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CERTIFICATE OF ANALYSIS

品名 Product name	盐酸特比萘芬 Terbinafine HCl	生产日期 Manuf. Date	2019-06-02
批号 Batch No	20190601	有效期 Expiry date	2021-06-01
报告日期 Report Date	2019-06-12	数量 Quantity	1500kg

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	符合 Complies
	Chloride	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 or slightly soluble in water, Freely soluble in anhydrous ethanol and methanol, slightly soluble in acetone.	符合 Complies
熔点 Melting point	204-208 °C	204.7-206.5 °C
有关物质 Related Substances	N-methyl-C-(naphthalene-1-yl) methanamine	≤0.10% Not Detected
	Cis-Terbinafine	≤0.10% 0.003%
	Trans-Isoterbinafine	≤0.10% Not Detected
	4-Methylterbinafine	≤0.10% 0.019%
	Terbinafine dimer	≤0.05% 0.035%
	Any other individual impurity	≤0.10% 0.007%
	总杂质 Total impurity	≤0.3% 0.07%
干燥失重 Loss on drying	≤0.5 %	0.19%
重金属 Heavy metals	≤10pmm	符合 Complies
灼烧残渣 Residue on ignition	≤0.10 %	0.06%
含量 Assay	99~101 % (on the dried basis)	99.85 %
结论 Determination	符合美国药典 40 版标准 Complies with USP40 standard	

Analyst : wangsulan

Checker: Wangyuan

Supervisor :Lihong