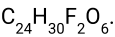


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# Fluocinolone Acetonide Topical Solution

» Fluocinolone Acetonide Topical Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of



**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<sub>U</sub>* and *R<sub>S</sub>* 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.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
FLUOCINOLONE ACETONIDE TOPICAL SOLUTION	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5

**Chromatographic Database Information:** [Chromatographic Database](#)

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