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CERTIFICATE OF ANALYSIS

品名 Product name	盐酸特比萘芬 Terbinafine HCl		
批号 Batch No	20120420	有效期 Expiry date	2014-04
报告日期 Report Date	2012-04-23	数量 Quantity	200kg

项目 Items	标准 Standard	检验结果 Results
外观 Appearance	白色或类白色粉末 White or off-white powder	符合 Complies
鉴别 Identification	IR, chloride 红外鉴别, 氯化物鉴别	符合 Complies
溶解性 Solubility	难溶或微溶于水, 溶于无水乙醇、甲醇、微溶于丙酮 Very slightly and slightly soluble in water, freely soluble in anhydrous ethanol and methanol, slightly soluble in acetone	符合 Complies
有关物质 Related Substances	B 杂质 Impurity B	≤0.1% 0.0021%
	单个不明杂质 Single unknown impurity	≤0.05% 0.0024%
	总杂质 Total impurity	≤0.3% 0.023%
干燥失重 Loss on drying	≤0.5 %	0.18 %
重金属 Heavy metals	≤10ppm	符合 Complies
PH	3.0~4.5	3.68
灼烧残渣 Residue on ignition	≤0.10 %	0.03%
含量 Assay	99~101 % (Titration)	99.92 %
储藏 Storage	密封、低温、干燥储藏 Keep tightly closed, Store in cool and dry place	
结论 Determination	符合美国药典 34 版标准 Complies with USP34 standard	

Analyst :Lihong

Checker: Wangyuan

Supervisor : wangsulah

