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Fluorometholone Ophthalmic Suspension

DEFINITION

Fluorometholone Ophthalmic Suspension is a sterile suspension of Fluorometholone in a suitable aqueous medium. It contains NLT 90.0% and NMT 110.0% of the labeled amount of fluorometholone ($C_{22}H_{29}FO_4$). It may contain suitable stabilizers, buffers, and antimicrobial agents.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Shake a quantity of Ophthalmic Suspension, nominally equivalent to 5 mg of fluorometholone, with 20 mL of acetone. Filter, and evaporate the filtrate to dryness. Dissolve the residue in 10 mL of acetone, filter, and evaporate the filtrate to dryness.

Acceptance criteria: Meets the requirements

• **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: Methanol and water (60:40)

Diluent: Methanol and water (1:1)

System suitability solution: 0.5 µg/mL each of USP Fluorometholone RS and USP Fluorometholone Related Compound A RS in *Diluent*

Standard stock solution: 0.5 mg/mL of USP Fluorometholone RS in methanol

Standard solution: 40 µg/mL of USP Fluorometholone RS in *Diluent*, from *Standard stock solution*

Sample solution: Nominally equivalent to 40 µg/mL of fluorometholone in *Diluent* prepared from a suitable quantity of well-shaken Ophthalmic Suspension

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between fluorometholone and fluorometholone related compound A, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fluorometholone ($C_{22}H_{29}FO_4$) in the portion of Ophthalmic Suspension 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 Fluorometholone RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of fluorometholone in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Mobile phase, Diluent, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.5 µg/mL of USP Fluorometholone RS in *Diluent*

Sample solution: Nominally equivalent to 100 µg/mL of fluorometholone in *Diluent* prepared from a suitable quantity of Ophthalmic Suspension

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between fluorometholone and fluorometholone related compound A, *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 Ophthalmic Suspension taken:

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

r_U = peak response for each impurity from the *Sample solution*

r_S = peak response of fluorometholone from the *Standard solution*

C_S = concentration of USP Fluorometholone RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of fluorometholone in the *Sample solution* (µg/mL)

Acceptance criteria

Each impurity: NMT 0.5%

Total impurities: NMT 1%

SPECIFIC TESTS

- **Sterility Tests ⟨71⟩:** Meets the requirements
- **pH ⟨791⟩:** 6.0–7.5

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards ⟨11⟩**

USP Fluorometholone RS

USP Fluorometholone Related Compound A RS

11β,17α-Dihydroxy-6α-methylpregna-1,4-diene-3,20-dione.

$C_{22}H_{30}O_4$ 358.47

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

Topic/Question	Contact	Expert Committee
FLUOROMETHOLONE OPHTHALMIC SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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