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分析证 CERTIFICATE OF ANALYSIS

品名 Product Name	维生素 B ₁₂ (氰钴胺) 质检专用单 Vitamin B ₁₂ (Cyanocobalamin) COA No.		a048	
批号 Batch No.	PA20240307	包装规格 Packing	1000g/瓶 (Bottle)	
数量 Quantity	29.03kg	生产日期 Mfg.Date	Mar.13.2024	
有效期 Exp.Date	Mar.12.2029	分析日期 Analysis Date	Mar.20.2024	
检验依据 According As	《美国药典》2024 和内控标准 USP2024 and enterprise standard.			
检验项目 Test Items	标准规定 Specifications	检验结果 Test Results	检验方法 Test methods	
性状 Characteristics	应为深红色结晶或无定形或结晶性红色粉末, 引湿性强。 Dark red crystals or amorphous or crystalline red powder, it is very hygroscopic.	本品为结晶性红色粉末。 Crystalline red powder.	目测 Visual method	
鉴别 Identification	A	在 278 ± 1, 361 ± 1 和 550 ± 2 nm 处有最大吸收。 The absorption spectrum exhibits maxima at 278 ± 1, 361 ± 1, and 550 ± 2 nm. A361nm/A278nm:1.70-1.90 A361nm/A550nm:3.15-3.40	符合规定 Complies A361nm/A278nm:1.88 A361nm/A550nm:3.30	UV
	B	加入亚硝基 R 盐后即出现红色或橙红色。加入盐酸煮沸后, 红色仍然存在。 A red or orange-red color appears immediately after the addition of nitroso R salt. The red color persists after boiling with the addition of hydrochloric acid.	符合规定 Complies	—
	C	样品溶液的主峰保留时间与标准溶液的保留时间一致。 The retention time of the major peak of the Sample solution corresponds to that of the Standard solution.	符合规定 Complies	HPLC
干燥失重 Loss on drying	≤12.0%	3.2%	USP<731>	
含量 Assay on dried basis	96.0%-102.0%	99.0%	UV	
总杂质 Total impurities	≤3.0%	1.60%	HPLC	
7β, 8β-Lactocyanocobalamin	≤1.0%	0.02%		
50-Carboxycyanocobalamin	≤0.5%	0.02%		
32-Carboxycyanocobalamin	≤2.0%	0.07%		
34-Methylcyanocobalamin	≤1.0%	0.62%		
8-epi-Cyanocobalamin	≤1.0%	0.16%		
其它任一未鉴别杂质 Any other unidentified impurity	≤0.5%	0.19%		
总需氧菌数 Total aerobic bacteria count	≤1000cfu/g	40cfu/g	USP<2021>	
霉菌、酵母菌数 Molds, Yeasts	≤100cfu/g	未检出 No detected	USP<2021>	
大肠埃希菌 E.coli	不得检出 No found	未检出 No detected	USP<2022>	
残留溶剂 Limit of residual solvents	丙酮≤0.5% Acetone≤0.5%	0.0046%	Enterprise	
结论 Conclusion	经检验, 本品符合《美国药典》2024 和内控标准的规定。 This product complies with the specification of USP 2024 and enterprise standard.			

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