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Fluocinonide Topical Solution

» Fluocinonide Topical Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{26}H_{32}F_2O_7$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Fluocinonide RS

Identification—Transfer an amount of Topical Solution, equivalent to about 2.5 mg of fluocinonide, to a glass-stoppered, 50-mL centrifuge tube containing 5 mL of water and 10 mL of methanol, add 20 mL of cyclohexane, shake vigorously, centrifuge, and discard the upper phase. Add 20 mL of water and 5 mL of chloroform, shake vigorously, centrifuge until the lower phase is clear, and discard the upper phase. The clear chloroform extract is the test solution. Proceed as directed in the *Identification* test under *Fluocinonide Cream* beginning with "Apply 10 µL of the *Test solution*."

Minimum fill ⟨755⟩: meets the requirements.

Alcohol content—

Standard solution—Dilute 20.0 mL of alcohol with methanol to volume in a 200-mL volumetric flask.

Internal standard solution—Dilute 20.0 mL of isopropyl alcohol with methanol to volume in a 100-mL volumetric flask.

Test preparation—Using a "to contain" pipet, transfer 2 mL of Topical Solution to a 100-mL volumetric flask, rinsing the pipet 3 times with methanol and collecting the rinsings in the volumetric flask. Add 5.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

Standard preparation—Pipet 6 mL of the *Standard solution* and 5 mL of the *Internal standard solution* into a 100-mL volumetric flask, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The gas chromatograph is equipped with a flame-ionization detector and a 2-mm × 1.8-m glass column that is packed with 80- to 100-mesh packing S3. The carrier gas is nitrogen or helium, flowing at a rate of about 40 mL per minute. The injection port and detector temperatures are maintained at about 225°. The column temperature is maintained at about 130°. Chromatograph the *Standard preparation*, record the chromatogram, and determine the peak response ratio as directed for *Procedure*. Adjust the carrier gas flow rate so that the resolution, *R,* of alcohol and isopropyl alcohol is not less than 1.5; the tailing factor of the alcohol peak is not more than 1.25; and the relative standard deviation for peak response ratios from replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (2 µL to 3 µL) of the *Test preparation* and the *Standard preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage (v/v) of C_2H_5OH in the Topical Solution taken by the formula:

$$(0.3)(95.45)(R_U/R_S)$$

in which 95.45 is the percentage (v/v) of C_2H_5OH in USP Alcohol; and R_U and R_S are the peak response ratios obtained from the *Test preparation* and the *Standard preparation*, respectively: between 28.4% and 39.0% of C_2H_5OH is present.

Assay—

Mobile phase—Use a mixture of acetonitrile and water (55:45). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Fluocinonide RS in acetonitrile to obtain a solution containing about 500 µg per mL. Transfer 2.0 mL of this solution to a 25-mL volumetric flask. Dilute with *Mobile phase* to volume, and mix to obtain a solution having a known concentration of about 40 µg of USP Fluocinonide RS per mL.

Assay preparation—Using a "to contain" pipet, transfer a volume of Topical Solution, equivalent to about 1 mg of fluocinonide, to a 25-mL volumetric flask, rinsing the pipet with about 5 mL of *Mobile phase*, and adding the rinsings to the volumetric flask, 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 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor for the analyte peak is not more than 1.5; and the relative standard deviation for replicate injections is not more than 1.5%.

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. Calculate the quantity, in mg, of $C_{26}H_{32}F_2O_7$ in each mL of the Topical Solution taken by the formula:

$$0.025(C/V)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Fluocinonide RS in the *Standard preparation*; V is the volume, in mL, of Topical Solution taken; and r_U and r_S are the peak responses due to fluocinonide 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
FLUOCINONIDE TOPICAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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