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Flurandrenolide Cream

» Flurandrenolide Cream 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 light.

USP Reference standards ⟨11⟩—

USP Flurandrenolide RS

Thin-layer chromatographic identification test ⟨201⟩—

Test solution—Extract a quantity of weighed Cream, equivalent to about 500 µg of flurandrenolide, as directed for the *Assay preparation*. Omit the addition of the internal standard, and evaporate the chloroform extracts on a steam bath under a stream of nitrogen to about 3 mL. Transfer the chloroform solution to a 10-mL flask, and evaporate with the aid of a stream of nitrogen to dryness. Dissolve the residue in 2 mL of chloroform.

Application volume: 4.0 µL.

Developing solvent system: a mixture of ethyl acetate and ethyl ether (70:30).

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—

Methanolic sodium chloride—Transfer 100 mL of sodium chloride solution (1 in 10) to a 500-mL volumetric flask. Dilute with methanol to volume, and mix.

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (70:30). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Transfer about 10 mg of testosterone to a 100-mL volumetric flask, add methanol to volume, and mix.

Standard preparation—Transfer about 16 mg of USP Flurandrenolide RS, accurately weighed, to a 100-mL volumetric flask, add methanol to volume, and mix. Transfer 3.0 mL of this solution to a 10-mL volumetric flask, add 4.0 mL of *Internal standard solution*, dilute with water to volume, and mix to obtain a solution having a known concentration of about 48 µg of USP Flurandrenolide RS per mL.

Assay preparation—Transfer an accurately weighed quantity of Cream, equivalent to about 500 µg of flurandrenolide, to a 125-mL separator. Add 50 mL of hexanes and 25 mL of *Methanolic sodium chloride*, and shake until the Cream is thoroughly dispersed. Allow the phases to separate, and drain the lower aqueous phase into a second 125-mL separator containing 15 mL of hexanes. Shake vigorously, allow the phases to separate, and drain the lower aqueous phase into a 250-mL separator containing 75 mL of water. Serially extract the hexane phases remaining in the two 125-mL separators with two additional 25-mL portions of *Methanolic sodium chloride*, adding each aqueous phase to the 250-mL separator. Discard the hexane phases. Extract the combined aqueous phases with four 25-mL portions of chloroform. Filter each chloroform extract through 10 g of anhydrous sodium sulfate into a 125-mL conical beaker. Rinse the sodium sulfate with water-washed chloroform, and add the wash to the beaker. Add 4.0 mL of *Internal standard solution* to the beaker containing the chloroform extract. Evaporate the solution on a steam bath under a stream of nitrogen nearly to dryness. Remove the beaker from the steam bath, and evaporate the remaining solution with the aid of nitrogen to dryness. Add 10 mL of *Mobile phase* to the beaker, and place it in an ultrasonic bath to dissolve the residue. Pass the solution through a suitable filter having a 0.5-µm porosity and a prefilter above the membrane filter to prevent clogging.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 240-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 2 for testosterone and 1.0 for flurandrenolide; the resolution, *R,* between the analyte and internal standard is not less than 2.0; and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of flurandrenolide ($C_{24}H_{33}FO_6$) in the portion of Cream taken by the formula:

$$10C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Flurandrenolide RS in the *Standard preparation;* 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 CREAM	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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