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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: