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Flurandrenolide Lotion

» Flurandrenolide Lotion contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of flurandrenolide ($C_{24}H_{33}FO_6$).

Packaging and storage—Preserve in tight containers, protected from heat, light, and freezing.

USP Reference standards ⟨11⟩—
USP Flurandrenolide RS

Identification—It responds to the *Identification* test under *Flurandrenolide Cream*.

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.

pH ⟨791⟩: between 3.5 and 6.0, determined in a 1 in 10 dilution of the Lotion in water containing 0.30 mL of saturated potassium chloride solution per 100 mL.

Assay—

Methanolic sodium chloride, *Mobile phase*, *Internal standard solution*, *Standard preparation,* and *Chromatographic system*—Prepare as directed in the *Assay* under *Flurandrenolide Cream*.

Assay preparation—Transfer an accurately weighed portion of Lotion, calculated from the density to contain about 500 µg of flurandrenolide, to a separator. (Determine the density by taring a 100-mL volumetric flask containing 50.0 mL of water, adding approximately 25 g of well-shaken Lotion, and again weighing, then carefully adjusting the contents of the volumetric flask with water from a buret to volume, and finally calculating the density taken by the formula:

$$A/B$$

in which A is the weight, in g, of the Lotion taken; and B is 50.0 mL minus the volume, in mL, of water necessary to adjust the contents of the volumetric flask to volume.) Proceed as directed for *Assay preparation* in the *Assay* under *Flurandrenolide Cream*, beginning with "Add 50 mL of hexane and 25 mL of *Methanolic sodium chloride*."

Procedure—Proceed as directed in the *Assay* under *Flurandrenolide Cream*. Calculate the quantity, in mg, of flurandrenolide ($C_{24}H_{33}FO_6$) in each mL of the Lotion taken by the formula:

$$10C(D/W)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Flurandrenolide RS in the *Standard preparation; D* is the density of the Lotion; W is the weight, in g, of Lotion taken; and R_U and R_S are the peak response ratios 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
FLURANDRENOLIDE LOTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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