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Famotidine Tablets

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DEFINITION

Famotidine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of famotidine ($C_8H_{15}N_7O_2S_3$).

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).

Standard solution: 4 mg/mL of [USP Famotidine RS](#) in [glacial acetic acid](#)

Sample solution: Transfer a portion of finely powdered Tablets, equivalent to about 40 mg of famotidine, to a 10-mL volumetric flask.

Dissolve in [glacial acetic acid](#) with the aid of sonication, dilute with [glacial acetic acid](#) to volume, and centrifuge to get a clear liquid.

Adsorbent: 0.25-mm layer of [chromatographic silica gel mixture](#)

Application volume: 10 μ L

Developing solvent system: [Ethyl acetate](#), [methanol](#), [toluene](#), and [ammonium hydroxide](#) (40:25:20:2)

Analysis: Allow the spots to dry, and develop the plate in a paper-lined chromatographic chamber equilibrated with *Developing solvent system* for about 1 h before use. Allow the chromatogram to develop until the solvent front has moved about 15 cm. Remove the plate, air-dry, and examine the plate under short-wavelength UV light.

Acceptance criteria: The principal spot from the *Sample solution* corresponds in appearance and R_f value to that of the *Standard solution*.

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

ASSAY

• PROCEDURE

Buffer: Dissolve 13.6 g of [sodium acetate trihydrate](#) in 750 mL of [water](#). Add 1 mL of [triethylamine](#), adjust with [glacial acetic acid](#) to a pH of 6.0, and dilute with [water](#) to 1 L.

Mobile phase: [Acetonitrile](#) and *Buffer* (7:93)

Diluent: Dissolve 6.8 g of [potassium phosphate, monobasic](#) in 750 mL of [water](#), adjust with 1 M [potassium hydroxide](#) to a pH of 6.0, and dilute with [water](#) to 1 L.

System suitability stock solution: Transfer 10 mg of famotidine to a 50-mL volumetric flask. Add 1 mL of 0.1 N [hydrochloric acid](#), heat at 80° for 30 min, and cool to room temperature. Add 2 mL of 0.1 N [sodium hydroxide](#), heat at 80° for 30 min, cool to room temperature, and neutralize by adding 1 mL of 0.1 N [hydrochloric acid](#). Dilute with *Diluent* to volume. Transfer 10 mL of this solution to a separate 50-mL volumetric flask containing 5 mg of famotidine dissolved in 8 mL of [methanol](#). Dilute with *Diluent* to volume. Transfer 25 mL of this solution to a 50-mL volumetric flask, and dilute with *Diluent* to volume. [NOTE—This solution is stable for up to 1 month.]

System suitability solution: Transfer 1–1.5 mL of the *System suitability stock solution* to a suitable container, add 1 drop of [hydrogen peroxide solution](#), and mix well.

[NOTE—Prepare fresh daily.]

Standard solution: Transfer 10 mg of [USP Famotidine RS](#) to a 100-mL volumetric flask, add 20 mL of [methanol](#), and sonicate for 5 min. Dilute with *Diluent* to volume.

Sample solution: Transfer NLT 10 Tablets to a 1-L volumetric flask. Add 200 mL of *Diluent*, and swirl to erode the Tablets. Add 200 mL of [methanol](#), and stir by mechanical means at 300 rpm for 1 h. Dilute with *Diluent* to volume, mix, and filter. Quantitatively dilute a portion of the clear filtrate with *Diluent* to obtain a solution containing about 0.1 mg/mL of famotidine.

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm $\times$ 15-cm; packing [L1](#)

Column temperature: 40°

Flow rate: 1.4 mL/min

Injection size: 50 μ L

System suitability

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

Suitability requirements

[NOTE—Identify peaks using [Table 1](#).]

Resolution: NLT 1.3 between the famotidine sulfamoyl propanamide and famotidine peaks, and NLT 1.3 between the famotidine and famotidine propanamide peaks, *System suitability solution*

Capacity factor: NLT 2.0 for the famotidine peak, *System suitability solution*

Relative standard deviation: Less than 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of famotidine ($C_8H_{15}N_7O_2S_3$) 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 Famotidine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

▲ Test 1 ▲ (RB 1-Aug-2023)

Medium: pH 4.5, 0.1 M phosphate buffer (13.6 g/L of [potassium phosphate, monobasic](#)); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Determine the amount of $C_8H_{15}N_7O_2S_3$ dissolved using one of the following methods.

Spectrophotometric method

Standard solution: [USP Famotidine RS](#) in *Medium* in a concentration similar to the one expected in the *Sample solution*

Sample solution: Pass a portion of the sample under test through a suitable filter.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 265 nm

Chromatographic method

Buffer, Mobile phase, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.14 mg/mL of [USP Famotidine RS](#) in *Medium*. Dilute this solution with *Medium* to obtain a solution containing ($L/900$) mg/mL, where L is the Famotidine Tablet label claim, in mg.

Sample solution: Pass a portion of the solution under test through a suitable filter.

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor: Greater than 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the amount of famotidine ($C_8H_{15}N_7O_2S_3$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim, mg/Tablet

V = volume of *Medium*, 900 mL

Tolerances: NLT 75% (Q) of the labeled amount of famotidine ($C_8H_{15}N_7O_2S_3$) is dissolved.

For Tablets labeled as chewable