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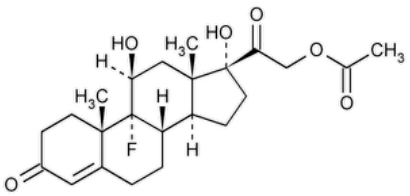
Fludrocortisone Acetate



$C_{23}H_{31}FO_6$ 422.49

Pregn-4-ene-3,20-dione, 21-(acetyloxy)-9-fluoro-11,17-dihy droxy-, (11β)-.

9-Fluoro-11β,17,21-trihydroxypregn-4-ene-3,20-dione 21-acetate CAS RN®: 514-36-3; UNII: V47IF0PVH4.

» Fludrocortisone Acetate contains not less than 97.0 percent and not more than 103.0 percent of $C_{23}H_{31}FO_6$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers, protected from light.

USP Reference standards ⟨11⟩—
USP Fludrocortisone Acetate RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020) ·

Specific rotation ⟨781S⟩: between +126° and +138°.
Test solution: 5 mg per mL, in acetone.

Loss on drying ⟨731⟩—Dry it in vacuum at 100° for 2 hours over magnesium perchlorate: it loses not more than 3.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Chromatographic purity—Dissolve about 100 mg of it in a mixture of 5 mL of chloroform and 1 mL of acetone in a 10-mL volumetric flask, and dilute with chloroform to volume. Dilute 1 mL of this solution with chloroform to 100 mL. Apply 10 µL, in 5-µL increments, of the test solution and of its dilution to a line parallel to and about 2.5 cm from the bottom of a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the plate in a suitable chamber containing a mixture of chloroform, methanol, and water (85:14:1) until the solvent front has moved about 15 cm. Remove the plate, air-dry, and examine under short-wavelength UV light: no spot in the chromatogram of the more concentrated test solution, other than the principal spot, is larger or more intense than the spot from the diluted test solution (1.0%).

Assay—

Standard preparation—Dissolve about 25 mg of USP Fludrocortisone Acetate RS, accurately weighed, in chloroform to make 250 mL, and mix. Pipet 10 mL of this solution into a 50-mL volumetric flask, add chloroform to volume, and mix.

Assay preparation—Prepare as directed under *Standard preparation*, using Fludrocortisone Acetate instead of the USP Reference Standard.

Procedure—Pipet 10 mL of the *Assay preparation* and the *Standard preparation*, respectively, into separate 25-mL volumetric flasks, and pipet 10 mL of chloroform into a third flask to provide a blank. Treat each flask as follows. Add 1.0 mL of a solution prepared by dissolving 50 mg of blue tetrazolium in 10 mL of methanol, and mix. Add 1.0 mL of a mixture of 1 volume of tetramethylammonium hydroxide TS and 4 volumes of methanol, mix, and allow to stand for 10 minutes. Dilute with a 1 in 100 solution of hydrochloric acid in methanol to volume. Concomitantly determine the absorbances of the solutions from the *Assay preparation* and the *Standard preparation* in 1-cm cells at about 525 nm, with a suitable spectrophotometer, against the reagent blank. Calculate the quantity, in mg, of $C_{23}H_{31}FO_6$ in the portion of Fludrocortisone Acetate taken by the formula:

$$1.25C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Fludrocortisone Acetate RS in the *Standard preparation;* and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
FLUDROCORTISONE ACETATE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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