

CERTIFICATE OF ANALYSIS

Product Name	Terbinafine Hydrochloride	Batch NO.	RY191007
Production date	2019.10.12	Expired Date	2021.10.11
CAS NO.	78628-80-5	Standard	EP9.0 standard
Tests	Limits	Test results	
Appearance	White or almost white powder	White powder	
Solubility	Freely soluble in anhydrous ethanol and in methanol,slightly soluble in acetone,very slightly or slightly soluble in water	Conforms	
Identification	IR absorption spectrum of sample should be consistent with spectrum of standard	Consistent with spectrum of standard	
Ethanol (By GC)	It gives reaction(a)of chlorides using anhydrous ethanol as solvent	Forward reaction	
Related substances	Impurity B≤0.15%	N.D.	
	Impurity E≤0.05%	N.D.	
	The single impurity ≤0.10%	0.03%	
	The total impurities ≤0.3%	0.08%	
Loss on drying	≤0.5%	0.10%	
Sulfated ash	≤0.1%	0.04%	
Residual solvents	Isopropyl alcohol≤5000ppm	44ppm	
	Ethyl acetate≤5000ppm	133ppm	
	Trichloromethane≤5000ppm	21ppm	
Assay	99.0%~101.0%(calculated on the dried basis)	99.6%	
Conclusion: This batch meets EP9.0 standard			

Tested by: Esther

Checked by: Alice

Approved by: Mich

