Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-C09997D1-9935-42E2-AD7E-373B469A154D_2_en-US
DOI: https://doi.org/10.31003/USPNF_M33520_02_01
DOI Ref: zs1a6

Fluocinonide Gel

» Fluocinonide Gel 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 Gel, equivalent to about 2.5 mg of fluocinonide, into a glass-stoppered, 50-mL centrifuge tube containing 20 mL of sodium chloride solution (1 in 10). Add 5 mL of chloroform and 15 mL of methanol, and shake vigorously. Centrifuge to clarify the chloroform layer, and remove the solid material present at the interphase. Discard the upper phase. Dry a portion of the chloroform layer over anhydrous sodium sulfate. Using the dried extract as the *Test preparation*, 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.

Assay—

Mobile phase—Prepare a 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 to a 100-mL volumetric flask, dilute with acetonitrile to volume, and mix. The final concentration is 20 µg per mL.

Assay preparation—Transfer an accurately weighed quantity of Gel, containing about 2 mg of fluocinonide, to a 100-mL volumetric flask. Add about 60 mL of acetonitrile, and dissolve the gel by heating on a steam bath. Cool to room temperature, dilute with acetonitrile to volume, and mix. Centrifuge a portion at about 2500 rpm for about 5 minutes. Filter a portion of the centrifugate through an acetonitrile-insoluble membrane filter. The filtrate is the *Assay 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 2 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 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 the portion of Gel 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 GEL	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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

Current DocID: GUID-C09997D1-9935-42E2-AD7E-373B469A154D_2_en-US
Previous DocID: GUID-C09997D1-9935-42E2-AD7E-373B469A154D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M33520_02_01
DOI ref: zs1a6