Griseofulvin Tablets

DEFINITION

Griseofulvin Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$).

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*.

ASSAY

• **PROCEDURE**

Mobile phase: Acetonitrile, tetrahydrofuran, and water (35:5:60). Degas for 5 min before use, and stir continuously during use.

Standard stock solution: 1.25 mg/mL of USP Griseofulvin RS in methanol

Standard solution: 0.125 mg/mL of USP Griseofulvin RS in *Mobile phase* from the *Standard stock solution*

Sample stock solution: Nominally 1.25 mg/mL of griseofulvin in methanol prepared as follows. Transfer the required number of finely powdered Tablets, based on the labeled amount, to a suitable volumetric flask and shake for at least 30 min in methanol. Dilute with methanol to volume, mix, and pass through a suitable filter.

Sample solution: 0.125 mg/mL of griseofulvin in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L10

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of USP Griseofulvin RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of the *Sample solution* (mg/mL)
P = potency of griseofulvin in USP Griseofulvin RS (µg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

Change to read:

• **DISSOLUTION** ⟨**711**⟩

Test 1 ● (RB 1-Jun-2013)

Medium: Water containing 40.0 mg/mL of sodium lauryl sulfate; 1000 mL

Apparatus 2: 75 rpm

Time: 90 min

Diluent: Methanol and water (40:10)

Sample solution: Sample per *Dissolution* ⟨711⟩ . Dilute with *Diluent*, if necessary.

Standard solution: USP Griseofulvin RS at a known concentration similar to that of the *Sample solution*, prepared in the same *Medium*

Analysis: Determine the percentage of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$) dissolved using UV absorption at the wavelength of maximum absorbance at about 291 nm.

Tolerances: NLT 75% (*Q*) of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$) is dissolved.

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

Medium: 4% sodium lauryl sulfate in water; 1000 mL

Apparatus 2: 50 rpm

Time: 45 min

Diluent: Methanol and water (40:10)

Standard solution: 10 µg/mL of USP Griseofulvin RS in *Diluent*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Diluent*, if necessary, to obtain a concentration similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: 291 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*
C_S = concentration of USP Griseofulvin RS in the *Standard solution* (µg/mL)
V = volume of the *Medium*, 1000 mL
D = dilution factor of the *Sample solution*
L = label claim (mg per Tablet)

Tolerances: NLT 80% (*Q*) of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$) is dissolved. ● (RB 1-Jun-2013)

• **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩

Procedure for content uniformity

Standard solution: 10 µg/mL of USP Griseofulvin RS in methanol

Sample solution: Transfer 1 Tablet to a suitable container; add a measured volume of methanol sufficient to yield a concentration of griseofulvin NMT 1 mg/mL; shake by mechanical means for 1 h, or longer if necessary, to disperse the specimen completely; and sonicate for 1 min. Centrifuge a portion of this solution, and quantitatively dilute a volume of the clear supernatant to obtain a *Sample solution* containing about 10 µg/mL of griseofulvin.

Blank: Methanol

Instrumental conditions

Mode: UV

Analytical wavelength: 292 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times P \times 100$$

A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*

C_S = concentration of USP Griseofulvin RS in the *Standard solution* (µg/mL)
C_U = nominal concentration of the *Sample solution* (µg/mL)
P = potency of griseofulvin in USP Griseofulvin RS (µg/mL)

Acceptance criteria: Meet the requirements

SPECIFIC TESTS

• **Loss on Drying** ⟨**731**⟩

Analysis: Dry the sample at 60° for 3 h in a capillary-stoppered bottle under vacuum.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

Change to read:

• **Labeling:** The label indicates that the griseofulvin contained is known as griseofulvin (microsize). •When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.• (RB 1-Jun-2013)

• **USP Reference Standards** ⟨**11**⟩

USP Griseofulvin RS