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

Felbinac Cutaneous Foam

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Felbinac Cutaneous Foam is a fluid foam containing Felbinac in solution in a suitable pressurised container.

The cutaneous foam complies with the requirements stated under Medicated Foams and with the following requirements.

Content of felbinac, $C_{14}H_{12}O_2$

95.0 to 105.0% of the stated amount.

In each of the following tests, discharge a quantity of the foam into a suitable vessel with the can upright. Quantitatively transfer the foam using methanol. Determine the sample weight by difference.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Dissolve a weighed quantity of the foam containing 60 mg of Felbinac in *methanol*, warming slightly if necessary to break the foam, and add sufficient *methanol* to produce 100 mL.
(2) 0.06% w/v solution of *felbinac BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel F_{254}* (Merck silica gel 60 F_{254} plates are suitable)
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 10 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 in position and colour 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

Alkalinity

pH of the foam, 7.0 to 8.6, Appendix V L. Ensure good contact between the foam and the electrode.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dissolve a weighed quantity of the foam containing 30 mg of Felbinac in *methanol*, warming slightly if necessary to break the foam, and add sufficient *methanol* to produce 50 mL.
(2) Dilute 1 volume of solution (1) to 100 volumes with the 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 the 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 factor* 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 weighed quantity of the foam containing 30 mg of felbinac in 60 mL of *methanol*, warming slightly, if necessary, to break the foam, add slowly, and with mixing, sufficient *water* to produce 100 mL and dilute 1 volume of the

resulting solution to 20 volumes with the mobile phase.
(2) 0.0015% w/v of *felbinac BPCRS* in the mobile phase.
(3) 0.0015% w/v each of *felbinac BPCRS* and o-*phenylbenzoic acid* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

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

SYSTEM SUITABILITY

The assay is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* 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 foam using the declared content of $C_{14}H_{12}O_2$ in *felbinac BPCRS*.

STORAGE

Felbinac Cutaneous Foam should be kept protected from light. It should not be refrigerated.