



HEBEI HUARONG PHARMACEUTICAL CO., LTD.

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Certificate of Analysis

Product: Cyanocobalamin **Cert. No.:** 210502101
Batch No. 012105021 **Mfg. Date :** Apr.28,2021
Weight: 40044g **Cert. Date :** May 19,2021
Retest Date: Apr.27,2026

Test Item	Specifications	Results
Characters	Dark red crystalline powder	Complies
Identification A (UV)	Absorption maxima at 278±1nm, 361±1nm and 550±2nm A361/A278 nm 1.70-1.90 A361/A550 nm 3.15-3.40	Complies 1.83 3.26
Identification B (Chemistry)	Positive	Positive
Identification C (HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution	Complies
Loss on drying	≤12.0%	3.3%
Assay(on dry basis) (UV)	96.0~102.0%	99.1%
Related substances (HPLC)		
Total impurities	≤3.0%	1.4%
7β,8β-Lactocyanocobalamin	≤1.0%	0.07%
50-Carboxycyanocobalamin	≤0.5%	Not Detected
34-Methylecyanocobalamin	≤2.0%	0.5%
32-Carboxycyanocobalamin	≤1.0%	Not Detected
8-Epi-Cyanocobalmin	≤1.0%	0.07%
Any other unidentified impurity	≤0.5%	0.23%
Residual solvent (GC)		
Acetone	≤0.5%	0.004%
Total plate count (Plate culture)	≤1000cfu/g	20cfu/g
Yeasts & Moulds	≤100cfu/g	<10cfu/g
E.coli	Negative in 1g	Negative
Salmonella	Negative in 10g	Negative
Staphylococcus aureus	Negative in 1g	Negative
As	≤1.0ppm	Not Detected
Pb	≤0.5ppm	Not Detected
Hg	≤0.1ppm	Complies
Cd	≤0.2ppm	Complies
Particle size	100% pass through 80 mesh	Complies

Conclusion: This product complies with the specifications of USP 2021+ FCC10.

Edited by: 孙晓茹

Checked by: 王明

Approved by: 张永月

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