



大连汉德姆精细化学品有限公司

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

## Certificate of Analysis

**Product Name:** Mecobalamin(Methylcobalamin)

**Batch No.:** HDC20220801

**Quantity:** 20.0kg

**Manufacturing Date:** Aug 1<sup>st</sup>, 2022

**Retest Date:** Jul 31<sup>st</sup>, 2025

**Packing:** 0.5kg/tin

Item	Specification	Method	Result
Appearance	Dark red crystals or crystalline powder	JP Monograph Visual method	Conforms
Identification	(1) UV: Compare the spectrum with the reference spectrum, both spectra exhibit similar intensities of absorption at the same wavelengths.	JP Monograph/JP <2.24>	Conforms
	(2) Cobalt: Meets JP requirement	JP Monograph	Conforms
Clarity and color of solution	The solution is clear and red color	JP Monograph	Conforms
Related substances	Each area of the peaks other than mecobalamin is not more than 0.5% of the peak area of mecobalamin	JP Monograph/JP <2.01>	0.4%
	The total area of the peaks other than mecobalamin is not more than 2.0%	JP Monograph/JP <2.01>	1.5%
Water	≤11.5%	JP Monograph/JP <2.48>	6.0%
Assay(on the anhydrous basis)	98.5%-101.0%	JP Monograph	99.8%
Acetone	≤5000ppm	In house/(GC)	13ppm
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 JP XVII and in house standard.**

**Product Usage: Not for Drug Use.**