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Fluocinonide Ointment

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

Packaging and storage—Preserve in collapsible tubes or tight containers.

USP Reference standards ⟨11⟩—
USP Fluocinonide RS

Identification—Weigh an amount of Ointment, equivalent to about 2.5 mg of fluocinonide, into a glass-stoppered, 50-mL centrifuge tube containing 20 mL of cyclohexane. Gently disperse to form a suspension. Add 5 mL of water and 10 mL of methanol. Shake vigorously, allow the phases to separate, and discard the upper phase. Add 20 mL of water and 5 mL of chloroform, shake vigorously, centrifuge, and transfer a portion of the chloroform layer to a small test tube containing about 200 mg of anhydrous sodium sulfate. Mix, and allow to stand until the extract is clear. Using the clear chloroform extract as the *Test preparation*, proceed as directed in the *Identification* under *Fluocinonide Cream*, beginning with "Apply 10 µL of the *Test solution*."

Minimum fill ⟨755⟩: meets the requirements.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and water (1:1). Adjust the ratio as necessary to obtain suitable chromatographic performance.

Standard preparation—Dissolve an accurately weighed quantity of USP Fluocinonide RS in acetonitrile to obtain a solution having a known concentration of about 400 µg per mL. Transfer 10.0 mL of this solution to a 100-mL volumetric flask. Dilute with methanol to volume, and mix. The final concentration of USP Fluocinonide RS is about 40 µg per mL.

Assay preparation—Transfer an accurately weighed quantity of Ointment, containing about 1.35 mg of fluocinonide, to a round-bottom, 50-mL centrifuge tube. Add 35.0 mL of methanol. Emulsify, using an ultrasonic probe, and centrifuge to bring the insoluble matter to the bottom. The clear supernatant is the *Assay preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—Proceed as directed under *Fluocinonide Cream*, except that the flow rate for the *Mobile phase* is about 1 mL per minute.

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 fluocinonide ($C_{26}H_{32}F_2O_7$) in the portion of Ointment taken by the formula:

$$0.035C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Fluocinonide RS in the *Standard preparation;* and r_U and r_S are the peak responses due to fluocinonide obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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Topic/Question	Contact	Expert Committee
FLUOCINONIDE OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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