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Fexofenadine Hydrochloride Tablets

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<https://www.uspnf.com/rb-fexofenadine-hcl-tablets-20240426>.

DEFINITION

Fexofenadine Hydrochloride Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of fexofenadine hydrochloride ($C_{32}H_{39}NO_4 \cdot HCl$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Standard solution: Transfer 60 mg of [USP Fexofenadine Hydrochloride RS](#) to a suitable capped tube and add 10 mL of a mixture of [acetonitrile](#) and [methanol](#) (10:1).

Sample solution: Transfer an equivalent to 60 mg of fexofenadine hydrochloride, from a sufficient number of weighed and finely powdered Tablets, to a suitable capped tube, and add 10 mL of a mixture of [acetonitrile](#) and [methanol](#) (10:1).

Analysis: Shake or mix the *Standard solution* and *Sample solution* on a vortex mixer for 1–2 min to disperse the sample. Allow the solution to stand for 10 min, or centrifuge for 2–3 min. Pass the liquid into a 50-mL beaker using a 0.45- μ m polytetrafluoroethylene syringe filter. Evaporate the solvent until about 0.5 mL remains, using a stream of nitrogen with gentle heating (do not exceed 75°). Add 5 mL of [water](#) and 5 drops of [dilute hydrochloric acid](#), and stir to induce precipitation. Chill in an ice bath for 30 min. Filter the solution through a 10- to 15- μ m sintered-glass crucible. Dry the precipitate in an air oven for 1 h at 105° oven for 1 h at 105°. Prepare a bromide dispersion from the residue.

Acceptance criteria: The IR absorption spectrum of the potassium bromide dispersion of the residue from the sample exhibits maxima only at the same wavelengths as that of a potassium bromide dispersion from the Standard.

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

ASSAY

• PROCEDURE

Solution A: [Glacial acetic acid](#) and [water](#) (17:983). Dilute 100 mL of this solution with [water](#) to 1 L.

Solution B: Dilute 15 mL of a solution containing [acetonitrile](#) and [triethylamine](#) (1:1) with *Solution A* to 1 L. Adjust with [phosphoric acid](#) to a pH of 5.25.

Diluent: [Acetonitrile](#) and *Solution A* (3:1)

Mobile phase: [Acetonitrile](#) and *Solution B* (9:16)

Standard stock solution: 0.25 mg/mL of [USP Fexofenadine Hydrochloride RS](#) in *Diluent*

Standard solution: 0.015 mg/mL from the *Standard stock solution* in *Mobile phase*

Sample stock solution: Transfer a sufficient number of whole Tablets (NLT 10) to a suitable volumetric flask, add *Solution A* (equivalent to 20% of the total flask volume), and shake by mechanical means at a high speed for 30 min or until the Tablets are fully disintegrated and finely dispersed. Add [acetonitrile](#) (sufficient to fill the flask to 80% of its volume), and shake by mechanical means for 60 min. Dilute with *Diluent* to volume. Pass a portion of this solution through a polytetrafluoroethylene filter having a 0.45- μ m or finer pore size, and use the filtrate. Dilute, if necessary, with *Diluent* to obtain a solution containing an equivalent to 1.2 mg/mL of fexofenadine hydrochloride.

Sample solution: 0.018 mg/mL from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L11](#)

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of $C_{32}H_{39}NO_4 \cdot HCl$ in the portion of Tablets 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 = nominal concentration of fexofenadine hydrochloride in the *Sample solution* (mg/mL)**Acceptance criteria:** 93.0%–107.0%**PERFORMANCE TESTS**• [DISSOLUTION \(711\)](#)**Test 1****Medium:** 0.001 N [hydrochloric acid](#); 900 mL, deaerated**Apparatus 2:** 50 rpm**Time:** 10 and 30 minDetermine the percentages of the labeled amount of $C_{32}H_{39}NO_4 \cdot HCl$ dissolved by using the following method.**Solution A:** 1.0 g of [monobasic sodium phosphate](#), 0.5 g of [sodium perchlorate](#), and 0.3 mL of concentrated [phosphoric acid](#) in 300 mL of [water](#)**Mobile phase:** [Acetonitrile](#) and *Solution A* (7:3)**Standard solution:** [USP Fexofenadine Hydrochloride RS](#) in *Medium* to obtain a solution having a known concentration similar to that expected for the solution under test. [NOTE—A small amount of [methanol](#), not exceeding 0.5% of the total volume, can be used to dissolve fexofenadine hydrochloride.]**System suitability solution:** 0.44 mg/mL of [USP Fexofenadine Related Compound A RS](#) in [water](#). Transfer 1.0 mL of this solution into a vial, and add 40 mL of the *Standard solution*. [NOTE—A small amount of [glacial acetic acid](#), not exceeding 5% of the total volume, can be used to dissolve fexofenadine related compound A.]**Sample solution:** Pass portions of the solution under test through a glass fiber filter having a 0.45- μ m pore size.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 220 nm**Column:** 4.6-mm $\times$ 10-cm; packing [L1](#)**Flow rate:** 1 mL/min**Injection volume:** 2–3 μ g column load of fexofenadine hydrochloride**System suitability****Samples:** *Standard solution* and *System suitability solution***Suitability requirements****Resolution:** NLT 2.0 between fexofenadine and fexofenadine 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 $C_{32}H_{39}NO_4 \cdot HCl$ dissolved in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times D \times V \times 100$$

 r_U = peak area from the *Sample solution* r_S = peak area from the *Standard solution* C_S = concentration of [USP Fexofenadine Hydrochloride RS](#) in the *Standard solution* (mg/mL) L = Tablet label claim (mg) D = dilution factor of the *Sample solution* V = volume of *Medium*, 900 mL**Tolerances:** NLT 60% (Q) of the labeled amount of $C_{32}H_{39}NO_4 \cdot HCl$ is dissolved in 10 min; NLT 80% (Q) of the labeled amount of $C_{32}H_{39}NO_4 \cdot HCl$ is dissolved in 30 min.