

## Terbinafine HCI EP11.0

Batch no

24110103

Mf date

Nov 01 2024

Retest

Oct 31 2026

Batch size

384 kg

Molecular Structure

Molecular Formula C<sub>21</sub>H<sub>26</sub>CIN

Molecular Weight

327.9

CAS Registry Number

78628-80-5

Dec 02 2024

<u>Tests</u>	Specifications		<u>Results</u>
Appearance	White or almost white cry	ystalline powder	Almost white powder
Solubility	Very slightly or slightly soluble in water, freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone		Conforms
Identification	IR, reaction of chlorides		Positive
Loss on drying	≤ 0.5%		0. 15%
Sulfated ash	≤ 0.1%		0. 02%
Related substances	Impurity B	≤ 0.15%	ND
	Impurity E	≤ 0.05%	ND
	Each unspecified impurity	/ ≤ 0.1%	0. 02%
	Total impurities	≤ 0.3%	0.06%
Residual solvents	Isopropanol	≤ 5000 ppm	ND
	Ethyl acetate	≤ 5000 ppm	ND
	Dichloromethane	≤ 600 ppm	ND
Assay (odb)	99.0 ~ 101.0%		100. 27%

Packaging & storage	Protected from light	
Conclusion	Material complies with EP11.0	