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Griseofulvin Oral Suspension

DEFINITION

Griseofulvin Oral Suspension contains NLT 90.0% and NMT 115.0% of the labeled amount of griseofulvin ($C_{17}H_{17}ClO_6$). It contains one or more suitable colors, diluents, flavors, preservatives, and wetting agents.

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**

Solution A: 100 mg/mL of sodium chloride in water

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. Transfer a measured volume of Oral Suspension, freshly mixed and free from air bubbles and equivalent to 125 mg of griseofulvin, to a glass-stoppered, 50-mL centrifuge tube. Add 20 mL of methylene chloride and 20 mL of *Solution A*. Insert the stopper into the tube, and mix by rotating the tube for 10 min. Separate the phases by centrifugation, carefully remove the lower methylene chloride layer with a needle and syringe, and filter through methylene chloride-prerinsed anhydrous sodium sulfate into a 100-mL volumetric flask. Repeat the extraction with two additional 20-mL portions of methylene chloride, combining the extracts in the volumetric flask. Dilute with methylene chloride to volume.

Sample solution: Nominally 0.125 mg/mL of griseofulvin prepared as follows. Transfer 5.0 mL of *Sample stock solution* to a 50-mL volumetric flask, and evaporate on a steam bath under a stream of nitrogen to dryness. Transfer 4.0 mL of *Mobile phase* to the flask, swirl to dissolve the residue, and dilute with *Mobile phase* to volume.

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 Oral Suspension 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

- **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for oral suspension packaged in single-unit containers
- **Deliverable Volume ⟨698⟩:** Meets the requirements

SPECIFIC TESTS

- **pH ⟨791⟩:** 5.5–7.5

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** The label indicates that the griseofulvin contained is known as griseofulvin (microsize).
- **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
GRISEOFULVIN ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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