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Fluticasone Propionate Lotion

DEFINITION

Fluticasone Propionate Lotion is fluticasone propionate in a suitable lotion base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of fluticasone propionate ($C_{25}H_{31}F_3O_5S$).

IDENTIFICATION

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

ASSAY

- **Procedure**

Buffer: 1.15 g/L of monobasic ammonium phosphate in water. Adjust with phosphoric acid to a pH of 3.5. Pass the solution through a suitable filter of 0.45-µm pore size.

Mobile phase: Acetonitrile, methanol, and *Buffer* (13:50:37)

Standard stock solution: 0.8 mg/mL of USP Fluticasone Propionate RS, prepared as follows. Transfer 40 mg of USP Fluticasone Propionate RS to a 50-mL volumetric flask. Add 10 mL of tetrahydrofuran and sonicate to dissolve. Dilute with methanol to volume.

Standard solution: 0.04 mg/mL of USP Fluticasone Propionate RS in methanol from *Standard stock solution*

Sample solution: Nominally 0.04 mg/mL of fluticasone propionate from Lotion, prepared as follows. Transfer a portion of Lotion to a suitable volumetric flask. Add tetrahydrofuran equivalent to about 20% of the flask volume and vortex until the Lotion is dispersed. Add methanol equivalent to 60% of the flask volume and sonicate for 10 min to dissolve. Dilute with methanol to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: 239 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

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

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 1.25 times the retention time of fluticasone propionate

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 5000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fluticasone propionate ($C_{25}H_{31}F_3O_5S$) in the portion of Lotion taken:

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

r_U = peak response of fluticasone propionate from the *Sample solution*

r_S = peak response of fluticasone propionate from the *Standard solution*

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

C_U = nominal concentration of fluticasone propionate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

IMPURITIES

• **Organic Impurities**

Solution A: Methanol, phosphoric acid, and water (30:0.5:970)

Solution B: Acetonitrile, methanol, and phosphoric acid (950:50:0.5)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	56	44
45	56	44
49	10	90
70	10	90
71	56	44
80	56	44

System suitability solution: 0.13 mg/mL of USP Fluticasone Propionate RS and 0.38 µg/mL of USP Fluticasone Propionate Related Compound D RS in methanol

Standard stock solution: 0.25 mg/mL of USP Fluticasone Propionate RS, prepared as follows. Transfer 25 mg of USP Fluticasone Propionate RS to a 100-mL volumetric flask. Add 25 mL of tetrahydrofuran and sonicate to dissolve. Dilute with methanol to volume.

Standard solution: 0.63 µg/mL of USP Fluticasone Propionate RS in methanol from *Standard stock solution*

Sample solution: Nominally 0.13 mg/mL of fluticasone propionate from Lotion, prepared as follows. Transfer a portion of Lotion, equivalent to 1.25 mg of fluticasone propionate, to a suitable volumetric flask. Add tetrahydrofuran equivalent to 20% of the flask volume and vortex until the Lotion is dispersed. Add methanol equivalent to 40% of the flask volume and sonicate for 10 min to dissolve. Dilute with methanol to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: 239 nm

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

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 40 µL

System suitability

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

[Note—See *Table 2* for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between fluticasone propionate related compound D and fluticasone propionate, *System suitability solution*

Relative standard deviation: NMT 5.0% from six replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fluticasone propionate related compound C, fluticasone propionate related compound D, or any individual unspecified degradation product in the portion of Lotion taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of fluticasone propionate related compound C, fluticasone propionate related compound D, or each unspecified degradation product from the *Sample solution*

r_S = peak response of fluticasone propionate from the *Standard solution*

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

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

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Fluticasone propionate related compound C[a]	0.67	0.82	0.10
Fluticasone propionate related compound D	0.91	1.1	0.30
Fluticasone propionate	1.0	1.0	—
Any unspecified degradation product	—	1.0	0.10
Total degradation products	—	—	1.0

[a] *S*-Fluoromethyl 17α-acetyloxy-6α,9α-difluoro-11β-hydroxy-16α-methyl-3-oxoandrosta-1,4-diene-17β-carbothioate.

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample: 50 mg/mL of Lotion in water

  Acceptance criteria: 4.0–6.0

- **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** Meets the requirements of the tests for absence of *Salmonella* species, *Escherichia coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. The total aerobic microbial count is NMT 10^2 cfu/g, and the total combined molds and yeasts count is NMT 10 cfu/g.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature. Do not refrigerate.
- **USP Reference Standards** ⟨11⟩

  USP Fluticasone Propionate RS

  USP Fluticasone Propionate Related Compound D RS

  S-Methyl 6α,9α-difluoro-11β-hydroxy-16α-methyl-3-oxo-17α-propionyloxyandrosta-1,4-diene-17β-carbothioate.

  $C_{25}H_{32}F_2O_5S$ 482.58

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