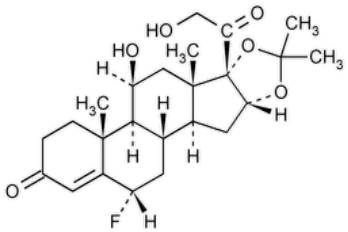
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-291F6F37-0788-4A7C-9DF9-4515F4268FD1_3_en-US
DOI: https://doi.org/10.31003/USPNF_M34030_03_01
DOI Ref: 81yt6

Flurandrenolide



$C_{24}H_{33}FO_6$ 436.51

Pregn-4-ene-3,20-dione, 6-fluoro-11,21-dihydroxy-16,17-[(1- methylethylidene)bis(oxy)]-, 6α11β,16α)-.

6α-Fluoro-11β,16α,17,21-tetrahydroxypregn-4-ene-3,20-dione, cyclic 16,17-acetal with acetone CAS RN®: 1524-88-5; UNII: 8EUL29XUQT.

» Flurandrenolide contains not less than 97.0 percent and not more than 102.0 percent of $C_{24}H_{33}FO_6$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers in a cold place, protected from light.

USP Reference standards ⟨11⟩—

USP Flurandrenolide 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: 20 µg per mL.

Medium: methanol.

Absorptivities at 237 nm, calculated on the dried basis, do not differ by more than 3.0%.

Specific rotation ⟨781S⟩: between +145° and +153°.

Test solution: 10 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry it in vacuum at 105° for 4 hours: it loses not more than 1.0% of its weight.

Ordinary impurities ⟨466⟩—

Test solution: methanol.

Standard solution: methanol.

Application volume: 10 µL.

Eluant: a mixture of toluene and isopropyl alcohol (90:10), in a nonequilibrated chamber.

Visualization: 1.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Dissolve Prednisone in *Mobile phase*, with the aid of sonication, to obtain a solution containing about 1 mg per mL.

Standard preparation—Transfer about 5 mg of USP Flurandrenolide RS, accurately weighed, to a 10-mL volumetric flask, add 2.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, sonicate to aid solution, and mix to obtain a solution having a known concentration of about 0.5 mg of USP Flurandrenolide RS per mL.

Assay preparation—Transfer about 5 mg of Flurandrenolide, accurately weighed, to a 10-mL volumetric flask, add 2.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, sonicate to aid solution, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 240-nm detector and a 4-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the order of elution is prednisone followed by flurandrenolide, the resolution; *R,* between the analyte and internal standard is not less than 2.0; and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.5 for prednisone and 1.0

for flurandrenolide. Calculate the quantity, in mg, of $C_{24}H_{33}FO_6$ in the portion of Flurandrenolide taken by the formula:

$$10C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Flurandrenolide RS in the *Standard preparation;* and R_U and R_S are the peak response ratios 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
FLURANDRENOLIDE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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

Current DocID: GUID-291F6F37-0788-4A7C-9DF9-4515F4268FD1_3_en-US
DOI: https://doi.org/10.31003/USPNF_M34030_03_01
DOI ref: 81yt6