



大连汉德姆精细化学品有限公司

**DALIAN HANDOM CHEMICALS CO.,LTD.**

### Certificate of Analysis

**Product Name:** Cyanocobalamin(Vitamin B<sub>12</sub>)

**Batch No.:** HDC20220927

**Quantity:** 49.0kg

**Manufacturing Date:** Sep 27<sup>th</sup>, 2022

**Retest Date:** Sep 26<sup>th</sup>, 2027

**Packing:** 1.0kg/tin

**Test Based On:** Ph. Eur. 10.3 and in-house standard.

Item	Specification	Method	Result
Characteristics	Dark red, crystalline powder or dark red crystals	Ph. Eur. Monograph:0547 Visual method	Conforms
Identification A	UV: Absorption maxima at 278nm, 361nm and 547-559nm.	Ph. Eur. Monograph/Ph.Eur.<2.2.25>	Conforms
	A <sub>361nm</sub> /A <sub>278nm</sub> : 1.70~1.90 A <sub>361nm</sub> /A <sub>547-559nm</sub> : 3.15~3.45		1.86 3.26
Identification B	UHPLC: The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution(c).	Ph. Eur. Monograph/Ph.Eur.<2.2.29>	Conforms
Loss on Drying	≤10.0%	Ph. Eur. Monograph/Ph.Eur.<2.2.32>	4.5%
Assay	97.0%~102.0%	Ph. Eur. Monograph/Ph.Eur.<2.2.25>	99.2%
Related Substances	Total impurities≤3.0%	Ph. Eur. Monograph/Ph.Eur.<2.2.29>(UHPLC)	0.6%
	7β, 8β-Lactone-cyanocobalamin≤0.7%		0.1%
	50-Carboxycyanocobalamin≤0.5%		Not detected
	34-Methylcyanocobalamin≤1.5%		0.2%
	32-Carboxycyanocobalamin≤0.5%		Not detected
	8-Epi-cyanocobalamin≤0.5%		0.1%
	Impurity F≤0.5%		Not detected
Unspecified impurities≤0.2%	0.1%		
Acetone	≤5000ppm	In house/(GC)	37ppm
The total aerobic microbial count	≤1000cfu/g	ChP 2020 <1105>	10cfu/g
The total combined yeasts/mould count	≤100cfu/g	ChP 2020 <1105>	<10cfu/g

**Conclusion: The product complies with the specification of Ph. Eur. 10.3 and in house standard.  
Product Usage: Not for Drug Use.**