



武汉福鑫化工有限公司

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CERTIFICATE OF ANALYSIS

Product: Terbinafine Hydrochloride

Mfg. date: Sept., 12, 2015

Exp. date: Sept., 11, 2018

Lot No.: 150912

Quantity: 500kg

Items	Specifications	Results
Appearance	White or almost white powder	White powder
Solubility	Practically insoluble in water and in acetone, soluble in ethanol and in methanol.	Conforms
Identification	(1) IR: The infrared absorption spectrum exhibits maximum only at the same wavelengths as that of the standard sample.	Conforms
	(2) It gives reaction of chlorides.	Conforms
Related substances	Impurity A NMT 0.1%	0.002%
	Impurity B NMT 0.1%	0.01%
	Impurity C NMT 0.1%	0.02%
	Impurity D NMT 0.1%	0.02%
	Any other impurity NMT 0.1%	0.04%
	Total impurities NMT 0.3%	0.14%
Loss on drying	NMT 0.5%	0.16%
Residual solvents (GC)	Acetone: $\leq 0.5\%$	Not detected
	Isopropanol: $\leq 0.5\%$	0.006%
	MIBK: $\leq 0.5\%$	Not detected
Sulphated ash	NMT 0.1%	0.02%
Assay	99~101% (dried substance)	99.86%
Conclusion	The product conforms to the EP8.0 standard.	

QC: Luo Xiaofeng

Tester: AT02

Re-tester: AT01