



CERTIFICATE OF ANALYSIS

Product name	TERBINAFINE HCl (E)-N-(6,6-Dimethyl-2-hepten-4-alkyne)-N-methyl-1-naphthalene methylamine hydrochloride		
Batch No	17021081	Expiry date	2019-02
Report Date	2017-02-22	Quantity	200kg

Items	Standard	Results
Appearance	White or off-white powder	Complies
Identification	UV, IR	Complies
Solubility	Very slightly or slightly soluble in water, freely soluble in anhydrous ethanol and methanol, slightly soluble in acetone	Complies
Related Substances	Impurity B	$\leq 0.15\%$ 0.008%
	Impurity E	$\leq 0.05\%$ Comply
	Single unknown impurity	$\leq 0.05\%$ 0.070%
	Total impurity	$\leq 0.30\%$ 0.118%
Loss on drying	$\leq 0.5\%$	0.05%
Heavy metals	$\leq 20\text{ppm}$	Complies
PH	3.0~4.5	3.73
Residue on ignition	$\leq 0.10\%$	Complies
Assay	99.0~101.0% (Titration)	99.85%
Storage	Keep tightly closed, Store in cool and dry place	
Determination	Complies with EP7.	

Analyst : wangsulan

Checker: Wangyuan

Supervisor :Lihong