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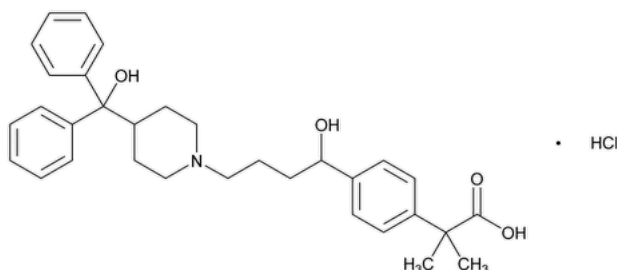
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Fexofenadine Hydrochloride


 $C_{32}H_{39}NO_4 \cdot HCl$ 538.12
Benzeneacetic acid, 4-[1-hydroxy-4-[4-(hydroxy diphenylmethyl)-1-piperidinyl]butyl]- α,α -dimethyl-, hydrochloride, ($\pm$);($\pm$)-p-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)piperidino]butyl]- α -methylhydratropic acid, hydrochloride CAS RN®: 153439-40-8; UNII: 2S068B75ZU.

DEFINITION

Fexofenadine Hydrochloride contains NLT 98.0% and NMT 102.0% of fexofenadine hydrochloride ($C_{32}H_{39}NO_4 \cdot HCl$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K
- **B.** The retention time of the fexofenadine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.**

Analysis: Examine the precipitate formed in *Other Components* for the *Content of Chloride* test.

Acceptance criteria: A white precipitate is observed.

ASSAY

PROCEDURE

Buffer: 6.64 g/L of monobasic sodium phosphate and 0.84 g/L of sodium perchlorate in water. Adjust with phosphoric acid to a pH of 2.0.

Diluent: Acetonitrile and *Buffer* (1:1)

Mobile phase: Acetonitrile and *Buffer* (7:13). Add 3 mL/L of triethylamine.

Standard solution: 0.06 mg/mL of [USP Fexofenadine Hydrochloride RS](#) and 0.005 mg/mL of [USP Fexofenadine Related Compound A RS](#) in *Mobile phase*

Sample stock solution: 1.0 mg/mL of Fexofenadine Hydrochloride in *Diluent*

Sample solution: 0.06 mg/mL of Fexofenadine Hydrochloride in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm $\times$ 25-cm; packing L11

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 10 between fexofenadine and fexofenadine related compound A

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for fexofenadine and NMT 3.0% for fexofenadine related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fexofenadine hydrochloride ($C_{32}H_{39}NO_4 \cdot HCl$) in the portion of Fexofenadine Hydrochloride 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 Fexofenadine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Fexofenadine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

OTHER COMPONENTS

• CONTENT OF CHLORIDE

Sample: 300 mg of Fexofenadine Hydrochloride

Blank: Methanol

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Endpoint detection: Potentiometrically

Analysis: Dissolve the *Sample* in 50 mL of methanol. Each mL of 0.1 N silver nitrate VS is equivalent to 3.545 mg of chloride.

Acceptance criteria: 6.45%–6.75% on the anhydrous basis

IMPURITIES

• RESIDUE ON IGNITION (281): NMT 0.1%

• LIMIT OF FEXOFENADINE RELATED COMPOUND B

Buffer: Glacial acetic acid and water (2.3:2000). Adjust with 6 N ammonium hydroxide to a pH of 4.0 ± 0.1 .

Mobile phase: Acetonitrile and *Buffer* (20:80)

System suitability solution: Add 1.2 mg of [USP Fexofenadine Related Compound B RS](#) to a 5-mL volumetric flask. Dilute with *Mobile phase* to volume. Transfer 2.0 mL of the solution into a 100-mL volumetric flask. Add 25 mg of [USP Fexofenadine Hydrochloride RS](#), and dilute with *Mobile phase* to volume.

Standard solution: 2.5 µg/mL of [USP Fexofenadine Hydrochloride RS](#) in *Mobile phase* from the *System suitability solution*

Sample solution: 0.25 mg/mL of Fexofenadine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L45

Flow rate: 0.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for fexofenadine related compound B and fexofenadine are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between fexofenadine and fexofenadine related compound B

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fexofenadine related compound B in the portion of Fexofenadine Hydrochloride taken:

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

r_U = peak response for fexofenadine related compound B from the *Sample solution*

r_S = peak response for fexofenadine from the *Standard solution*

C_S = concentration of [USP Fexofenadine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

F = relative response factor for fexofenadine related compound B relative to fexofenadine, 0.8

Acceptance criteria: NMT 0.2%

• OTHER ORGANIC IMPURITIES

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

Sample solution: Use the *Sample stock solution* in the Assay.