



HEBEI HUARONG PHARMACEUTICAL CO., LTD.

Add: No.8, Weier Road, Ningjin Salinization Industrial Park, Xingtai, Hebei Province, China P.C.: 055550

Tel: 86-319-5510828

http://www.e-cspec.com

E-mail: hrpc@mail.ecspec.com

Certificate of Analysis

Product:	<u>Cyanocobalamin</u>	Cert. No.:	<u>01231203001</u>
Batch No.	<u>012312030</u>	Mfg. Date :	<u>Dec.16,2023</u>
Weight:	<u>35082g</u>	Cert. Date :	<u>Dec.22,2023</u>
Retest Date:	<u>Dec.15,2028</u>		

Test item	Specifications	Results
Characters	Dark red crystals or crystalline red powder	Complies <i>→ Lengkap</i>
Solubility	Sparingly soluble in water and in ethanol(96 percent),practically insoluble in acetone	Complies <i>→ Lengkap</i>
Identification A (UV)	Absorption maxima at278±1nm, 361±1nm and 550±2nm A361/A278 nm 1.70-1.90 A361/A550 nm 3.15-3.40	Complies ✓ 1.81 3.22
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%	5.1% ✓
Assay(on dry basis) (UV)	96.0~102.0%	99.3% ✓
Related substances (HPLC)		
Total impurities	≤3.0% ✓	1.4%
7β,8β-Lactocyanocobalamin	≤1.0% ✓	Not Detected
50-Carboxycyanocobalamin	≤0.5% ✓	0.1%
32-Carboxycyanocobalamin	≤2.0% ✓	Not Detected
34-Methylcyanocobalamin	≤1.0% ✓	0.4%
8-Epi-Cyanocobalmin	≤1.0% ✓	Not Detected
Any other unidentified impurity	≤0.5% ✓	0.3%
✗ Residual solvent (GC)		
Acetone	≤0.5%	Not Detected
Total plate count (Plate culture)	≤1000cfu/g	<10cfu/g
Yeasts & Moulds	≤100cfu/g	<10cfu/g
Bacterial endotoxins	<200EU/mg	<200EU/mg

Conclusion: This product complies with the specifications of USP 2023.

Edited by: *孙淑娟*

Checked by:

江米

Approved by:

张京同

2023.12.22

2023.12.22

2023.12.22



Butuh penyesuaian terlampir

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufaktur saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Cyanocobalamin	Hebei Huarong	USP 2023	USP 47/ FI VI			Pemerian disesuaikan dengan USP 47	RD.02-SBA/116.00	Update SPBB dan Penyesuaian CoA dari Manufaktur
					Residual Solvent		Kelarutan disesuaikan dengan USP 47		Penyesuaian CoA dari Manufaktur
					Identifikasi D (nanoram)		Cemaran Organik disesuaikan dengan USP 47		Update SPBB

Diperiksa Oleh

Disetujui Oleh,


25/10/24
Koordinator QC


25/10/24
Koordinator TS


25/10/24
Koordinator QA


25/10/24
Manajer QA