Pregna-1,4-diene-3,20-dione, 9-fluoro-11,16,17,21-tetrahydroxy-, (11*β*,16α).
9-Fluoro-11*β*,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione [124-94-7].

» Triamcinolone contains not less than 97.0 percent and not more than 102.0 percent of $C_{21}H_{27}FO_6$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Triamcinolone RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 20 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 +65° and +72°.

Test solution: 2 mg per mL, in dimethylformamide.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 4 hours: it loses not more than 2.0% of its weight.

Residue on ignition ⟨281⟩: 0.5%.

Heavy metals, *Method II* ⟨231⟩: 0.0025%.

Assay—

Mobile phase—Prepare a degassed solution containing about 60 volumes of methanol and 40 volumes of water such that the retention times for triamcinolone and hydrocortisone are about 5 and 10 minutes, respectively.

Internal standard solution—Dissolve hydrocortisone in *Mobile phase* to obtain a solution having a concentration of about 0.3 mg per mL.

Standard preparation—Transfer about 10 mg of USP Triamcinolone RS, accurately weighed, to a 50-mL volumetric flask, dissolve in *Internal standard solution*, dilute with the same solvent to volume, and mix.

Assay preparation—Using about 10 mg of Triamcinolone, accurately weighed, prepare as directed under *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 1.5 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 2.0%, and the resolution factor between triamcinolone and hydrocortisone is not less than 3.0.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph by means of a suitable microsyringe or sampling valve, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{27}FO_6$ in the portion of Triamcinolone taken by the formula:

$$50C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Triamcinolone RS in the *Standard preparation*, and R_U and R_S are the peak response ratios of triamcinolone to hydrocortisone obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Triamcinolone Tablets

» Triamcinolone Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{27}FO_6$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Triamcinolone RS

Identification—Powder a number of Tablets, equivalent to about 25 mg of triamcinolone, and digest with 25 mL of acetone for 15 minutes. Filter through a fine-porosity, sintered-glass filtering funnel into about 100 mL of solvent hexane, swirl the liquid, and allow to stand for 30 minutes. Collect the crystals that form, wash the crystals with three 10-mL portions of water followed by 2 mL of acetone, and dry at 60° for 1 hour: the dried crystals so obtained respond to *Identification* test *A* under *Triamcinolone.*

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{21}H_{27}FO_6$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 238 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, in comparison with a Standard solution having a known concentration of USP Triamcinolone RS in the same *Medium.*

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{21}H_{27}FO_6$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase, *Internal standard solution*, *Standard preparation,* and *Chromatographic system*—Prepare as directed in the *Assay* under *Triamcinolone.*

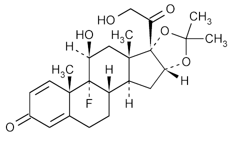
Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of triamcinolone, to a suitable container. Add 50.0 mL of *Internal standard solution*, and shake vigorously by mechanical means for 10 minutes. Centrifuge for 10 minutes or until a clear supernatant is obtained.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Triamcinolone*. The relative retention times are about 1.0 for triamcinolone and 1.9 for hydrocortisone. Calculate the quantity, in mg, of $C_{21}H_{27}FO_6$ in the portion of Tablets taken by the formula:

$$50C(R_U / R_S)$$

in which the terms are as defined therein.

Triamcinolone Acetonide



$C_{24}H_{31}FO_6$ 434.51
Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11*β*,16α)-.
9-Fluoro-11*β*,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone [76-25-5].

» Triamcinolone Acetonide contains not less than 97.0 percent and not more than 102.0 percent of $C_{24}H_{31}FO_6$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—
USP Fluoxymesterone RS
USP Triamcinolone Acetonide RS

Identification—

A: *Infrared Absorption* ⟨197K⟩: recrystallized from methanol.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 20 µg per mL.

Medium: methanol.

Specific rotation ⟨781S⟩**:** between +118° and +130°.

Test solution: 5 mg per mL, in dimethylformamide.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 4 hours: it loses not more than 1.5% of its weight.

