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Fluconazole Tablets

DEFINITION

Fluconazole Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of fluconazole ($C_{13}H_{12}F_2N_6O$).

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 absorption spectrum of the major peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the corresponding peak of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 2.89 g of [tetramethyl ammonium bromide](#) and 0.51 g of [sodium acetate trihydrate](#) in 750 mL of [water](#). Adjust with [glacial acetic acid](#) to a pH of 5.0. Pass through a suitable filter of 0.45- μ m pore size.

Mobile phase: [Acetonitrile](#), [water](#), and *Buffer* (22:15:75)

Diluent: [Methanol](#) and [water](#) (30:70)

Standard solution: 0.4 mg/mL of [USP Fluconazole RS](#) in *Diluent*. Sonicate if necessary to dissolve.

Sample stock solution: Nominally 2–4 mg/mL of fluconazole prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask, add [water](#) up to 10% of the flask volume and swirl to disperse the tablets. Add an additional 60% of the flask volume of *Diluent* and sonicate for 45 min with intermittent shaking. Dilute with *Diluent* to volume. Centrifuge a suitable portion of this solution for 15 min.

Sample solution: Nominally 0.4 mg/mL of fluconazole in *Diluent* from *Sample stock solution*. Pass through a suitable filter of 0.45- μ m pore size.

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 261 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 40 μ L

Run time: NLT 1.5 times the retention time of the fluconazole 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 fluconazole ($C_{13}H_{12}F_2N_6O$) in the portion of Tablets taken:

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

r_U = peak response of fluconazole from the *Sample solution*

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

C_S = concentration of [USP Fluconazole RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

DISSOLUTION (711)

Test 1

Medium: Water; 500 mL (900 mL for Tablets labeled to contain more than 100 mg)

Apparatus 2: 50 rpm

Time: 45 min

Buffer: 0.01 M [anhydrous sodium acetate](#) solution. Adjust with [glacial acetic acid](#) to a pH of 5.0.

Mobile phase: [Methanol](#), [acetonitrile](#), and *Buffer* (20:10:70)

Standard solution: 2 mg/mL of [USP Fluconazole RS](#) in *Medium*. Sonicate the solution to facilitate dissolution, if necessary. Quantitatively dilute a portion of this solution with *Medium* to obtain a final concentration similar to the one expected in the *Sample solution*.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 261 nm

Column: 3.9-mm × 15-cm; 4-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1100 theoretical plates

Tailing factor: NMT 3.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fluconazole ($C_{13}H_{12}F_2N_6O$) dissolved:

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

r_U = peak response of fluconazole from the *Sample solution*

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

C_S = concentration of [USP Fluconazole RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 or 900 mL

Tolerances: NLT 75% (Q) of the labeled amount of fluconazole ($C_{13}H_{12}F_2N_6O$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets *Dissolution Test 2*.

Medium: Water; 900 mL (for all Tablet strengths)

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: [Water](#) and [acetonitrile](#) (4:1)

Standard stock solution: 1.1 mg/mL of [USP Fluconazole RS](#) in methanol

Standard solution: Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of ($L/900$) mg/mL, where L is the label claim in mg/Tablet.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 50 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*