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Fluocinolone Acetonide Ointment

» Fluocinolone Acetonide Ointment 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—Evaporate 10.0 mL of the *Assay preparation* obtained in the *Assay* to dryness, and dissolve the residue in 1 mL of chloroform: it responds to the *Thin-layer Chromatographic Identification Test ⟨201⟩*, 50 µL of the test solution and 50 µL of the 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 a suitable quantity of USP Norethindrone RS in methanol to obtain a solution containing about 850 µg per mL.

Diluted internal standard solution—Transfer 5.0 mL of *Internal standard solution* to a 250-mL flask. Dilute with methanol to volume, and mix.

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 10.0 mL of this solution and 2.0 mL of *Internal standard solution* to a 100-mL volumetric flask. Dilute with methanol to volume, and mix. The concentration of USP Fluocinolone Acetonide RS in the *Standard preparation* is 20 µg per mL.

Mobile solvent—Prepare a mixture of acetonitrile and water (1:1). Adjust the ratio as necessary to obtain suitable chromatographic performance.

Assay preparation—Transfer an accurately weighed portion of Ointment, equivalent to about 0.7 mg of fluocinolone acetonide, to a 50-mL, round-bottom centrifuge tube. Add 35.0 mL of *Diluted internal standard solution*, emulsify using an ultrasonic probe, and centrifuge to bring the insoluble matter to the bottom. The clear supernatant is the *Assay preparation.*

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 50-cm × 4-mm column that contains packing L1 so as to provide a resolution factor, *R* (see *Chromatography ⟨621⟩*), of at least 2.0 between peaks for norethindrone and fluocinolone acetonide. Three replicate injections of the *Standard preparation* show a relative standard deviation of not more than 1.5%.

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% of full-scale. Calculate the quantity, in mg, of $C_{24}H_{30}F_2O_6$ in the portion of Ointment taken by the formula:

$$0.035C(R_U/R_S)$$

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 the internal standard obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Chromatographic Database Information: Chromatographic Database

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