Heavy metals—Carefully ignite 1.0 g in a muffle furnace at about 550° until thoroughly charred. Cool, add to the contents of the crucible 5 drops of sulfuric acid and 2 mL of nitric acid, cautiously heat until reaction has ceased, then ignite in a muffle furnace at 500° to 600° until the carbon is entirely burned off. Cool, add 2 mL of hydrochloric acid, and slowly evaporate on a steam bath to dryness. Moisten the residue with 1 drop of hydrochloric acid and 5 mL of hot water, and digest for 2 minutes. Add 1 drop of phenolphthalein TS, then add 6 N ammonium hydroxide dropwise until the reaction is alkaline. Render the solution acid with 1 N acetic acid, then add 1 mL of excess, transfer to a beaker, and add water to make 10 mL. Pipet 2.5 mL (equivalent to 25 µg of lead) of *Standard Lead Solution* (see *Lead* ⟨231⟩) into a second beaker, add 3 mL of water and 1 drop of phenolphthalein TS, render just alkaline with 6 N ammonium hydroxide, then render acid with 1 N acetic acid, and add 1 mL in excess. Dilute with water to 10 mL. To each beaker add 5 mL of freshly prepared hydrogen sulfide TS, mix, and allow to stand for 5 minutes. Pass each solution through a separate, acid-resistant, white, plain membrane filter of 0.22-µm pore size and 25 mm in diameter, collecting the precipitates on the filter disks: the color of the precipitate from the solution under test is not darker than that from the control. The heavy metals limit is 0.0025%.

Chromatographic purity—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (17:8). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Test solution—Transfer about 25 mg of Triamcinolone Acetonide, accurately weighed, to a 50-mL volumetric flask; dissolve in 25 mL of methanol, shake vigorously to aid dissolution; dilute with *Mobile phase* to volume; and mix.

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 1.5 mL per minute. Chromatograph the *Test solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between triamcinolone acetonide and any impurity peak is not less than 1.0.

Procedure—Inject about 20 µL of the *Test solution* into the chromatograph, record the chromatogram for not less than four times the retention time of triamcinolone acetonide, and measure all of the peak responses. Calculate the percentage of each impurity in the portion of Triamcinolone Acetonide taken by the formula:

$$100(r_i / r_s)$$

in which r_i is the peak response for each impurity; and r_s is the sum of the responses of all the peaks: not more than 0.3% of any individual impurity is found, and not more than 0.8% of total impurities is found.

Assay—

Mobile phase—Prepare a solution of acetonitrile in water containing approximately 30% (v/v) of acetonitrile.

Internal standard solution—Dissolve USP Fluoxymesterone RS in methanol to obtain a solution having a concentration of about 50 µg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Triamcinolone Acetonide RS in *Internal standard solution* to obtain a solution having a known concentration of about 75 µg per mL. Mix an accurately measured volume of the resulting solution with an equal volume of *Mobile phase* to obtain a *Standard preparation* containing about 37.5 µg of USP Triamcinolone Acetonide RS per mL.

Assay preparation—Using about 37 mg of Triamcinolone Acetonide, accurately weighed, proceed as directed for *Standard preparation.*

Procedure—Introduce equal volumes (between 15 µL and 25 µL) of the *Assay preparation* and the *Standard preparation* into a high-pressure liquid chromatograph (see *Chromatography* ⟨621⟩) operated at room temperature, by means of a suitable microsyringe or sampling valve. Adjust the operating parameters with *Mobile phase* on the column so that the separation of triamcinolone acetonide and internal standard is optimized, with a retention time of about 14.5 minutes for triamcinolone acetonide. Typically, the apparatus is fitted with a 4-mm × 30-cm column containing packing L1 and is equipped with a UV detector capable of monitoring absorbance at 254 nm, and a suitable recorder. In a suitable chromatogram, the coefficient of variation for five replicate injections of a single specimen is not more than 3.0%; and the resolution factor, *R* (see *Chromatography* ⟨621⟩), between the peaks for triamcinolone acetonide and fluoxymesterone is not less than 2.0. Measure the heights of the internal standard and triamcinolone acetonide peaks at the same retention times obtained from the *Assay preparation* and the *Standard preparation.* Calculate the quantity, in mg, of $C_{24}H_{31}FO_6$ in the portion of Triamcinolone Acetonide taken by the formula:

$$1000C(R_U / R_S)$$

in which *C* is the concentration, in mg per mL, of USP Triamcinolone Acetonide RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak heights of triamcinolone acetonide to the internal standard obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Triamcinolone Acetonide Topical Aerosol

» Triamcinolone Acetonide Topical Aerosol is a solution of Triamcinolone Acetonide in a suitable propellant in a pressurized container. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_{24}H_{31}FO_6$.

Packaging and storage—Preserve in pressurized containers, and avoid exposure to excessive heat.

USP Reference standards ⟨11⟩—
USP Triamcinolone Acetonide RS

Identification—Apply 20 µL of a solution prepared as directed for *Assay preparation* in the *Assay* but without the addition of the *Internal standard solution*, and 20 µL of a solution of USP Triamcinolone Acetonide RS in methanol containing 30 µg per mL, to a line parallel to and about 1.5 cm from the bottom edge of a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel. Proceed as directed in the *Identification* test under