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# Fluticasone Propionate Inhalation Powder

## DEFINITION

Fluticasone Propionate Inhalation Powder contains NLT 90% and NMT 110% of the labeled amount of fluticasone propionate ( $C_{25}H_{31}F_3O_5S$ ).

## IDENTIFICATION

### Change to read:

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

(IRA 1-Sep-2022)

## ASSAY

### Change to read:

#### • PROCEDURE

**Buffer:** 0.01 M [sodium dodecyl sulfate](#) containing 0.1% [glacial acetic acid](#)

**Solution A:** [Methanol](#) and *Buffer* (20:80)

**Mobile phase:** [Acetonitrile](#) and *Solution A* (49:51)

**Diluent:** [Methanol](#) and [water](#) (70:30)

**Standard solution:** 6–12 µg/mL of [USP Fluticasone Propionate RS](#) in *Diluent*

**Sample solution:** Nominally 6–12 µg/mL of fluticasone propionate from NLT 12 unit doses in *Diluent*

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 239 nm

**Column:** 4.6-mm × 5-cm; 3.5-µm packing [L1](#)

**Flow rate:** 2 mL/min

**Column temperature:** 40°

**Injection volume:** 50 µL

#### System suitability

**Sample:** *Standard solution*

[NOTE—The retention time for the peak due to fluticasone propionate will be within the range of 1.0–1.6 min.]

#### Suitability requirements

**Tailing factor:** NMT 1.5

**Relative standard deviation:** NMT 2.0%

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

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

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

$r_U$  = ▲peak▲ (IRA 1-Sep-2022) response from the *Sample solution*

$r_S$  = ▲peak▲ (IRA 1-Sep-2022) response 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)

**Acceptance criteria:** 90%–110%

Delete the following:

▲PERFORMANCE TESTS▲ (IRA 1-Sep-2022)

## IMPURITIES

Change to read:

## • ORGANIC IMPURITIES

[NOTE—Protect sample and standard solutions from light.]

**Solution A:** Prepare a solution of 0.05% (v/v) [phosphoric acid](#) in [acetonitrile](#).

**Solution B:** Prepare a solution of 0.05% (v/v) [phosphoric acid](#) in [methanol](#).

**Solution C:** Prepare a solution of 0.05% (v/v) [phosphoric acid](#) in [water](#).

**Mobile phase:** See [▲Table 1](#).

**Table 1**▲ (IRA 1-Sep-2022)

| Time (min) | Solution A (%) | Solution B (%) | Solution C (%) |
|------------|----------------|----------------|----------------|
| 0          | 42             | 3              | 55             |
| 40         | 53             | 3              | 44             |
| 60         | 87             | 3              | 10             |
| 70         | 87             | 3              | 10             |
| 70.1       | 42             | 3              | 55             |
| 90         | 42             | 3              | 55             |

**System suitability solution:** Dissolve 2 mg of [USP Fluticasone Propionate System Suitability Mixture RS](#) in 12 mL of *Solution A*. Add 8 mL of *Solution C*, and mix.

**Sensitivity solution:** 0.5 µg/mL of [USP Fluticasone Propionate RS](#) in *Solution A*

**Sample solution:** Nominally 100 µg/mL of fluticasone propionate from NLT 10 unit doses prepared as follows. Transfer the contents of the appropriate number of unit doses into a suitable volumetric flask. Add 60% of the flask volume of [▲Solution A](#),▲ (IRA 1-Sep-2022) and sonicate for 2 min. Add 40% of the flask volume of [▲Solution C](#),▲ (IRA 1-Sep-2022) mix, and allow the solution to equilibrate. Dilute with [▲Solution C](#),▲ (IRA 1-Sep-2022) to volume if necessary. Mix, allow any undissolved excipient material to settle, and inject the supernatant.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 239 nm

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

**Flow rate:** 1 mL/min

**Column temperature:** 40°

**Injection volume:** 100 µL

#### System suitability

**Samples:** *System suitability solution* and *Sensitivity solution*

#### Suitability requirements

**Resolution:** NLT 0.6 between fluticasone propionate related compound B and fluticasone propionate related compound C; NLT 1.5 between fluticasone propionate related compound D and fluticasone propionate, *System suitability solution*

**Tailing factor:** NMT 1.3 for fluticasone propionate, *System suitability solution*

**Signal-to-noise ratio:** NLT 10 for fluticasone propionate, *Sensitivity solution*

#### Analysis

**Sample:** *Sample solution*

Calculate the percentage of each fluticasone propionate related impurity in the portion of sample taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$  = peak response of each impurity from the *Sample solution*

$r_T$  = total peak response for all peaks ≥0.05% by area of the peak due to fluticasone propionate from the *Sample solution*

**Acceptance criteria:** See [▲Table 2](#).

**Table 2**▲ (IRA 1-Sep-2022)