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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 *Triamcinolone Acetonide Cream*, beginning with "Place the plate in a developing chamber." The specified result is obtained.

Microbial enumeration tests ⟨61⟩ and Tests for specified microorganisms ⟨62⟩—It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Other requirements—It meets the requirements for *Pressure Test*, *Minimum Fill*, and *Leakage Test* under *Topical Aerosols ⟨603⟩*.

Assay—

Mobile phase—Prepare a degassed solution of water and acetonitrile (70:30).

Internal standard solution—Dissolve fluoxymesterone in methanol to obtain a solution having a concentration of about 25 µg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Triamcinolone Acetonide RS in methanol to obtain a solution having a concentration of about 100 µg per mL. Transfer 15.0 mL of this solution to a 50-mL volumetric flask, add 25.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix. This solution has a known concentration of about 30 µg per mL.

Assay preparation—Fit the valve of a previously weighed Triamcinolone Acetonide Aerosol container with a suitable tube assembly so that the contents can be sprayed directly into the bulb portion of a 100-mL volumetric flask containing 50.0 mL of *Internal standard solution* and 20 mL of methanol. Spray a portion of the contents, equivalent to about 3 mg of triamcinolone acetonide, into the flask, determining the exact amount sprayed by difference. Place in a sonic bath for about 5 minutes to expel the propellant. Dilute with methanol to volume, and mix. [Note—The propellant is extremely flammable. When evaporating, observe proper precautions and work under an explosion-proof hood.]

Procedure—Introduce equal volumes (between 15 µL and 25 µL) of the *Assay preparation* and the *Standard preparation* into a chromatograph (see *Chromatography ⟨621⟩*) operated at room temperature and fitted with a 3.9-mm × 30-cm column, packed with packing L1, and equipped with a 254-nm detector. Adjust the operating parameters and the *Mobile phase* composition such that the separation of triamcinolone acetonide and internal standard is optimized, with a retention time of about 14 minutes for triamcinolone acetonide. In a suitable system, the relative standard deviation for five replicate injections of the *Standard preparation* is not more than 3.0%. Measure the responses 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 µg, of $C_{24}H_{31}FO_6$ in the portion of Topical Aerosol taken by the formula:

$$100C(R_U/R_S)$$

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

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

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