Griseofulvin Tablets

**DEFINITION**
Griseofulvin Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of griseofulvin (C₁₇H₁₇ClO₆).

**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 (C₁₇H₁₇ClO₆) in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_2}{r_1} \right) \times \left( \frac{C_l}{C_o} \right) \times P \times 100
\]

\[
\begin{align*}
  r_1 &= \text{peak response from the Sample solution} \\
  r_2 &= \text{peak response from the Standard solution} \\
  C_l &= \text{concentration of USP Griseofulvin RS in the Standard solution (mg/mL)} \\
  C_o &= \text{nominal concentration of the Sample solution (mg/mL)} \\
  P &= \text{potency of griseofulvin in USP Griseofulvin RS (µg/mL)} \\
  A_i &= \text{absorbance of the Standard solution} \\
  A_s &= \text{absorbance of the Sample solution} \\
  D &= \text{dilution factor of the Sample solution} \\
  V &= \text{volume of the Standard solution, 1000 mL} \\
  L &= \text{label claim (mg per Tablet)}
\end{align*}
\]

**Acceptance criteria:** 90.0%–115.0%

**PERFORMANCE TESTS**

**Change to read:**

- **Dissolution** (711)
  - **Test 1** (88 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 (C₁₇H₁₇ClO₆) dissolved using UV absorption at the wavelength of maximum absorbance at about 291 nm.

**Tolerances:** NLT 75% (Q) of the labeled amount of griseofulvin (C₁₇H₁₇ClO₆) 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 (C₁₇H₁₇ClO₆) dissolved:**

\[
\text{Result} = \left( \frac{A_s}{A_i} \right) \times V \times 100 \times \left( \frac{D}{V} \right)
\]

- **A_s** = absorbance of the Sample solution
- **A_i** = absorbance of the Standard solution
- **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 (C₁₇H₁₇ClO₆) dissolved.

- **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 (C₁₇H₁₇ClO₆) in the portion of Tablets taken:**

\[
\text{Result} = \left( \frac{A_s}{A_i} \right) \times \left( \frac{C_i}{C_o} \right) \times P \times 100
\]

- **A_s** = absorbance of the Sample solution
- **A_i** = absorbance of the Standard solution

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2 Griseofulvin

\[ C_s = \text{concentration of USP Griseofulvin RS in the Standard solution (µg/mL)} \]
\[ C_u = \text{nominal concentration of the Sample solution (µg/mL)} \]
\[ P = \text{potency of griseofulvin in USP Griseofulvin RS (µg/mL)} \]

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.

• USP Reference Standards (11)
  USP Griseofulvin RS

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