



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

Tel: 086-579-86733319 Fax: 086-579-86730319

Certificate of Analysis

品名 Product Name	卡比多巴 Carbidopa	批号 Batch No.	C02-20190506
生产日期 Manufacturing Date	05/17/2019	复验日期 Retest Date	05/16/2022
生产数量/规格 Quantities/Spec.	200kg/25kg/drum	报告日期 Report Date	06/21/2019
质量标准 Specifications	EP9.4	报告编号 Report No.	C02-2019004(EP)
项目 Items	标准 Specifications	结果 Results	
性状 Characters	外观 Appearance	白色或类白色粉末 White or yellowish white powder	类白色粉末 Yellowish -white powder
	溶解性 Solubility	在水中微溶, 在乙醇(96%)中极微溶解, 在二氯甲烷中几乎不溶, 在稀无机酸中易溶 Slightly soluble in water; very Slightly soluble in ethanol(96percent);practically insoluble in methylene chloride.it dissolves in dilute solutions of mineral acids	符合规定 Meets the requirements
鉴别 Identification	A、比旋度 A、 Specific optical	应符合比旋度项下的检测 Complies with specific optical rotation test	一致 Complies
	C、红外 C、 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
溶液颜色 Appearance of solution		颜色澄清不得深于BY ₆ 或B ₆ Clear and not more than reference solution BY ₆ or B ₆	颜色澄清并浅于BY ₆ Clear and less than reference solution BY ₆
比旋度 Specific optical rotation		-22.5°~-26.5°(Dried substance)	-23.8°
肼基 Hydrazine		不得过20ppm Not more than 20ppm	小于20ppm Less than 20ppm
杂质A Impurity A		不得过0.5% Not more than 0.5%	0.18%
杂质J Impurity J		不得过0.25% Not more than 0.25%	未检出 Undetected
杂质D+E Impurity D+E		不得过0.2% Not more than 0.2%	0.02%
杂质F Impurity F		不得过0.15% Not more than 0.15%	未检出 Undetected
杂质H Impurity H		不得过0.15% Not more than 0.15%	未检出 Undetected
杂质I Impurity I		不得过0.15% Not more than 0.15%	未检出 Undetected
未知杂质 Unspecified impurity		不得过0.10% Not more than 0.10%	0.02%
总杂质 Total impurities		不得过1.0% Not more than 1.0%	0.3%



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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
干燥失重 Loss on drying	6.9%~7.9%		7.5%
硫酸盐灰份 Sulphated ash	不得过0.1% Not more than 0.1%		0.03%
含量 Assay	98.5%~101.0%		99.3%
结论 Conclusion	产品符合 EP 9.4 标准 The batch complies with the EP 9.4 Specifications.		
Tested by:	10 伟芳	Check by QC:	Check by QA:
Date:	2019-06-21	Date:	Date: