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浙江野风药业股份有限公司检验报告书

Zhejiang Wild Wind Pharmaceutical Co.,Ltd.

Add:Beijiang Industrial Zone,Geshan Town, Dongyang ,Zhejiang ,China

Certificate of Analysis

品名 Product Name	卡比多巴 Carbidopa	批号 Batch No	C02-20160604
生产日期 Manufacturing Date	2016-06-13	失效日期 Expiry Date	2019-06-12
数量/规格 Quantity, Spec.	100kg/20kg/dnm	报告日期 Report Date	2016-07-11
报告编号 Report No	C02-2016024	检测依据 Test Basis	USP37

项目 Items	标准 Specifications	结果 Results
性状 Characters	外观 Appearance 白色至乳白色粉末 White to creamy white powder	乳白色粉末 Creamy white powder
	溶解性 Solubility 微溶于水,易溶于 3 N 的盐酸,微溶于甲醇,几乎不溶于乙醇、丙酮、氯仿、乙醚。 Slightly soluble in water, freely soluble in 3 N hydrochloric acid; Slightly soluble in methanol; practically insoluble in alcohol, in acetone, in chloroform, and in ether.	符合规定 Meets the requirements
鉴别 Identification	A、红外 A、IR 供试品红外光吸收图谱应与对照品图谱一致 The spectrum of sample complies with the spectrum obtained with standard	一致 Complies
	B、含量测定项下保留时间 Assay: RT 主峰保留时间与对照品一致 Corresponds to the peak obtained with the standard	一致 Corresponds
比旋度 Specific rotation	-21.0° ~ -23.5°	-21.9°
干燥失重 Loss on drying	6.9% ~ 7.9%	7.4%
灼烧残渣 Residue on ignition	不得过 0.1% Not more than 0.1%	0.04%
重金属 Heavy metals	不得过 0.001% Not more than 0.001%	小于 0.001% Less than 0.001%
卡比多巴 Methyldopa	不得过 0.5% Not more than 0.5%	0.22%
卡比多巴相关化合物 A Carbidopa related compound A	不得过 0.5% Not more than 0.5%	未检出 Undetected
残留溶剂 Residual solvents	甲醇 Methanol 不得过 3000ppm Not more than 3000ppm	检测限以下 Below LOD
	异丙醇 2-Propanol 不得过 5000ppm Not more than 5000ppm	检测限以下 Below LOD
	三氯甲烷 Chloroform 不得过 60ppm Not more than 60ppm	检测限以下 Below LOD
	苯 Benzene 不得过 2ppm Not more than 2ppm	检测限以下 Below LOD
	甲苯 Toluene 不得过 890ppm Not more than 890ppm	检测限以下 Below LOD
	环己酮 Cyclohexanone 不得过 20ppm Not more than 20ppm	检测限以下 Below LOD
粒度 Particle Size	90% < 30um, 100% < 180um	100% < 30um, 100% < 180um
含量 Assay	98.0% ~ 102.0%	99.6%
结论 Conclusion	产品符合药典规定 The product meets with the specifications	
Tested by: 周南芳 Check by QC: Checked by QA:		