Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-1B939D24-34B2-4173-8569-F30B92DCB560_1_en-US
DOI: https://doi.org/10.31003/USPNF_M33405_01_01
DOI Ref: w6ren

Flunisolide Nasal Solution

» Flunisolide Nasal Solution is an aqueous, buffered solution of Flunisolide. It is supplied in a form suitable for nasal administration. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{24}H_{31}FO_6$.

Packaging and storage—Preserve in tight containers, protected from light, and store at controlled room temperature.

USP Reference standards ⟨11⟩—

USP Flunisolide RS

Identification—Proceed as directed in the *Assay*, except to inject 50 µL to 200 µL of a mixture of the *Assay preparation* and the *Standard preparation* (1:1) onto the column, adjusting the response to obtain a response that is between 50% and 90% full scale: a single peak is observed in the chromatogram for the mixed solution.

pH ⟨791⟩: between 4.5 and 6.0, a silver-silver chloride (internal element) electrode being used in conjunction with a fiber junction calomel electrode.

Quantity delivered per spray—Prime the spray pump by delivering 10 sprays into a fume hood. Accurately weigh the entire assembly, record the weight, and deliver 8 more sprays into the hood. Again weigh the assembly, and record the weight. Calculate the quantity, in µg, of $C_{24}H_{31}FO_6$ delivered per spray taken by the formula:

$$[(W_1 - W_2)/8][A/D]$$

in which W_1 and W_2 are the first and second weights, respectively, in g; A is the quantity, in µg per mL, of $C_{24}H_{31}FO_6$ found in the *Assay;* and D is the density of Nasal Solution, in g per mL. The quantity delivered is between 17 µg and 33 µg per spray.

Assay—

Mobile phase—Prepare a suitable degassed solution of water, acetonitrile, and glacial acetic acid (69:30:1 to 64:35:1). Adjust the ratio as necessary to obtain suitable chromatographic performance.

Internal standard solution—Dissolve norethindrone in acetonitrile to obtain a solution containing about 300 µg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Flunisolide RS in a mixture of acetonitrile and *Mobile phase* (1:1) to obtain a solution having a known concentration of about 250 µg per mL. Transfer 1.0 mL of this solution, and 1.0 mL of *Internal standard solution*, by means of "to contain" pipets, to a 50-mL volumetric flask. Rinse the pipets with *Mobile phase*, adding the rinsings to the flask, dilute with *Mobile phase* to volume, and mix. The final concentration of USP Flunisolide RS is about 5 µg per mL.

Assay preparation—Transfer an accurately measured volume of Nasal Solution, equivalent to about 250 µg of flunisolide, to a 50-mL volumetric flask, and add 1.0 mL of *Internal standard solution* by means of "to contain" pipets. Rinse the pipets with *Mobile phase*, adding the rinsing to the flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 25-cm column that contains 5- to 10-µm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte and the internal standard is not less than 5.0; and the relative standard deviation for replicate injections is not more than 1.5%.

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 0.6 for flunisolide and 1.0 for norethindrone. Calculate the quantity, in mg, of $C_{24}H_{31}FO_6$ in each mL of the Nasal Solution taken by the formula:

$$(434.51/443.51)(50C/V)(R_U/R_S)$$

in which 434.51 and 443.51 are the molecular weights of $C_{24}H_{31}FO_6$ and $C_{24}H_{31}FO_6 \cdot ½H_2O$, respectively; C is the concentration, in mg per mL, of USP Flunisolide RS in the *Standard preparation; V* is the volume, in mL, of Nasal Solution taken; and R_U and R_S are the peak response ratios of the flunisolide peak and the norethindrone 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
FLUNISOLIDE NASAL SOLUTION	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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