

Specification Sheet

Product Name	Vitamin B12 Powder (Cyanocobalamin)	Specification	FWK-VB12 (0.1% cws)
Test Standard	USP/EP	Shelf Life	24 Months
Packing size	25kg/drum	/	/
Inspection Item	Quality Requirements	Test Method	
Description	From light red to brown powder, no foreign matter and no odor.	Visual	
Cyanocobalamin Assay	$\geq 0.1\%$	HPLC	
Loss on Drying	$\leq 5.0\%$	USP<731> Ph.Eur.2.2.32	
Bulk Density Tapped Density	0.40g/ml-0.80g/ml	USP<616> Ph.Eur.2.9.34	
Particle Size	90% pass through sieve 80 mesh	USP<786> Ph.Eur.2.9.38	
**Mercury (as Hg)	$\leq 0.10\text{ppm}$	USP<233> Ph.Eur.2.4.20	
**Cadmium (as Cd)	$\leq 1.00\text{ppm}$	USP<233> Ph.Eur.2.4.20	
Arsenic (as As)	$\leq 2.00\text{ ppm}$	USP<211> Ph.Eur.2.4.2	
Lead (as Pb)	$\leq 2.00\text{ ppm}$	USP<251> Ph.Eur.2.4.10	
Total aerobic microbial count	$\leq 1000\text{cfu/g}$	USP<2021> Ph.Eur.2.6.12	
Total moulds and yeasts count	$\leq 100\text{cfu/g}$	USP<2021> Ph.Eur.2.6.12	
Enterobacterial	$\leq 10\text{cfu/g}$	USP<2021> Ph.Eur.2.6.13	
**Escherichia coil	n.d./g	USP<2022> Ph.Eur.2.6.13	
**Salmonella	n.d./10g	USP<2022> Ph.Eur.2.6.13	
**Staphylococcus aureus	n.d./g	USP<2022> Ph.Eur.2.6.13	
Conclusion	The product is inspected in accordance with USP/EP standard.		
Remarks	1.storage in ambient temperature. 2. ** Analyzed as per six batches, not less than once per year.		

Analyst:

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Approver:

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