


济南健丰化工有限公司
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CERTIFICATE OF ANALYSIS

Product Name : Terbinafine Hydrochloride Batch NO. : 20110801 Manufacture date: 02/08/2011 Quantity :100kg Perform standard : EP 6.6		
		
Item of analysis	Standard	Result of analysis
Description	White or almost white powder	White powder
Solubility	Very slightly or slightly soluble in water ,freely soluble in anhydrous ethanol and in methanol ,slightly soluble in acetone	Conforms
Identification	A: IR:	The infrared absorption spectrum exhibits maximum only at the same wavelengths as that of the standard sample
	B:	It gives reaction of chlorides
Related substances:	Impurity B NMT0.1%	0.004%
	Impurity E NMT0.05%	Not detected
	Any other impurity NMT0.1%	0.03%
	Total of impurity NMT0.3 %	0.15%
Loss on drying:	NMT0.5%	0.17%
Sulphated ash	NMT0.1%	0.02%
Assay	99.0%~101.0%(dried substance)	99.83%
Conclusion :Conform to EP6.6		
Exam	Analyst	Checker