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

Fludrocortisone Tablets

General Notices

Action and use

Mineralocorticoid.

DEFINITION

Fludrocortisone Tablets contain Fludrocortisone Acetate.

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

Content of fludrocortisone acetate, $C_{23}H_{31}FO_6$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Complies with the test for *identification of steroids*, Appendix III A, using *impregnating solvent I* and *mobile phase B*. Apply separately to the plate 20 µL of each of the following solutions. For solution (1) shake a quantity of the powdered tablets containing 1 mg of fludrocortisone acetate with 20 mL of *chloroform* for 5 minutes, filter, evaporate the filtrate to dryness and dissolve the residue in 4 mL of a mixture of 9 volumes of *chloroform* and 1 volume of *methanol*. Solution (2) contains 0.025% w/v of *fludrocortisone acetate BPCRS* in a mixture of 9 volumes of *chloroform* and 1 volume of *methanol*.
B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to fludrocortisone acetate in the chromatogram obtained with solution (2).

TESTS

Uniformity of content

Tablets containing less than 2 mg and/or less than 2% w/w of Fludrocortisone Acetate comply with the requirement stated under Tablets using the following method of analysis. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions protected from light. Solution A contains 0.002% w/v of *norethisterone BPCRS* in *acetonitrile*.

(1) Place a single tablet in a centrifuge tube, add 1 mL of *water*, shake on a vortex-type mixer for 1 minute, add 4.0 mL of solution A and shake again for 1 minute. Shake for a further 40 minutes on a mechanical shaker, centrifuge and use the clear supernatant solution.
(2) 4 volumes of a 0.0025% w/v solution of *fludrocortisone acetate BPCRS* in solution A and 1 volume of *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Spherisorb ODS 1 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 240 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

40 volumes of *acetonitrile* and 60 volumes of *water*.

DETERMINATION OF CONTENT

Calculate the content of $C_{23}H_{31}FO_6$ in each tablet using the declared content of $C_{23}H_{31}FO_6$ in *fludrocortisone acetate BPCRS*.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Solution A contains 0.01% w/v of *norethisterone BPCRS* (internal standard) in *acetonitrile*.

(1) Shake a quantity of the powdered tablets containing 0.5 mg of fludrocortisone acetate with 2 mL of *water* for 1 minute, add 4 mL of solution A and 4 mL of *acetonitrile* and shake on a mechanical shaker for 40 minutes. Dilute the mixture to 20 mL with *acetonitrile*, centrifuge and use the supernatant liquid.
(2) 20 mL of solution A, 25 mL of a 0.01% w/v solution of *fludrocortisone acetate BPCRS* in *acetonitrile* and 10 mL of *water* diluted to 100 mL with *acetonitrile*.
(3) Prepare in the same manner as solution (1) but using 8 mL of *acetonitrile* in place of 4 mL of solution A and 4 mL of *acetonitrile*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Uniformity of content may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{23}H_{31}FO_6$ in the tablets using the declared content of $C_{23}H_{31}FO_6$ in *fludrocortisone acetate BPCRS*.