

济南健丰化工有限公司
JINAN JIANFENG CHEMICAL CO.LTD.

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CERTIFICATE OF ANALYSIS

Product name: Bezafibrate		
Batch No.: 20120328		
Report Date: 2012/03/28		
Perform standard: EP 5.0		
Item of analysis	Standard	Result of analysis
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol.	Practically insoluble in water, sparingly soluble in ethanol .
Appearance of solution	Clear and not more intensely coloured than BY ₅	<BY ₅
Identification	The sample IR absorption spectrum should match the reference standard.	The sample IR absorption spectrum match the reference standard.
Melting Point	181° -185°	184°
Related substances	Impurity A ≤0.5%	ND.
	Impurity B ≤0.5%	<0.05%
	Impurity C ≤0.5%	ND.
	Impurity D ≤0.5%	ND.
	Impurity E ≤0.5%	ND.
	Any other impurity ≤0.1%	0.05%
	Total Impurity ≤0.75%	0.31%
Chloride	≤300ppm	<300ppm
Loss on drying	≤0.5%	0.02%
Sulphated ash	≤0.1%	<0.04
Heavy metals	≤10ppm	<10ppm
Assay	98%-102%	100.6%
Conclusion: Conforms to the standard of EP 5.0		
审查者 (Exam) 闫海波 化验者 (Analyst) 周忠山 复核者 (Checker) 孙绪丁		