Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-631B3D55-ABC6-453D-B20D-00ECBD6E214D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M34070_01_01
DOI Ref: 220q9

Flurandrenolide Tape

» Flurandrenolide Tape is a nonporous, pliable, adhesive-type tape having Flurandrenolide impregnated in the adhesive material, the adhesive material on one side being transported on a removable, protective slit-paper liner. Flurandrenolide Tape contains not less than 80.0 percent and not more than 125.0 percent of the labeled amount of $C_{24}H_{33}FO_6$.

Packaging and storage—Preserve at controlled room temperature.

USP Reference standards ⟨11⟩—
USP Flurandrenolide RS

Identification—Extract a portion of Tape, equivalent to about 200 µg of flurandrenolide, as directed for the *Assay preparation* in the *Assay*. 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 1.0 mL of a mixture of equal volumes of chloroform and methanol, warming gently to effect solution: it meets the requirements of the *Thin-Layer Chromatographic Identification Test ⟨201⟩*, 5 µL each of the test solution and Standard solution being applied, and the solvent mixture consisting of ethyl acetate and 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*.

Assay—

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

Flurandrenolide standard solution—Dissolve about 7 mg of USP Flurandrenolide RS, accurately weighed, in 50 mL of methanol in a 100-mL volumetric flask. Dilute with methanol to volume, and mix.

Internal standard solution—Dissolve about 4 mg of Testosterone in 50 mL of methanol in a 100-mL volumetric flask. Dilute with methanol to volume, and mix.

Standard preparation—Pipet 3.0 mL of *Flurandrenolide standard solution* and 4.0 mL of *Internal standard solution* into a 10-mL volumetric flask. Dilute with water to volume, and mix.

Assay preparation—Accurately measure and cut a portion of Tape, equivalent to about 200 µg of flurandrenolide. Remove and discard the paper liner from the portion of Tape. Touch the flattened end of a glass rod to the adhesive side of the Tape, and carefully transfer the tape to the bottom of a 600-mL beaker containing 15 mL of anhydrous methanol, taking care that the adhesive side of the tape does not adhere to the wall of the beaker. Remove the glass rod from the tape, and wash it with 5 mL of anhydrous methanol, adding the wash to the beaker. Place the beaker containing the Tape and the methanol in an ultrasonic bath for 3 minutes, rotating the beaker in such manner that the methanol is in contact with all portions of the Tape. Transfer the methanol to a 250-mL separator. Extract the Tape, using sonication, with two additional 20-mL portions of anhydrous methanol, adding each portion to the separator. To the combined methanol extract add 15 mL of sodium chloride solution (1 in 10) and 50 mL of hexane, and shake vigorously. Allow the phases to separate, and drain the lower aqueous phase into a second separator containing 15 mL of hexane. Shake vigorously, allow the phases to separate, and drain the lower phase into a third 250-mL separator containing 100 mL of water. Serially extract the hexane phases remaining in the two separators with one 25-mL portion of *Methanolic sodium chloride*, adding the extract to the third 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. Evaporate the solution on a steam bath under a stream of nitrogen to near 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 solvent* to the beaker, and place it in an ultrasonic bath to dissolve the residue. Pass the solution through a suitable porosity filter having a 0.5-µm filter with a prefilter above the membrane filter to prevent clogging.

Procedure—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 2 for testosterone and 1.0

for flurandrenolide. Calculate the quantity, in µg, of $C_{24}H_{33}FO_6$ in the portion of Tape taken by the formula:

$$10C(R_U/R_S)$$

in which C is the concentration, in µg 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 TAPE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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