

CERTIFICATE OF ANALYSIS

Product name: Gemfibrozil 产品名称: 吉非罗齐		Date of Mfg.: 2023/11/16 生产日期:	
Batch No.: CJF202311279-02 批号:		Report Date: 2023/11/27 报告日期:	
Batch Size: 750 kg 批量:		Retest Date: 2026/11/15 复验期:	
Quality Specification: USP 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	
Identification 鉴别	A. The sample IR absorption spectrum should match the reference standard 红外吸收光谱应与对照品图谱匹配	A. Match with the RS IR absorption spectrum. 红外吸收光谱与对照品图谱匹配	
	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	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 individual impurity 其它最大单个杂质	Not more than 0.08 % ≤0.08 %	0.02 %
	Total impurities 总杂质	Not more than 0.5 % ≤0.5 %	0.05 %
Residual solvents 残留溶剂	Tetrahydrofuran 四氢呋喃	Not more than 720 ppm ≤720 ppm	<LOD(1ppm)
	Ethyl formate 甲酸乙酯	Not more than 5000 ppm ≤5000 ppm	34ppm
Assay, on anhydrous basis 含量, 以无水物计算		98.0 %~102.0 %	98.8 %
Conclusion: Up to the standard. 结论: 合格			

