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Famotidine for Oral Suspension

DEFINITION

Famotidine for Oral Suspension contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of famotidine ($C_8H_{15}N_7O_2S_3$) when constituted as directed. It contains one or more suitable buffers, colors, diluents, flavors, and preservatives.

IDENTIFICATION

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

ASSAY

• **Procedure**

Buffer A: Dissolve 13.6 g of sodium acetate trihydrate in 900 mL of water, and adjust with glacial acetic acid to a pH of 6.0 ± 0.1, before final dilution to 1 L.

Buffer B: Dissolve 13.6 g of monobasic sodium phosphate in 900 mL of water, adjust with 1 M sodium hydroxide to a pH of 7.0 ± 0.1, and dilute with water to 1 L.

Solution A: Acetonitrile and *Buffer A* (7:93)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	100	0
42	52	48
43	100	0
45	100	0

Diluent: Acetonitrile and *Buffer B* (7:93)

Standard solution: 0.16 mg/mL of USP Famotidine RS in *Diluent*

Sample solution: Transfer to a 100-mL volumetric flask a portion of Famotidine for Oral Suspension, equivalent to about 40 mg of famotidine, freshly mixed and free from air bubbles and constituted as directed in the labeling. Add 10 mL of methanol, sonicate for 5 min, add 70 mL of *Diluent*, sonicate for an additional 5 min, and dilute with *Diluent* to volume. Dilute 10.0 mL of this solution with *Diluent* to 25.0 mL, and filter.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 268 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: Greater than 2000 theoretical plates

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

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 Famotidine for Oral Suspension 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

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for *Content Uniformity*. For the product in multi-dose containers, the unit is a 5-mL aliquot of the suspension, constituted as directed in the labeling.

IMPURITIES

• **Organic Impurities**

Mobile phase, Diluent, Standard solution, Sample solution and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability stock solution: Transfer 16 mg of famotidine to a 50-mL volumetric flask. Dissolve in 1.0 mL of 1 N hydrochloric acid, heat at 80° for 30 min, and cool to room temperature. Add 2.0 mL of 1 N sodium hydroxide, heat at 80° for 30 min, and cool to room temperature. Add 1.0 mL of 1 N hydrochloric acid to neutralize, and dilute with *Diluent* to volume.

System suitability solution: Transfer 16 mg of famotidine to a 50-mL volumetric flask. Add 10 mL of *Diluent*, and sonicate to dissolve. Add 5 drops of hydrogen peroxide solution, heat at 80° for 15 min, and cool to room temperature. Add 20 mL of *System suitability stock solution*, and dilute with *Diluent* to volume.

System suitability

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

[Note—Identify the components of the *System suitability solution* based on the relative retention times listed in *Table 2*.]

Suitability requirements

Resolution: Greater than 1.5 between famotidine and famotidine propanamide, *System suitability solution*

Column efficiency: Greater than 2000 theoretical plates, *Standard solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the total of famotidine sulfamoyl propanamide and famotidine propanamide in the portion of Famotidine for Oral Suspension taken:

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

r_U = sum of the peak areas for famotidine sulfamoyl propanamide and famotidine propanamide from the *Sample solution*

r_S = peak area of famotidine 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

Total of famotidine sulfamoyl propanamide and famotidine propanamide: Less than 2.0%

Table 2

Name	Relative Retention Time
Famotidine sulfoxide[a]	0.3
Famotidine propionic acid (famotidine related compound F)[b]	0.5
Famotidine sulfamoyl propanamide (famotidine related compound C)[c]	0.7
Famotidine	1.0
Famotidine propanamide (famotidine related compound D)[d]	1.2

[a] 3-[[2-(Diaminomethyleneamino)thiazol-4-yl]methylsulfinyl]-*N*'-sulfamoylpropanimidamide.

[b] 3-[[2-(Diaminomethyleneamino)thiazol-4-yl]methylthio]propanoic acid.

[c] 3-[[2-(Diaminomethyleneamino)thiazol-4-yl]methylthio]-*N*-sulfamoylpropanamide.

[d] 3-[[2-(Diaminomethyleneamino)thiazol-4-yl]methylthio]propanamide.

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^2 cfu/g. The total combined molds and yeasts count is NMT 10^2 cfu/g. It meets the requirements of the tests for the absence of *Salmonella* species and *Escherichia coli*.

• **pH ⟨791⟩:** 6.5–7.5, in the suspension constituted as directed in the labeling

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light. Store at 25°, excursions permitted between 15° and 30°.

• **USP Reference Standards ⟨11⟩**
USP Famotidine RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
FAMOTIDINE FOR ORAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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