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Fluocinolone Acetonide Cream

» Fluocinolone Acetonide Cream contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{24}H_{30}F_2O_6$.

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

USP Reference standards ⟨11⟩—

USP Fluocinolone Acetonide RS
USP Norethindrone RS

Identification—Transfer a quantity of the Cream, equivalent to about 0.5 mg of fluocinolone acetonide, to a centrifuge tube, disperse it in 5 mL of water, add 10 mL of chloroform, shake, and centrifuge. Remove and discard the aqueous layer, add 10 mL of water to the tube, shake, and centrifuge. Dry about 2 mL of the chloroform extract over about 200 mg of anhydrous sodium sulfate: the dried extract responds to the *Thin-Layer Chromatographic Identification Test ⟨201⟩*, 50 µL of the dried chloroform extract and 50 µL of a Standard solution containing about 50 µg per mL of USP Fluocinolone Acetonide RS being applied, and a mixture of chloroform and diethylamine (2:1) being used for development.

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—

Internal standard solution—Dissolve USP Norethindrone RS in acetonitrile to obtain a solution containing about 200 µg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Fluocinolone Acetonide RS in acetonitrile to obtain a solution having a known concentration of about 300 µg per mL. Transfer 5.0 mL of this solution, 6.0 mL of *Internal standard solution*, and 15.0 mL of water to a 50-mL volumetric flask. Dilute with acetonitrile to volume, and mix. The *Standard preparation* contains 30 µg of USP Fluocinolone Acetonide RS per mL.

Mobile solvent—Prepare a mixture of water and acetonitrile (5:3). Adjust the ratio as necessary to obtain suitable chromatographic performance.

Assay preparation—Dissolve an accurately weighed portion of Cream, equivalent to about 0.75 mg of fluocinolone acetonide, in about 10 mL of acetonitrile by heating on a steam bath. Transfer the mixture to a 25-mL volumetric flask with the aid of three 2-mL portions of acetonitrile. Add 3.0 mL of *Internal standard solution* and 5.0 mL of water, cool, and mix. Dilute with acetonitrile to volume, mix, and cool in an ice bath. Centrifuge or filter the mixture to obtain a clear solution.

Apparatus—Use a high-pressure liquid chromatograph (see *Chromatography ⟨621⟩*) of the general type equipped with a detector for monitoring UV absorbance at about 254 nm, and capable of providing a flow rate of about 2 mL per minute for the *Mobile solvent*. Use a column that contains packing L1.

Procedure—Chromatograph equal volumes of the *Assay preparation* and the *Standard preparation*. Three replicate injections of the *Standard preparation* show a resolution factor of not less than 2.0 between the peaks for norethindrone and fluocinolone acetonide and a relative standard deviation of not more than 1.5%. Calculate the quantity, in mg, of $C_{24}H_{30}F_2O_6$ in the portion of Cream taken by the formula:

$$0.025C(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Fluocinolone Acetonide RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak areas of fluocinolone acetonide and norethindrone 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
FLUOCINOLONE ACETONIDE CREAM	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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

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