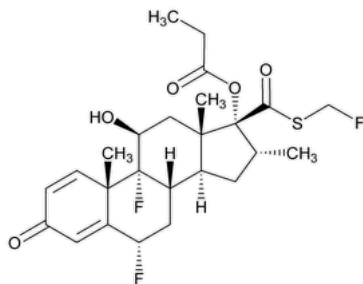


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Fluticasone Propionate

Change to read:



$C_{25}H_{31}F_3O_5S$ 500.57

Androsta-1,4-diene-17-carbothioic acid, 6,9-difluoro-11-hydroxy-16-methyl-3-oxo-17-(1-oxopropoxy)-, (6 α ,11 β ,16 α ,17 α)-S-(fluoromethyl) ester;
 S-Fluoromethyl 6 α ,9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxyandrosta-1,4-diene-17 β -carbothioate;

▲6 α ,9-Difluoro-17-[[[(fluoromethyl)sulfanyl]carbonyl]-11 β -hydroxy-16 α -methyl-3-oxoandrosta-1,4-dien-17 α -yl] propanoate▲ (USP 1-Dec-2022) CAS
 RN®: 80474-14-2; UNII: O2GMZ0LF5W.

Change to read:

DEFINITION

Fluticasone Propionate contains NLT 98.0% and NMT ▲102.0%▲ (USP 1-Dec-2022) of ▲fluticasone propionate▲ (USP 1-Dec-2022) ($C_{25}H_{31}F_3O_5S$),
 calculated on the anhydrous, solvent-free basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** ▲197A, 197K, or▲ (USP 1-Dec-2022) 197M
- **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

Change to read:

• PROCEDURE

Buffer: 1.15 g/L of [monobasic ammonium phosphate](#), adjusted with [phosphoric acid](#) to a pH of 3.5 ▲▲ (USP 1-Dec-2022)

Mobile phase: [Methanol](#), [acetonitrile](#), and *Buffer* (50:15:35)

System suitability solution: ▲0.04 mg/mL of [USP Fluticasone Propionate RS](#) and 0.008 mg/mL of [USP Fluticasone Propionate Related Compound D RS](#)▲ (USP 1-Dec-2022) in *Mobile phase*

Standard solution: 0.04 mg/mL of [USP Fluticasone Propionate RS](#) in *Mobile phase*

Sample solution: 0.04 mg/mL of Fluticasone Propionate in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 239 nm

Column: 4.6-mm × 25-cm; 5- μ m packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

System suitability

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

[NOTE—The relative retention times for fluticasone propionate and fluticasone propionate related compound D are about 1.0 and 1.10, respectively.]

Suitability requirements

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

Relative standard deviation: NMT ▲0.73%,▲ (USP 1-Dec-2022) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fluticasone propionate ($C_{25}H_{31}F_3O_5S$) in the portion of Fluticasone Propionate 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 = concentration of Fluticasone Propionate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–▲102.0%▲ (USP 1-Dec-2022) on the anhydrous, solvent-free basis

IMPURITIES

Change to read:

• **ORGANIC IMPURITIES**

Solution A: 0.5 mL of [phosphoric acid](#) in 1000 mL of [acetonitrile](#)

Solution B: 0.5 mL of [phosphoric acid](#) in 1000 mL of [methanol](#)

Solution C: 0.5 mL of [phosphoric acid](#) in 1000 mL of [water](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	42	3	55
40	53	3	44
60	87	3	10
70	87	3	10
75	42	3	55

System suitability solution: ▲0.2 mg/mL of [USP Fluticasone Propionate System Suitability Mixture RS](#) prepared as follows. Transfer a suitable amount of [USP Fluticasone Propionate System Suitability Mixture RS](#) to an appropriate volumetric flask and dissolve in 50% of the flask volume of *Solution A*. Sonication may be used to aid dissolution. Dilute with *Solution C* to volume.

Sensitivity stock solution: 0.1 mg/mL of [USP Fluticasone Propionate RS](#) prepared as follows. Transfer a suitable amount of [USP Fluticasone Propionate RS](#) to an appropriate volumetric flask and dissolve in 50% of the flask volume of *Solution A*. Sonication may be used to aid dissolution. Dilute with *Solution C* to volume.

Sensitivity solution: 0.1 µg/mL of [USP Fluticasone Propionate RS](#) from *Sensitivity stock solution* in *Solution C* ▲ (USP 1-Dec-2022)

Sample solution: 0.2 mg/mL ▲ of Fluticasone Propionate ▲ (USP 1-Dec-2022) prepared as follows. ▲ Transfer a suitable amount of Fluticasone Propionate to an appropriate volumetric flask and dissolve in 50% of the flask volume of *Solution A*. Sonication may be used to aid dissolution. Dilute with *Solution C* to volume. ▲ (USP 1-Dec-2022)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 239 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution* ▲ and *Sensitivity solution* ▲ (USP 1-Dec-2022)

Suitability requirements