



浙江精进药业有限公司

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CERTIFICATE OF ANALYSIS

Product name: Gemfibrozil 产品名称: 吉非罗齐		Date of Mfg.: 2019/09/08 生产日期:	
Batch No.: CJF20190908-03 批号:		Report Date: 2019/09/16 报告日期:	
Batch Size: 625Kg 批量:		Retest Date: 2022/09/07 复验期:	
Quality Specification: USP42 质量规格:		Package: 25 Kg/drum 包装:	
Subject 项目		Specification 标准	Result 结果
Appearance 外观		White crystalline powder 白色结晶性粉末	White crystalline powder 白色结晶性粉末
Solubility 溶解度		Practically insoluble in water; soluble in alcohol, in methanol and in chloroform. 几乎不溶于水, 可溶于乙醇、甲醇和氯仿。	Qualified 符合要求
Identification 鉴别		A. The sample IR absorption spectrum should match the reference standard 红外吸收光谱应与对照图谱匹配	Match with the RS IR absorption spectrum. 红外吸收光谱与对照图谱匹配
		B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay 样品溶液中主峰的保留时间应与含量项下标准溶液主峰的保留时间匹配	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay 样品溶液中主峰的保留时间与含量项下标准溶液主峰的保留时间匹配
Water 水分		Not more than 0.25 % ≤0.25 %	0.01%
Related compounds 相关物质	Related compound A 杂质 A	Not more than 0.10 % ≤0.10 %	<0.01%
	Any other impurity 其它最大单个杂质	Not more than 0.08 % ≤0.08 %	<0.01%
	Total impurities 总杂质	Not more than 0.5 % ≤0.5 %	0.03%
Residual solvents 残留溶剂	Tetrahydrofuran 四氢呋喃	Not more than 720 ppm ≤720 ppm	<LOD(2ppm)
	Ethyl formate 甲酸乙酯	Not more than 5000 ppm ≤5000 ppm	49ppm
Assay, on anhydrous basis 含量, 以无水物计算		98.0 %~102.0 %	100.1%
Particle size 粒度		80 % < 100 microns 100 % < 600 microns	符合规定 Comply
Conclusion: Up to the standard. 结论: 合格			

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