



Jinan Hongfangde Pharmatech Co., Ltd.
Tel:86-531-88870908 Fax:86-531-88870908
sdhfdchem@163.com
www.hfdpharma.com

CERTIFICATE OF ANALYSIS

Product name	Terbinafine HCl		
Batch No	20190301	CAS No.	78628-80-5
Manufacture Date	2019-03-05	Expiry date	2021-02-28
Report Date	2019-03-15	Quantity	1625kg

Items	Standard	Results	
Appearance	White or off-white powder	Comply	
Identification	A:IR	Comply	
	B: Chloride	Comply	
Solubility	Very slightly or slightly soluble in water, Freely soluble in anhydrous ethanol and methanol, slightly soluble in acetone.	Comply	
Melting point	204-208°C	204.5-206.2°C	
Related Substances	N-methyl-C-(naphthalene-1-yl)methanamine	≤0.10%	Not Detected
	Cis-Terbinafine	≤0.10%	0.003%
	Trans-Isoterbinafine	≤0.10%	Not Detected
	4-Methylterbinafine	≤0.10%	0.019%
	Terbinafine dimer	≤0.05%	0.035%
	Any other individual impurity	≤0.10%	0.007%
	Total impurities	≤0.3%	0.07%
Loss on drying	≤0.50%	0.17%	
Residue on ignition	≤0.10%	0.06%	
Assay	98~102% (on the dried basis)	99.75%	
Storage	Keep tightly closed. Store in a cool dry place.		
Determination	Complies with USP40 standard		

Analyst : wangsulan

Checker: Wangyuan

Supervisor :Lihong