



Edition: BP 2025 (Ph. Eur. 11.6 update)

Griseofulvin Tablets

[General Notices](#)

Action and use

Antifungal.

DEFINITION

Griseofulvin Tablets contain Griseofulvin.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of griseofulvin, $C_{17}H_{17}ClO_6$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Extract a quantity of the powdered tablets containing 0.125 g of Griseofulvin with 20 mL of [dichloromethane](#), add 1 g of [anhydrous sodium sulfate](#), shake and filter. Evaporate the filtrate to dryness and dry at a pressure not exceeding 0.7 kPa for 1 hour. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of griseofulvin ([RS 172](#)).

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the [dissolution test for tablets and capsules](#), [Appendix XII B1](#).

TEST CONDITIONS

- Use Apparatus 2, rotating the paddle at 100 revolutions per minute.
- Use 1000 mL of a 1.5% w/v solution of [sodium dodecyl sulfate](#), at a temperature of 37°, as the medium.

PROCEDURE

After 45 minutes withdraw a 10-mL sample of the medium and filter. Measure the [absorbance](#) of the filtrate, suitably diluted if necessary with [methanol](#) (80%), at the maximum at 291 nm, [Appendix II B](#), using a 1.5% w/v solution of [sodium dodecyl sulfate](#) in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of griseofulvin, $C_{17}H_{17}ClO_6$, in the medium taking 725 as the value of A(1%, 1 cm) at the maximum at 291 nm.

LIMITS

The amount of griseofulvin released is not less than 75% of the stated amount.

Related substances

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions in mobile phase B.

- (1) Disperse a quantity of powdered tablets containing 0.25 g of Griseofulvin in mobile phase B and dilute to 500 mL.
- (2) Dilute 1 volume of solution (1) to 100 volumes.
- (3) 0.05% w/v of [griseofulvin for system suitability EPCRS](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography](#) (5 μm) (Discovery C18 is suitable).
- (b) Use gradient elution and the mobile phase described below.
- (c) Use a flow rate of 1.0 mL per minute.
- (d) Use a column temperature of 30°.
- (e) Use a detection wavelength of 290 nm.
- (f) Inject 10 μL of each solution.

MOBILE PHASE

Mobile phase A 20 volumes of 0.1 % v/v [formic acid](#) adjusted to pH 4.5 with [dilute ammonia R2](#) and 80 volumes of [water](#).

Mobile phase B 15 volumes of [water](#), 20 volumes of 0.1 % v/v [formic acid](#) adjusted to pH 4.5 with [dilute ammonia R2](#) and 65 volumes of [acetonitrile](#).

| Time (Minutes) | Mobile phase A (% v/v) | Mobile phase B (% v/v) | Comment |
|----------------|------------------------|------------------------|-----------------|
| 0-3 | 50 | 50 | isocratic |
| 3-13 | 50→40 | 50→60 | linear gradient |
| 13-16 | 40→10 | 60→90 | linear gradient |
| 16-24 | 10 | 90 | isocratic |

When the chromatograms are recorded under the prescribed conditions, the relative retention times with reference to griseofulvin (retention time about 16 minutes) are: impurity A, about 0.4; impurity B, about 0.7 and impurity C, about 1.1.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [peak-to-valley ratio](#) is at least 3.0, where H_p is the height above the baseline of the peak due to impurity C and H_v is the height above the baseline of the lowest point of the curve separating this peak from the peak due to griseofulvin.

LIMITS

Identify any peak corresponding to impurity A in the chromatogram obtained with solution (1) and multiply the area of this peak by a correction factor of 0.6.

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity B is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (3.0%);

the area of any peak corresponding to impurity A is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (2.0%);

the area of any peak corresponding to impurity C is not greater than 0.75 times the area of the principal peak in the chromatogram obtained with solution (2) (0.75%);

the area of any other [secondary peak](#) is not greater than 0.2 times the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of all [secondary peaks](#) is not greater than five times the area of the principal peak in the chromatogram obtained with solution (2) (5.0%).

Disregard any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

ASSAY

Weigh and powder 20 tablets. Carry out the method for liquid chromatography, [Appendix III D](#), using the following solutions.

- (1) Disperse a quantity of powdered tablets containing 0.25 g of Griseofulvin in mobile phase B and dilute to 500 mL.
- (2) 0.05% w/v of [griseofulvin for LC assay and identification EPCRS](#).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{17}H_{17}ClO_6$ in the tablets from the chromatograms obtained and using the declared content of $C_{17}H_{17}ClO_6$ in [griseofulvin EPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Griseofulvin.