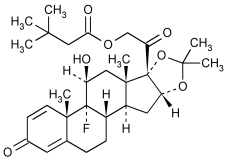
Triamcinolone Hexacetonide



$C_{30}H_{41}FO_7$ 532.64

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

9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone 21-(3,3-dimethylbutyrate) [*5611-51-8*].

» Triamcinolone Hexacetonide contains not less than 97.0 percent and not more than 102.0 percent of $C_{30}H_{41}FO_7$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—***USP Triamcinolone Hexacetonide RS*.

Identification, *Infrared Absorption* ⟨197K⟩.

Change to read:

Specific rotation ⟨781S⟩: •between +91° and +98°.• (RB 1-Jul-2009)

Test solution: 10 mg per mL, in chloroform.

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

Heavy metals, *Method II* ⟨231⟩: 0.002%.

Limit of triamcinolone acetonide—

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

Standard solution—Dissolve an accurately weighed quantity of triamcinolone acetonide in methanol, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.004 mg per mL.

Test solution—Use the *Assay preparation*.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for all of the peaks. Calculate the percentage of triamcinolone acetonide in the portion of Triamcinolone Hexacetonide taken by the formula:

$$100(C / D)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of triamcinolone acetonide in the *Standard solution; D* is the concentration, in mg per mL, of triamcinolone hexacetonide in the *Test solution;* and r_U and r_S are the peak responses for triamcinolone acetonide obtained from the *Test solution* and the *Standard solution*, respectively: not more than 1.0% is found.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (75 : 25). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Triamcinolone Hexacetonide RS in methanol, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.4 mg per mL.

System suitability solution—Dissolve suitable quantities of triamcinolone acetonide and USP Triamcinolone Hexacetonide RS in methanol to obtain a solution containing about 0.4 mg per mL of each.

Assay preparation—Transfer about 40 mg of Triamcinolone Hexacetonide, accurately weighed, to a 100-mL volumetric flask. Dissolve in and dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.27 for triamcinolone acetonide and 1.0 for triamcinolone hexacetonide; the resolution, *R,* between triamcinolone acetonide and triamcinolone hexacetonide is not less than 7.5; the tailing factor for triamcinolone hexacetonide is not more than 1.3; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 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 $C_{30}H_{41}FO_7$ in the portion of Triamcinolone Hexacetonide taken by the formula:

$$100C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Triamcinolone Hexacetonide RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.