



河北华荣制药有限公司

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Certificate of Analysis

Product:	<u>Cyanocobalamin</u>	Cert. No.:	<u>01240703901</u>
Batch No.	<u>012407039</u>	Mfg. Date :	<u>Jul.12,2024</u>
Weight:	<u>40092g</u>	Cert. Date :	<u>Jul.23,2024</u>
Retest Date:	<u>Jul.11,2029</u>	Manufacturer Material Code:	<u>20001497</u>

Test item	Specifications	Methods	Results
Characters	Dark red crystals or crystalline red powder	USP2024	Complies
Solubility	Sparingly soluble in water and in ethanol(96 percent),practically insoluble in acetone	USP2024	Complies
Identification A (UV)	Absorption maxima at278±1nm, 361±1nm and 550±2nm	USP2024	Complies
	A361/A278 nm 1.70-1.90	USP2024	1.84
	A361/A550 nm 3.15-3.40	USP2024	3.25
Identification B (Chemistry)	Positive	USP2024	Positive
Identification C (HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution	USP2024	Complies
Pseudo cyanocobalamin	Complies	FCC13	Complies
Loss on drying	≤12.0%	USP2024	2.6%
Assay(on dry basis) (UV)	96.0~102.0%	USP2024	99.2%
Related substances (HPLC)			
Total impurities	≤3.0%	USP2024	1.8%
7β,8β-Lactocyanocobalamin	≤1.0%	USP2024	Not Detected
50-Carboxycyanocobalamin	≤0.5%	USP2024	0.1%
32-Carboxycyanocobalamin	≤2.0%	USP2024	Not Detected
34-Methylcyanocobalamin	≤1.0%	USP2024	0.6%
8-Epi-Cyanocobalmin	≤1.0%	USP2024	Not Detected
Any other unidentified impurity	≤0.5%	USP2024	0.3%
Residual solvent (GC)			
Acetone	≤0.5%	In-house	0.002%
Total plate count (Plate culture)	≤1000cfu/g	ChP (1105)	<10cfu/g
Yeasts & Moulds	≤100cfu/g	ChP (1105)	<10cfu/g
E.coli	Negative in 1g	ChP (1106)	Negative
Salmonella	Negative in 10g	ChP (1106)	Negative
Staphylococcus aureus	Negative in 1g	ChP (1106)	Negative
Coliforms	Negative	ChP (1106)	Negative
As	≤1.0ppm	In-house	Not Detected
Pb	≤0.5ppm	In-house	Not Detected
Hg	≤0.1ppm	In-house	Complies
Cd	≤0.2ppm	In-house	Complies
Particle size	100% pass through 80 mesh	In-house	Complies

Conclusion: This product complies with the specifications of USP 2024+FCC13.

Edited by: 张京

Checked by: 张京

Approved by: 张京

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