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Fluocinonide Cream

» Fluocinonide Cream 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 Cream, equivalent to about 2.5 mg of fluocinonide, into a glass-stoppered, 100-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.* Separately apply 10 µL of the *Test solution* and 10 µL of a Standard solution having a concentration of 0.5 mg per mL of USP Fluocinonide RS in chloroform to equidistant points about 2 cm from one end of a thin-layer chromatographic plate (see *Chromatography ⟨621⟩*), coated with a 0.25-mm layer of chromatographic silica gel. Allow the applications to dry, and develop the chromatogram in a suitable chromatographic chamber using a mixture of chloroform and acetone (4:1). Air-dry, and view under short-wavelength UV light: the principal spot from the *Test solution* corresponds to that obtained from the Standard solution.

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.*

Minimum fill ⟨755⟩: meets the requirements.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and water (1:1). 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 having a known concentration of about 200 µg per mL. Transfer 10.0 mL of this solution and 10.0 mL of water to a 100-mL volumetric flask. Dilute with acetonitrile to volume, and mix. The final concentration of USP Fluocinonide RS is 20 µg per mL.

Assay preparation—Transfer an accurately weighed quantity of Cream, containing about 2 mg of fluocinonide, to a 100-mL volumetric flask. Add about 60 mL of acetonitrile, and dissolve the cream by heating on a steam bath. Add 10.0 mL of water, and allow to cool. Dilute with acetonitrile to volume, and mix. Filter the mixture through a fine-sintered glass funnel, using vacuum, and use the filtrate.

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 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 4500 theoretical plates and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Chromatograph equal volumes (about 20 µL) of the *Assay preparation* and the *Standard preparation*, record the chromatograms, and measure the peak responses due to fluocinonide. Calculate the quantity, in mg, of fluocinonide ($C_{26}H_{32}F_2O_7$) in the portion of Cream taken by the formula:

$$0.1C(r_U/r_S)$$

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.

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

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

Chromatographic Database Information: Chromatographic Database

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