdr or dark red crystals	Complies	Ph Eur.monograph:0547 Visual method
Identification A	UV:Absorption maxima at 278nm,361nm and 547-559nm.278nm,361nm.547-559nm	Complies	Ph Eur. Monograph/Ph.Eur.<2.2.25>
	A _{361nm} /A _{278nm} :1.70~1.90 A _{361nm} /A _{547-559nm} :3.15~3.45	1.86 3.26	
Identification B	UHPLC:The principal peak in the choromatogram obtained with the test solution is similar in retention time and size to the principal peak in the choromatogram obtained with reference solution(c)	Complies	Ph Eur. Monograph/Ph.Eur.<2.2.29>
Loss on drying	≤10.0%	3.6%	Ph Eur. Monograph/Ph.Eur.<2.2.32>
Assay	97.0%~102.0%	98.9%	Ph Eur. Monograph/Ph.Eur.<2.2.25>
Related substances	Total impurities≤3.0%	1.2%	Ph Eur. Monograph/Ph.Eur.<2.2.29> (UHPLC)
	7β,8β-Lactone-cyanocobalamin≤0.7%	0.1%	
	50-Carboxy cyanocobalamin≤0.5%	Not detected	
	34-Methyl cyanocobalamin≤1.5%	0.5%	
	32-Carboxy cyanocobalamin≤0.5%	Not detected	
	8-Epi- cyanocobalamin≤0.5%	0.2%	
	Impurity F ≤0.5%	Not detected	
	Unspecified impuritiets≤0.2%	0.2%	



Acetone	$\leq 5000\text{ppm}$	Not detected	In house/(GC) (GC)SOP-QC-104-04
The total aerobic Microbial count	1000cfu/g	75cfu/g	ChP 2020<1105> 2020<1105>
The total combined Yeasts/mould count	$\leq 100\text{cfu/g}$	<10cfu/g	ChP 2020<1105> 2020<1105>



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