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Terbinafine Compounded Oral Suspension

DEFINITION

Terbinafine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled content of terbinafine ($C_{21}H_{25}N$). Prepare Terbinafine Compounded Oral Suspension containing 25 mg/mL of terbinafine as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Terbinafine (as Terbinafine Hydrochloride)	2500 mg (2810 mg)
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

Calculate the required quantity of each ingredient for the total amount to be prepared. If using tablets, place the required number of tablets in a suitable mortar, and comminute the tablets to a fine powder or add *Terbinafine Hydrochloride* powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a terbinafine suspension that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (2:3), with 0.15% triethylamine and 0.15% phosphoric acid. Make adjustments if necessary.

Standard stock solution: 1.0 mg/mL of USP Terbinafine Hydrochloride RS in methanol

Standard solution: Transfer 0.5 mL of *Standard stock solution* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume to obtain a solution containing 5 µg/mL of terbinafine, and pass through a suitable filter of 0.22-µm pore size.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Accurately pipet 1.0 mL to a 25-mL volumetric flask. Dilute with methanol to volume to obtain a nominal concentration of 1 mg/mL of terbinafine. Mix the sample again. Accurately pipet 0.5 mL of the diluted terbinafine solution to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a nominal concentration of 5 µg/mL of terbinafine.

Chromatographic system

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

Mode: LC

Detector: UV 224 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L1

Flow rate: 0.4 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time of the terbinafine peak is 5.1 min.]

Suitability requirements

Relative standard deviation: NMT 5.8%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of terbinafine in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.3–5.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 30 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **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 COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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