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SPECIFICATION SHEET

Product Name	Vitamin B12 (Methylcobalamin)
According	JP XVI and in house standard

TESTS		SPECIFICATION	TEST PROTOCOL	
ASSAY				
Assay		≥98.5% - 101.0%	JP Monograph	
PHYSICAL CONTROL				
Ap		Dark red crystals or crystalline powder	JP Monograph Visual Mehtod	
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>	
		(2) Cobalt: Meets JP requirements	JP Monograph	
Purity	(1) Clarity and color of solution	Solution is clear and red color	JP Monograph	
	(2) Related substance	Each area of the peaks other than mecobalamin is not larger than 0.5% of the peak area of mecobalamin	JP Monograph/JP<2.01>	
		The total of the peaks other than mecobalamin is not larger than 2.0%		
Water		≤11.5%	JP Monograph/JP<2.48>	
Particle Size (≤60 mesh)		≥90%	Standard Mesh	
CHEMICAL CONTROL				
Lead (Pb)		≤0.5mg/kg	Atomic absorption spectrometry	
Arsenic (As)		≤3mg/kg	Ch.P. Appendix VIII J	
RESIDUAL				
Residual Solvent		Acetone ≤5000ppm	64ppm	In house / (GC)
MICROBIOLOGICAL CONTROL				
Total plate Count		≤1000cfu/g	ChP<1105>	
Total Yeast & Mold		≤100cfu/g		
Salmonella		Negative		
E.Coli		Negative		

Note: The above information is based on the specification sheet received from the manufacturer of this product and not intended as a substitute for strict quality control analysis by the purchaser of this product.

Reviewed by : _____

Abdullah Malik (QA)