

SPECIFICATION

Product Name: Terbinafine Hydrochloride IP Grade
Chemical Formula: C ₂₁ H ₂₅ N · HCl
CAS Number: 78628-80-5
Molecular Weight: 327.90 g/mol
Appearance: White crystalline powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specifications Min./Max.
Identification:			
By IR	-	Complies	The infra-red absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from terbinafine HCL working standard.
Chloride Test	-	Complies	Positive test for chlorides.
Loss on drying	%	0.31	NMT 0.5%
Sulphated Ash	%	0.05%	NMT 0.1%
Related Substances by HPLC:			
Terbinafine related compound A	%	Not detected	NMT 0.1%
Terbinafine related compound B	%	0.5%	NMT 0.1%
Terbinafine related compound C	%	Not detected	NMT 0.1%
Terbinafine related compound D	%	Not detected	NMT 0.1%
Terbinafine dimer	%	Not detected	NMT 0.05%

Any other individual impurity	%	0.01%	NMT 0.1%
Total impurities	%	0.08%	NMT 0.3%
Assay by HPLC (on dry basis)	%	99.5%	NLT 98.0% and NMT 102.0%
Residual Solvents (by GC-HS ppm):			
o-xylene	PPM	Not detected	NMT 195 PPM
Petroleum ether	PPM	Not detected	NMT 290 PPM
Acetonitrile	PPM	Not detected	NMT 410 PPM
Methylene chloride	PPM	Not detected	NMT 500 PPM
Tetrahydrofuran	PPM	Not detected	NMT 500 PPM
Toluene	PPM	Not detected	NMT 700 PPM
Acetone	PPM	333 PPM	NMT 2000 PPM
Ethyl acetate	PPM	Not detected	NMT 2000 PPM

Physical Properties

- Solubility: Soluble in water. Soluble in ethanol. Soluble in methanol. Soluble in acetone. Soluble in ether. Soluble in chloroform.

Shelf Life & Storage

- Shelf Life: 5 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a tightly closed, light-resistant, moisture-resistant container in a cool, dry, and well-ventilated place, protected from moisture, heat, direct sunlight, and contamination.

Applications

- Use: Widely used in the manufacture of pharmaceutical formulations for the treatment of fungal infections caused by dermatophytes, certain yeasts, and other susceptible fungi.
- Dosage: Depends on the type of fungal infection, patient age, body weight, and dosage form

Packaging

- Standard Packing: 25 Kgs pp bag with inner liner or as per customer requirement.



RAWPHARMA BIZ PRIVATE LIMITED

1101-CITY CENTRE-2, SCIENCE CITY ROAD,
SOLA, AHMEDABAD, GUJARAT, 380060

Mobile: +91-8320310672

E-mail: info@rawpharmabiz.com

Website: www.rawpharmabiz.com

- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.

* Specifications are based on the manufacturer's provided specifications.



RAWPHARMA

Biz