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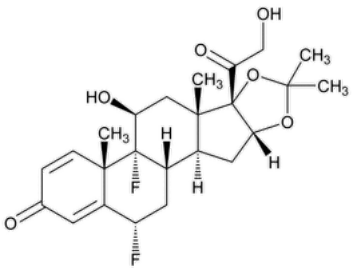
Fluocinolone Acetonide



$C_{24}H_{30}F_2O_6$(anhydrous) 452.49
Dihydrate 488.53

Pregna-1,4-diene-3,20-dione, 6,9-difluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (6α,11β,16α)-;
6α,9-Difluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione, cyclic 16,17-acetal with acetone CAS RN®: 67-73-2; UNII: 0CD5FD6S2M.

DEFINITION

Fluocinolone Acetonide is anhydrous or contains two molecules of water of hydration. It contains NLT 97.0% and NMT 102.0% of fluocinolone acetonide ($C_{24}H_{30}F_2O_6$), calculated on the dried basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K:** If a difference appears, dissolve portions of both the sample and the USP Reference Standard in ethyl acetate, evaporate to dryness, and repeat the test on the residues.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, tetrahydrofuran, and water (13:10:77)

Diluent: Acetonitrile and tetrahydrofuran (13:10)

Standard solution: 0.2 mg/mL of USP Fluocinolone Acetonide RS, prepared as follows. Transfer a suitable amount of USP Fluocinolone Acetonide RS to a suitable volumetric flask, and dissolve in a volume of *Diluent* equal to 23% of the flask volume. Dilute with water to volume.

Sample solution: 0.2 mg/mL of Fluocinolone Acetonide, prepared as follows. Transfer a suitable amount of Fluocinolone Acetonide to a suitable volumetric flask, and dissolve in a volume of *Diluent* equal to 23% of the flask volume. Dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 2.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fluocinolone acetonide ($C_{24}H_{30}F_2O_6$) in the portion of Fluocinolone Acetonide taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Fluocinolone Acetonide in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the dried basis

Change to read:

• **Organic Impurities**

Protect the solutions from light throughout the test.

Mobile phase: Acetonitrile and water (45:55), prepared as follows. Mix 450 mL of acetonitrile and 500 mL of water, and allow to equilibrate. Add water to make 1000 mL.

System suitability solution: 0.25 mg/mL each of USP Fluocinolone Acetonide RS and USP Triamcinolone Acetonide RS, prepared as follows. Transfer suitable amounts of USP Fluocinolone Acetonide RS and USP Triamcinolone Acetonide RS to a suitable volumetric flask. Dissolve in 45% of the flask volume of acetonitrile, and dilute with water to volume.

Standard solution: 0.025 mg/mL of USP Fluocinolone Acetonide RS in acetonitrile

Sample solution: 2.5 mg/mL of Fluocinolone Acetonide in acetonitrile

Chromatographic system

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

Mode: LC

Detector: UV 238 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: 4 times the retention time of fluocinolone acetonide

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for triamcinolone acetonide and fluocinolone acetonide are 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between triamcinolone acetonide and fluocinolone acetonide, *System suitability solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Fluocinolone Acetonide taken:

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

r_U = peak response of any impurity from the *Sample solution*

r_S = peak response of fluocinolone acetonide from the *Standard solution*

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

C_U = concentration of Fluocinolone Acetonide in the *Sample solution* (mg/mL)

Acceptance criteria

Any individual impurity: NMT 1%; NMT one such peak is greater than 0.5%.

Total impurities: NMT 2.5%. Disregard any peak below 0.05% of the peak area of fluocinolone acetonide from the ▲*Sample solution*▲ (ERR 1-Jun-2022) ·

SPECIFIC TESTS

• **Optical Rotation,** *Specific Rotation*⟨781S⟩

Sample solution: 10 mg/mL in methanol

Acceptance criteria: +98° to +108°

• **Loss on Drying** ⟨731⟩

Analysis: Dry under vacuum at 105° for 3 h.

Acceptance criteria: NMT 1.0% for anhydrous Fluocinolone Acetonide; NMT 8.5% for hydrous Fluocinolone Acetonide

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Label it to indicate whether it is anhydrous or hydrous.

• **USP Reference Standards** ⟨11⟩

USP Fluocinolone Acetonide RS

USP Triamcinolone Acetonide RS

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

Topic/Question	Contact	Expert Committee
FLUOCINOLONE ACETONIDE	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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