



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

Felbinac Gel

[General Notices](#)

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Felbinac Gel is a solution of Felbinac in a suitable water-miscible basis.

The gel complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.

Content of felbinac, C₁₄H₁₂O₂

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for [thin-layer chromatography, Appendix III A](#), using the following solutions.

- (1) Dilute a quantity of the gel containing 30 mg of Felbinac with sufficient [acetone](#) to produce 5 mL and mix.
- (2) 0.6% w/v solution of [felbinac BPCRS](#) in [acetone](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel F₂₅₄](#) (Merck [silica gel 60 F₂₅₄](#) plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 5 µL of each solution.
- (d) Develop the plate to 12 cm.
- (e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#) (first examination). Spray the plate with a mixture of equal volumes of [formaldehyde solution](#) and [sulfuric acid](#) and heat at 110° for 10 minutes (second examination).

MOBILE PHASE

1 volume of [glacial acetic acid](#), 25 volumes of [acetone](#) and 50 volumes of [hexane](#).

CONFIRMATION

In the first examination:

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

In the second examination:

The principal spots in the chromatograms obtained with solutions (1) and (2) are an intense purple colour.

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Acidity or alkalinity

pH, 7.0 to 8.0, [Appendix V L](#).

Related substances

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

- (1) Dissolve a weighed quantity of the gel containing 30 mg of Felbinac in [methanol](#) and add sufficient [methanol](#) to produce 50 mL.
- (2) Dilute 1 volume of solution (1) to 100 volumes with mobile phase and further dilute 1 volume of this solution to 10 volumes with the same solvent.
- (3) 0.00006% w/v of [4-acetylbiphenyl](#) and 0.00006% w/v of [biphenyl](#) in [methanol](#)
- (4) 0.001% w/v of [felbinac BPCRS](#) and 0.001% w/v of *o*-phenylbenzoic acid in mobile phase.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (10 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel for chromatography](#) (10 µm) (Partisil ODS3 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 2 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 254 nm.
- (f) Inject 50 µL of each solution.
- (g) For solution (1) allow the chromatography to proceed for at least twice the retention time of the principal peak.

MOBILE PHASE

45 volumes of a 0.1% v/v solution of [glacial acetic acid](#) and 55 volumes of [methanol](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the [resolution](#) between the two principal peaks is at least 3.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to 4-acetylbiphenyl is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (0.1%);

the area of any peak corresponding to biphenyl is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (0.1%);

the area of any other [secondary peak](#) is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

ASSAY

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

- (1) Dissolve a quantity of the gel containing 30 mg of Felbinac in 70 mL of mobile phase, add sufficient mobile phase to produce 100 mL, mix and dilute 1 volume of the resulting solution to 20 volumes with mobile phase.
- (2) 0.0015% w/v of [felbinac BPCRS](#) in mobile phase.
- (3) 0.0015% w/v of [felbinac BPCRS](#) and 0.0015% w/v of *o*-phenylbenzoic acid in mobile phase.

CHROMATOGRAPHIC CONDITIONS

Use the chromatographic conditions described under Related substances, with the exception of the run time. Inject 20 μ L of each solution.

SYSTEM SUITABILITY

The Assay is not valid unless, in the chromatogram obtained with solution (3), the resolution between the two principal peaks is at least 3.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{14}H_{12}O_2$ in the gel from the chromatograms obtained using the declared content of $C_{14}H_{12}O_2$ in felbinac BPCRS.