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Terbinafine Tablets

DEFINITION
Terbinafine Tablets contain Terbinafine Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of terbinafine ($C_{21}H_{25}N$).

IDENTIFICATION
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

Buffer solution: 0.85 g/L of monobasic potassium phosphate in water. Add 1 g of sodium 1-decanesulfonate and adjust with dilute phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer solution* (2:3)

Standard solution: 0.2 mg/mL of USP Terbinafine Hydrochloride RS in *Mobile phase* (equivalent to 0.19 mg/mL of terbinafine)

Sample stock solution: Nominally equivalent to 0.5 mg/mL of terbinafine in *Mobile phase*, from crushed, finely powdered Tablets. [Note—Sonicate for 20 min with intermittent shaking.]

Sample solution: Nominally equivalent to 0.2 mg/mL of terbinafine in *Mobile phase*, from the *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 3.9-mm × 15-cm; 5-µm packing L7

Flow rate: 1.8 mL/min

Injection volume: 5 µL

Run time: 1.5 times the retention time of the terbinafine peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of terbinafine ($C_{21}H_{25}N$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Terbinafine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of terbinafine in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of terbinafine, 291.44

M_{r2} = molecular weight of terbinafine hydrochloride, 327.90

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: pH 3.0 citrate buffer; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 32 µg/mL of USP Terbinafine Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Dilute with *Medium*, if necessary.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: 283 nm

Cell: 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of terbinafine ($C_{21}H_{25}N$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times (M_{r1}/M_{r2}) \times V \times D \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Terbinafine Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

M_{r1} = molecular weight of terbinafine, 291.44

M_{r2} = molecular weight of terbinafine hydrochloride, 327.90

V = volume of *Medium*, 500 mL

D = dilution factor for the *Sample solution*

Tolerances: NLT 80% (*Q*) of the labeled amount of terbinafine ($C_{21}H_{25}N$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Buffer solution, Mobile phase, and **Sample solution:** Proceed as directed in the *Assay*.

Standard solution: 0.7 µg/mL of USP Terbinafine Hydrochloride RS in *Mobile phase* (equivalent to 0.6 µg/mL of terbinafine)

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 15-cm; 5-µm packing L7

Flow rate: 1.8 mL/min

Injection volume: 50 µL

Run time: 4 times the retention time of the terbinafine peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 10.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of any individual impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*

r_S = peak response of terbinafine from the *Standard solution*

C_S = concentration of USP Terbinafine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of terbinafine in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 1*)

M_{r1} = molecular weight of terbinafine, 291.44

M_{r2} = molecular weight of terbinafine hydrochloride, 327.90

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
N-Methyl-1-(naphthalen-1-yl) methanamine	0.14	1.5	0.2
Terbinafine	1.0	—	—
Any other individual impurity	—	1.0	0.2
Total impurities	—	—	0.7

• **Limit of Terbinafine Dimer**

Diluent: Acetonitrile and water (4:1)

Solution A: 1 mL/L of triethylamine in water

Solution B: 1 mL/L of triethylamine in a mixture of acetonitrile and water (19:1)

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	40	60
8	30	70
18	30	70
24	16	84
26	5	95
30	0	100
37	40	60

Time (min)	Solution A (%)	Solution B (%)
45	40	60

Standard solution: 1.4 µg/mL of USP Terbinafine Hydrochloride RS in *Diluent* (equivalent to 1.2 µg/mL of terbinafine)

Sample solution: Nominally equivalent to 2.5 mg/mL of terbinafine in *Diluent*, from crushed, finely powdered Tablets. [NOTE—Sonicate for 20 min with intermittent shaking.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 52°

Flow rate: 1 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 10.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the terbinafine dimer in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of the terbinafine dimer from the *Sample solution*

r_S = peak response of terbinafine from the *Standard solution*

C_S = concentration of USP Terbinafine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of terbinafine in the *Sample solution* (mg/mL)

F = relative response factor for the terbinafine dimer

M_{r1} = molecular weight of terbinafine, 291.44

M_{r2} = molecular weight of terbinafine hydrochloride, 327.90

Acceptance criteria: See *Table 3*.

Table 3

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Terbinafine	1.0	—	—
Terbinafine dimer[a]	2.0	2.1	0.05

[a] (2*E*,4*E*)-4-(4,4-Dimethylpent-2-ynylidene)-N^1,N^5-dimethyl-N^1,N^5-bis(naphthalen-1-ylmethyl)pent-2-ene-1,5-diamine.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light. Store at controlled room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Terbinafine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TERBINAFINE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

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