



宁夏金维制药股份有限公司
Ningxia Kingvit Pharmaceutical Co., Ltd.

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分析证

CERTIFICATE OF ANALYSIS

品名 Product Name	维生素 B ₁₂ (氰钴胺) Vitamin B ₁₂ (Cyanocobalamin)	报告单号 COA NO.	a494
批号 Batch No.	PA20211211	包装规格 Packing	1000g/瓶 (Bottle)
数量 Quantity	45.28kg	生产日期 Mfg.Date	Dec.13.2021
有效期 Exp.Date	Dec.12.2026	分析日期 Analysis Date	Dec.20.2021
检验依据 According As	《美国药典》43 版和内控标准 USP43 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	应为深红色结晶或结晶性粉末，无臭、无味； 引湿性强。 Dark red crystal or crystalline powder, with no smell and no taste;hygroscopicity.	本品为深红色结晶性粉末， 无臭、无味。 Dark red crystalline powder, with no smell and no taste.	目测 Visual Method
鉴别 Identification A	A361nm/A278nm:1.70-1.90 A361nm/A550nm:3.15-3.40	1.85 3.21	UV
Identification B	样品溶液主峰保留时间与对照品一致 The retention time of major peak of the sample solution corresponds to that of the standard solution.	符合规定 Complies	HPLC
Identification C	应呈正反应 Positive	符合规定 Complies	
干燥失重 Loss on drying	≤12.0%	1.9%	USP<731>
含量 Assay on dried basis	96.0%-102.0%	99.4%	UV
总杂 Total impurities	≤3.0%	1.02%	
7β、8β-lactocyanocobalamin	≤1.0%	0.06%	
50-carboxycyanocobalamin	≤0.5%	0.07%	
34-methylcyanocobalamin	≤2.0%	0.11%	HPLC
32-carboxycyanocobalamin	≤1.0%	0.09%	
8-Epi-cyanocobalamin	≤1.0%	0.10%	
其它任一未鉴别杂质 Any other unidentified impurity	≤0.5%	0.16%	
总需氧菌数 Total aerobic bacteria count	≤1000cfu/g	50cfu/g	USP<2021>
霉菌、酵母菌数 Molds、Yeasts	≤100cfu/g	未检出 No found	USP<2021>
大肠埃希菌 E.coli	不得检出 No found	未检出 No found	USP<2022>
细菌内毒素 Endotoxin	≤0.30EU/mg	符合规定 Complies	Enterprise
残留溶剂 Limit of residual solvents	丙酮≤0.5% Acetone≤0.5%	0.017%	Enterprise
结论 Conclusion	经检验,本品符合《美国药典》43 版和内控标准的规定。 This product complies with the specification of USP43 and enterprise standard.		

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