

化验报告单

CERTIFICATE OF ANALYSIS

产品名称 Product Name	维生素 B12 (氰钴胺) Cyanocobalamine	产品批号 Batch No.	HYD230704
CAS NO.	68-19-9	生产日期 Man. Date	2023-07-14
有效日期 Expiry Date	2028-07-13	报告日期 Report Date	2023-07-30
外观性状 Characteristics	深红色结晶性粉末或深红色结晶 Dark red crystalline powder or dark red crystals		符合规定 Complies
鉴别 Identification	UV 在 278nm, 361nm 与 547-559nm 的波长处有最大吸收。 Absorption maxima at 278nm,361nm and 547-559nm. 278nm~361nm (1.70~1.90) 1.85 547nm~559nm(3.15~3.45) 3.26		符合规定 Complies
	HPLC 测试溶液的主峰保留时间和大小与参照溶液的相似。 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.		
干燥失重 Loss on drying	≤10.0%		5.6%
有关物质 Related substances	Total impurities ≤3.0%		1.4%
	7β,8β-Lactocyanocobalamin ≤0.7%		0.6%
	34-Methylcyanocobalamin ≤1.5%		0.1%
	8-Epi-cyanocobalamin ≤0.5%		0.2%
	Unspecified impurities ≤0.2%		0.2%
溶剂残留 Residue solvent	丙酮 Acetone ≤5000ppm		12PPM
需氧菌总数 The total aerobic microbial count	≤1000cfu/g		35cfu/g
酵母菌和霉菌 The total combined yeasts/mould count	≤100cfu/g		<10cfu/g
细菌内毒素 Bacterial Endotoxin	<0.3EU/μg		符合规定 Complies
含量 Assay	97.0%—102.0%		99.0%
结论 Conclusion	本品符合 USP43 质量标准。 Complies with USP43standard.		

检验人 (Tester): 李飞 复核(Re-tester):张雨 主管(Director)李波

