



DALIAN HANDOM CHEMICALS CO.,LTD.

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Certificate of Analysis

Product Name: Terbinafine Hydrochloride

Molecular Formula: C₂₁H₂₆ClN

Batch No.: HDC20230208

Manufacturing Date: Feb 8th, 2023

Report Date: Feb 9th, 2023

CAS No.: 78628-80-5

Molecular Weight: 327.891

Batch Quantity: 930kg

Retest Date: Feb 7th, 2025

Packing Size: 25kg/Drum

Test Items	Specifications	Test Results
Appearance	White or almost white powder	Conforms
Solubility	Very slightly or slightly soluble in water, freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone	Conforms
Identification	Infrared absorption spectrophotometry. <i>Comparison: terbinafine hydrochloride CRS</i>	Conforms
	It gives reaction (a) of chlorides <i>using anhydrous ethanol R as solvent</i>	Conforms
Related Substances	Impurity B: Not more than 0.15%	0.02%
	Impurity E: Not more than 0.05%	0.06%
	Unspecified Impurities: each impurity not more than 0.1%	0.33%
	Sum of impurities: Not more than 0.3%	0.39%
Loss on Drying	Not more than 0.5%	0.068%
Sulphated Ash	Not more than 0.1%	0.024%
Residual Solvents	Ethyl Acetate: Not more than 0.5%	0.0061%
	Dichloromethane: Not more than 0.06%	Not detected
	Isopropanol: Not more than 0.5%	0.012%
Particle Size	Meets the requirements	D90: ≤100 Micron
Assay	99.0% ~ 101.0%	100.08%

Conclusion: The testing results of this batch are complied with the Standard of EP 9.0.

Storage Conditions: Preserved in unopened original containers in a dark place at room temperature; kept away from direct sunlight, heat and moisture.