

Trafa Pharmaceutical Supplies, LLC

140 Padgette Steet, Unit D, Chicopee, MA 01022, USA Tel: 1-866-99-Trafa (87232) FAX: 1-800-627-1880 Email: SalesUSA@TrafaPharmaSupplies.com

Website: www.TrafaPharmaSupplies.com

Specification Sheet

opeomoduon oneet			
Product and Batch Information			
Product Name:	Vitamin B12	According:	USP36 / In house
	(Cyanocobalamin) Mannitol	J	standard
Origin:	Canada		
Analysis Item	Specification	Test Method	
Active Ingredients			
Assay	1.00%	USP Monograph	
Physical Control			
Identification	A: A351nm/A278nm : 1.70 ~ 1.90	USP Monograph	
	A361nm/A550nm : 3.15 ~ 3.40		
	B: Meets USP requirement	USP Monograph	
	C: HPLC - The retention time		
	of the major peak of the	USP Monograph	
	sample solution corresponds		
	to that of the standard solution		
Appearance	Dark red crystalline powder	Visual	
	or dark red crystals		
Loss on Drying	≤10%	USP Monography / USP	SP<731>
	Total immunities <20/		
Related substances	Total impurities ≤3% 7β, 8β - Lactocyanocobalamin ≤1%	USP Monograph	
	34 - Methylcyanocobalamin ≤2%		
	8-Epi-cyanocobalamin≤1%		
	2 *		
	Any other impurity (include 50-Carboxycyanocobalamin, 32-		
	Carboxycyanocobalamin) \(\leq 0.5\%		
Residual Solvent	Acetone ≤0.5%	In house/ (GC)	
Chemical Control		, ,	
Heavy Metal	≤10ppm	USP231	
Arsenic	≤2 ppm	USP231	
Cadmium	≤1 ppm	USP231	
Lead	≤2 ppm	USP231	
Mercury	≤1 ppm	USP231	
Microbiological Control			
Total plate count	≤800 cfu/g	USP<2021>	
Yeast & Mold		USP<2021>	
E.Coli	Negative	USP<2022>	
Conclusion	The product complies with the specification of USP36 and in house		
	standard.		
,			

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)