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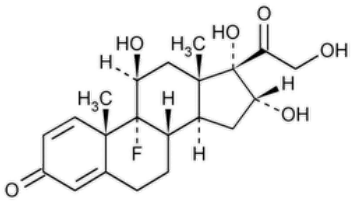
Triamcinolone



$C_{21}H_{27}FO_6$ 394.43

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,16,17,21-tetrahydroxy-, (11β,16α).

9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione CAS RN®: 124-94-7; UNII: 1ZK20VI6TY.

» 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—

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 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%.

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.

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

Topic/Question	Contact	Expert Committee
TRIAMCINOLONE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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

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