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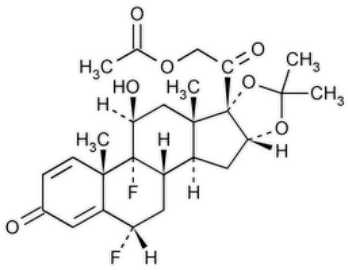
Fluocinonide



$C_{26}H_{32}F_2O_7$ 494.52

Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-6,9-difluoro-11-hydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (6α,11β,16α)-.

6α,9-Difluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione, cyclic 16,17-acetal with acetone, 21-acetate CAS RN®: 356-12-7; UNII: 2W4A77YPAN.

» Fluocinonide contains not less than 97.0 percent and not more than 103.0 percent of $C_{26}H_{32}F_2O_7$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Fluocinonide RS

Identification—

Change to read:

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

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)* —

Solution: 10 µg per mL.

Medium: methanol.

Absorptivities at 238 nm, calculated on the dried basis, do not differ by more than 3.0%.

Specific rotation ⟨781S⟩: between +81° and +89°.

Test solution: 10 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry it at 105° for 3 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: negligible, from 100 mg.

Chromatographic purity—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay*.

Test preparation—Transfer about 25 mg of fluocinonide, accurately weighed, to a 10-mL volumetric flask, add acetonitrile to volume, and mix.

Procedure—Inject 30 µL of the *Test preparation* into the chromatograph, record the chromatogram, and measure the area responses of all peaks. Calculate the area percentage of each peak observed in the chromatogram. The largest secondary peak is not more than 1.0% of the total area, and no other secondary peak is more than 0.5% of the total area. The sum of the areas of all peaks, other than the main peak, does not constitute more than 2.0% of the total area.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and water (1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 25 mg of USP Fluocinonide RS, accurately weighed, to a 100-mL volumetric flask, add acetonitrile to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a solution having a known concentration of about 0.025 mg of USP Fluocinonide RS per mL.

Assay preparation—Using about 25 mg of Fluocinonide, accurately weighed, proceed as directed for *Standard preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (about 30 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{26}H_{32}F_2O_7$ in the portion of Fluocinonide taken by the formula:

$$1000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Fluocinonide RS in the *Standard preparation;* and r_U and r_S are the peak responses due to the fluocinonide obtained 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
FLUOCINONIDE	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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