



河北华北制药华恒药业有限公司

Hebei North China Pharmaceutical Huaheng Pharmaceutical Co., Ltd.

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CERTIFICATE NO. 检验报告编号: C2009006

检验报告

Certificate of Analysis

Product 品名	氰钴胺(维生素 B12)Cyanocobalamin (Vitamin B12)	Date of Certificate 报告日期	2020-09-27
Batch No. 批号	C200901S	Date of Manufacture 生产日期	2020-09-18
Quantity 数量	37.365kg	Date of Expiry 有效期	2025-09-17

Analysis Contents 分析项目	Analysis Standard 分析标准	Analysis Results 分析结果
Characters 性状	Dark red crystalline or crystalline powder 深红色结晶或结晶性粉末	complied 符合规定
Solubility 溶解度	Sparingly soluble in water and in ethanol(96.0%), practically insoluble in acetone 微溶于水 and 乙醇(96.0%), 几乎不溶于丙酮	complied 符合规定
Identification 鉴别		
Absorbance 吸光度 A ₃₆₁ /A ₅₄₇₋₅₅₉	3.15-3.45	3.29
Absorbance 吸光度 A ₃₆₁ /A ₂₇₈	1.70-1.90	1.86
Chemical identification 化学鉴别	positive 化学反应呈正反应	complied 符合规定
TLC 薄层色谱	Should comply with the regulations 应符合规定	complied 符合规定
Assay (anhydrous substance) 含量(以干品计)	96.0%-102.0%	100.1%
Loss on drying 干燥失重	≤12.0%	2.7%
Related substances 相关物质	≤3.0%	0.5%
Residual solvent 残余溶剂		
acetone 丙酮	≤5000ppm	27ppm
ethanol 乙醇	≤5000ppm	82ppm
Microbial limit 微生物限度		
Total aerobic bacteria 需氧菌总数	≤1000cfu/g	<50cfu/g
Mould and yeasts 霉菌和酵母菌	≤100cfu/g	<50cfu/g

Conclusion: This product complied with the specifications of Ph.Eur.9.0 And BP 2019 Edition

质量专用章: 本批产品符合 9.0 版欧洲药典和 2019 版英国药典

Storage 储存条件: Preserve in tight, Light-resistant containers. 避光密封容器保存。

Reported by 报告人: 任彦昆

Reviewed by 审核人: 高志花

Approved by 批准人: 王淑平



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Analysis Contents 分析项目	Analysis Standard 分析标准	Analysis Results 分析结果
Characters 性状	Dark red crystalline or crystalline powder 深红色结晶或结晶性粉末	complied 符合规定
Identification 鉴别		
Absorbance 吸光度 A_{361}/A_{430}	3.15-3.40	3.29
Absorbance 吸光度 A_{361}/A_{278}	1.70-1.90	1.86
Chemical identification 化学鉴别	positive 化学反应呈正反应	complied 符合规定
HPLC 高效液相	The retention time of the main peak of the HPLC sample is the same as that of the control sample. HPLC 样品主峰保留时间与对照品一致	complied 符合规定
Assay (anhydrous substance) 含量(以干品计)	96.0%-102.0%	100.1%
Loss on drying 干燥失重	≤12.0%	2.7%
Related substances 相关物质		
Total impurity 总杂	≤3.0%	0.5%
Any individual impurity 单杂		
7β, 8β-Cyanocobalamin Lactate	≤1.0%	0.1%
50-Carboxycyanocobalamin	≤0.5%	not detected 未检出
34-Methylcyanocobalamin	≤2.0%	0.4%
32-Carboxycyanocobalamin	≤1.0%	not detected 未检出
8-EPic-Cyanocobalamin	≤1.0%	0.1%
Any other unidentified impurities 其它任何未识别杂质	≤0.5%	0.1%
Residual solvent 残留溶剂		
acetone 丙酮	≤5000ppm	27ppm
ethanol 乙醇	≤5000ppm	82ppm
Microbial limit 微生物限度		
Total aerobic bacteria 需氧菌总数	≤1000cfu/g	<50cfu/g
Mould and yeasts 霉菌和酵母菌	≤100cfu/g	<50cfu/g

Conclusion: This product complied with the specifications of USP42
结论: 本批产品符合 42 版美国药典

Storage 储存条件: Preserve in tight, Light-resistant containers. 避光密封容器保存。

Reported by 报告人: 任召昆 Reviewed by 审核人: 冯小松 Approved by 批准人: 王淑平