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Ultramicrosize Griseofulvin Tablets

DEFINITION

Ultramicrosize Griseofulvin Tablets are composed of ultramicrosize crystals of Griseofulvin dispersed in Polyethylene Glycol 6000 or dispersed by other suitable means. They 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 prepared as follows. Weigh and powder NLT 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 125 mg of griseofulvin, to a 100-mL volumetric flask. Add 70 mL of methanol, shake by mechanical means for 30 min, and dilute with methanol to volume. Filter a portion of this solution, discarding the first 5 mL of the filtrate.

Sample solution: Nominally 0.125 mg/mL of griseofulvin in *Mobile phase* from the *Sample stock solution* prepared as follows. Dilute 5.0 mL of the clear filtrate from the *Sample stock solution* with *Mobile phase* to 50 mL.

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:

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

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 griseofulvin in the *Sample solution* (mg/mL)

P = potency of griseofulvin in USP Griseofulvin RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 5.4 g/L of sodium lauryl sulfate in water; 1000 mL

Apparatus 2: 75 rpm

Time: 45 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 in the *Sample solution*, prepared in the same medium

Instrumental conditions

Mode: UV

Analytical wavelength: 291 nm

Analysis

Samples: *Sample solution* and *Standard solution*

Determine the amount of griseofulvin ($C_{17}H_{17}ClO_6$) dissolved.

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

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

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

Sample solution: Nominally 10 µg/mL of griseofulvin in methanol prepared as follows. Transfer 1 Tablet to a suitable container; add a 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 measured volume of the clear supernatant to obtain a solution containing 10 µg/mL of griseofulvin.

Blank: Methanol

Instrumental conditions

Mode: UV

Analytical wavelength: 292 nm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

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

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

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* (mg/mL)

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

P = potency of griseofulvin in USP Griseofulvin RS (µg/mg)

F = conversion factor, 0.001 mg/µg

▲▲ (CN 1-Aug-2023)

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Sample: 100 mg

Analysis: Dry at 60° for 3 h in a capillary-stoppered bottle under vacuum at a pressure not exceeding 5 mm of mercury.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Griseofulvin RS

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

Topic/Question	Contact	Expert Committee
ULTRAMICROSIZE GRISEOFULVIN TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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