

检验报告单
CERTIFICATE OF ANALYSIS

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产品名称: 盐酸特比萘芬 Product Name: Terbinafine hydrochloride	
代码: TA Code:	生产日期: 2019.03.13 Manuf.Date:
生产批号: 190304TA Batch NO.:	报告日期: 2019.03.21 Report Date:
批量: ---- Batch Size:	有效期至: 2021.03.12 Valid to:
报告单号: A190366 COA NO.:	检验标准: EP9.0 Specification:

检验结果 Analytical Results

项目 Item	检验标准 Acceptance criteria	结果 Result
外观 Appearance	白色或类白色粉末 White or almost white powder	白色粉末 White powder
溶解性 Solubility	易溶于无水乙醇和甲醇; 微溶于丙酮; 极微溶解或微溶于水 Freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone, very slightly or slightly soluble in water.	符合规定 Conforms
鉴别 Identification	样品红外吸收图谱应与对照品图谱一致 IR absorption spectrum of sample should be consistent with spectrum of standard 本品的无水乙醇溶液显氯化物的鉴别反应 It gives reaction (a) of chlorides using anhydrous ethanol as solvent	与对照品图谱一致 Consistent with spectrum of standard 呈正反应 Forward reaction
有关物质 Related substances	杂质 B (Impurity B) $\leq 0.15\%$ 杂质 E (Impurity E) $\leq 0.05\%$ 未知单个杂质 (Unspecified impurity) $\leq 0.10\%$ 总杂质 (Total impurities) $\leq 0.3\%$	未检出 N.D 未检出 N.D 0.07% 0.16% 0.30%
干燥失重 Loss on drying	$\leq 0.5\%$	
硫酸灰分 Sulfated ash	$\leq 0.1\%$	0.05%
残留溶剂 Residual solvents	异丙醇 (Isopropyl alcohol) $\leq 5000\text{ppm}$ 乙酸乙酯 (Ethyl acetate) $\leq 5000\text{ppm}$ 三氯甲烷 (Trichloromethane) $\leq 60\text{ppm}$	276ppm 269ppm 33ppm
含量 Assay	99.0%~101.0% (按干燥品计) (Calculated on the dried basis)	99.5%

结论:
Conclusion:

合格