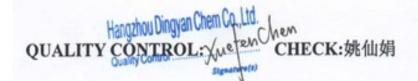
CERTIFICATE OF ANALYSIS

NO: DYC021310291

Product name	Terbinafine hydrochloride
CAS Number	78628-80-5
Molecule Structure	HCI N
Molecule Formula	C21H25N
Batch number	20140201
Manufacture Date	2014-02-01
Testing date	2014-02-01

Items	Standard	Result
Appearance	white or almost white powder	Complies
Solubility	Very slightly or slightly soluble in water,	Complies
	freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone	
Identification	A:IR the infrared absorption spectrum	
	exhibits maximum only at the same wavelengths as that of the standard sample	Complies
	B: It gives reaction of chlorides	
Related substances	Impurity B 0.15% max	N.D
	Impurity E 0.05% max	N.D
	Any other impurity 0.1% max	0.05%
	Total of impurity 0.3% max	0.11%
Loss on drying	0.5% max	0.22%
Sulphated ash	0.1% max	0.05%
Residual solvents	Isopropyl alcohol 5000ppm max	320ppm
	Ethyl acetate 5000ppm max	290ppm
	Chloroform 60ppm	5ppm
Assay	99.0~101.0%(dried substance)	99.85%
Conclusion	Meet the EP7.2 standard	



INSPECTOR: 刘清风