Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2021
Document Type: USP Monographs
DocId: GUID-6A1316E6-552C-4AAC-8349-B2268812329E_2_en-US
DOI: https://doi.org/10.31003/USPNF_M12655_02_01
DOI Ref: giw1f

Add the following:

▲Fludrocortisone Acetate Compounded Oral Suspension

DEFINITION

Fludrocortisone Acetate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of fludrocortisone acetate ($C_{23}H_{31}FO_6$).

Prepare Fludrocortisone Acetate Compounded Oral Suspension 0.1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Fludrocortisone Acetate Tablets[a] equivalent to	10 mg of fludrocortisone acetate
Ora-Blend,[b] a sufficient quantity to make	100 mL

[a] Fludrocortisone Acetate 0.1-mg tablets, Teva Pharmaceuticals USA, North Wales, PA.

[b] Perrigo, Allegan, MI.

Place the *Fludrocortisone Acetate Tablets* in a suitable container and triturate to a fine powder. Add a small amount of *Ora-Blend*, and mix well to form a smooth paste. Add a sufficient amount of *Ora-Blend* to make the container contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add a sufficient amount of *Ora-Blend* to bring to final volume. Mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (44:56)

Diluent: Acetonitrile, water, and 1 N hydrochloric acid (44:55:1)

Standard stock solution: Transfer 20 mg of USP Fludrocortisone Acetate RS into a 200-mL volumetric flask, add about 10 mL of acetonitrile, and sonicate for 5 min. Dilute with *Diluent* to volume.

Standard solution: Transfer 0.5 mL of *Standard stock solution* into a 25-mL volumetric flask, and dilute with *Diluent* to volume.

Sample solution: Transfer 1 mL of Oral Suspension into a 50-mL volumetric flask. Add about 40 mL of *Diluent*, sonicate for 10 min, and then bring to volume with *Diluent*. Pass through a polyvinylidene difluoride filter of 0.22-µm pore size, discarding the first 10 drops.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Temperatures

Autosampler: 4°

Column: 25°

Flow rate: 2 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for fludrocortisone acetate is about 5.6 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fludrocortisone acetate ($C_{23}H_{31}FO_6$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of fludrocortisone acetate from the *Sample solution*

r_S = peak response of fludrocortisone acetate from the *Standard solution*

C_S = concentration of USP Fludrocortisone Acetate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of fludrocortisone acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.5–5.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days from the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **Labeling:** Label it to indicate that it is to be well shaken before use and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Fludrocortisone Acetate RS▲ (USP 1-Dec-2021)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
FLUDROCORTISONE ACETATE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 50(5)

Current DocID: GUID-6A1316E6-552C-4AAC-8349-B2268812329E_2_en-US

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