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Fluocinolone Acetonide Topical Solution

» Fluocinolone Acetonide Topical Solution 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 tight containers.

USP Reference standards ⟨11⟩—

USP Fluocinolone Acetonide RS

Identification—Transfer a quantity of Topical Solution, equivalent to about 0.5 mg of fluocinolone acetonide, to a separator, add 5 mL of water, and extract with 10 mL of chloroform. Withdraw the chloroform layer into a second separator, wash with 10 mL of water, and 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 the Standard solution 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*.

Assay—

Internal standard solution—Dissolve norethindrone 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 200 µg per mL. Transfer 5.0 mL of this solution, 4.0 mL of *Internal standard solution*, 10 mL of propylene glycol, and about 25 mL of acetonitrile to a 50-mL volumetric flask. Mix, cool to room temperature, dilute with acetonitrile to volume, and mix. The final concentration of USP Fluocinolone Acetonide RS is 20 µg per mL.

Mobile solvent—Prepare a mixture of water and acetonitrile (3:2). Adjust the ratio as necessary to obtain suitable chromatographic performance.

Assay preparation—Transfer an accurately measured volume of Topical Solution, equivalent to about 0.5 mg of fluocinolone acetonide, to a 25-mL volumetric flask. Add 2.0 mL of *Internal standard solution* and 10 mL of acetonitrile. Mix, cool to room temperature, dilute with acetonitrile to volume, and mix.

Apparatus—Use a suitable 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 containing packing L1 so as to provide a resolution factor, *R*, of at least 2.0 between peaks for norethindrone and fluocinolone acetonide.

Procedure—Chromatograph equal volumes of the *Assay preparation* and the *Standard preparation*, adjusting the system as necessary to obtain peaks of between about 50% and 90% full-scale. Calculate the quantity, in mg, of $C_{24}H_{30}F_2O_6$ 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 Fluocinolone Acetonide RS in the *Standard preparation*; V is the volume, in mL, of Solution taken; and R_U and R_S are the ratios of the areas of the fluocinolone acetonide peak to the internal standard peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
FLUOCINOLONE ACETONIDE TOPICAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

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Chromatographic Database Information: Chromatographic Database

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