Method of preparation Prepare as directed under Powder, with Famotidine.

Identification Weigh a portion of Famotidine Powder, equivalent to 0.01 g of Famotidine according to the labeled amount, add 50 mL of 0.05 mol/L potassium dihydrogenphosphate TS, shake well, and centrifuge. To 5 mL of the supernatant liquid add 0.05 mol/L potassium dihydrogenphosphate TS to make 50 mL, and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 263 nm and 267 nm.

Dissolution test Being specified separately.

Assay Weigh accurately a portion of Famotidine Powder, equivalent to about 0.02 g of famotidine ($C_8H_{15}N_7O_2S_3$), add 20 mL of water, and shake well. Add 20 mL of methanol, then shake well, add methanol to make exactly 50 mL, and centrifuge. Pipet 5 mL of the supernatant liquid, add exactly 2 mL of the internal standard solution, add the mobile phase to make 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of famotidine for assay, previously dried in vacuum with phosphorus (V) oxide at 80°C for 4 hours, dissolve in methanol to make exactly 50 mL. Pipet 10 mL of this solution, and add methanol to make exactly 50 mL. Pipet 5 mL of this solution, add exactly 2 mL of the internal standard solution, add the mobile phase to make 20 mL, and use this solution as the standard solution. Perform the test with 5 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak area of famotidine to that of the internal standard.

$$\text{Amount (mg) of famotidine } (C_8H_{15}N_7O_2S_3) = \text{amount (mg) of famotidine for assay} \times \frac{Q_T}{Q_S} \times \frac{1}{5}$$

Internal standard solution—To 5 mL of a solution of methyl parahydroxybenzoate in methanol (1 in 500) add water to make 50 mL.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 2 g of sodium 1-heptane sulfonate in 900 mL of water, adjust to pH 3.0 with acetic acid (100), and add water to make 1000 mL. To this solution add 240 mL of acetonitrile and 40 mL of methanol.

Flow rate: Adjust the flow rate so that the retention time of famotidine is about 6 minutes.

System suitability—

System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, famotidine and the internal standard are eluted in this order with the resolution between these peaks being not less than 11.

System repeatability: When the test is repeated 6 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of famotidine to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Tight containers.

Famotidine Tablets

ファモチジン錠

Famotidine Tablets contain not less than 94% and not more than 106% of the labeled amount of famotidine ($C_8H_{15}N_7O_2S_3$: 337.45).

Method of preparation Prepare as directed under Tablets, with Famotidine.

Identification Weigh a portion of powdered Famotidine Tablets, equivalent to 0.01 g of Famotidine according to the labeled amount, add 50 mL of 0.05 mol/L potassium dihydrogenphosphate TS, shake well, and centrifuge. To 5 mL of the supernatant liquid add 0.05 mol/L potassium dihydrogenphosphate TS to make 50 mL, and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 263 nm and 267 nm.

Content uniformity To 1 tablet of Famotidine Tablets add 2 mL of water, shake to disintegrate, then add a suitable amount of methanol, and shake well. Add methanol to make exactly V mL of a solution containing about 0.2 mg of famotidine ($C_8H_{15}N_7O_2S_3$) per mL, and centrifuge. Pipet 10 mL of the supernatant liquid, add exactly 2 mL of the internal standard solution, add the mobile phase to make 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of famotidine for assay, previously dried in vacuum with phosphorus (V) oxide at 80°C for 4 hours, dissolve in methanol to make exactly 100 mL. Pipet 10 mL of this solution, and add methanol to make exactly 50 mL. Pipet 10 mL of this solution, add exactly 2 mL of the internal standard solution, add the mobile phase to make 20 mL, and use this solution as the standard solution. Perform the test with 5 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the operating conditions described in the Assay, and calculate the ratios, Q_T and Q_S, of the peak area of famotidine to that of the internal standard.

$$\text{Amount (mg) of famotidine } (C_8H_{15}N_7O_2S_3) = \text{amount (mg) of famotidine for assay} \times \frac{Q_T}{Q_S} \times \frac{V}{500}$$

Internal standard solution—To 5 mL of a solution of methyl paraphydroxybenzoate in methanol (1 in 500) add water to make 50 mL.

Dissolution test Being specified separately.

Assay Take a number of Famotidine Tablets, equivalent to 0.2 g of famotidine ($C_8H_{15}N_7O_2S_3$), add 50 mL of water, and disintegrate by shaking well. Add 100 mL of methanol, then shake well, add methanol to make exactly 200 mL, and centrifuge. Pipet 5 mL of the supernatant liquid, add exact-

ly 5 mL of the internal standard solution, add the mobile phase to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of famotidine for assay, previously dried in vacuum with phosphorus (V) oxide at 80°C for 4 hours, dissolve in methanol to make exactly 100 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, add the mobile phase to make 50 mL, and use this solution as the standard solution. Perform the test with 5 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak area of famotidine to that of the internal standard.

$$\text{Amount (mg) of famotidine } (C_8H_{15}N_7O_2S_3) = \text{amount (mg) of famotidine for assay} \times \frac{Q_T}{Q_S} \times 2$$

Internal standard solution—To 5 mL of a solution of methyl parahydroxybenzoate in methanol (1 in 500) add water to make 50 mL.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 2 g of sodium 1-heptane sulfonate in 900 mL of water, adjust to pH 3.0 with acetic acid (100), and add water to make 1000 mL. To this solution add 240 mL of acetonitrile and 40 mL of methanol.

Flow rate: Adjust the flow rate so that the retention time of famotidine is about 6 minutes.

System suitability—

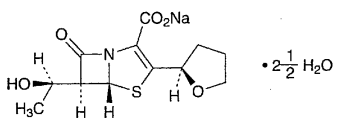
System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, famotidine and the internal standard are eluted in this order with the resolution between these peaks being not less than 11.

System repeatability: When the test is repeated 6 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of famotidine to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Tight containers.

Faropenem Sodium

ファロペネムナトリウム



$C_{12}H_{14}NNaO_5S.2\frac{1}{2}H_2O$: 352.34

Monosodium (5*R*,6*S*)-6-[(1*R*)-1-hydroxyethyl]-7-oxo-3-[(2*R*)-tetrahydrofuran-2-yl]-4-thia-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylate hemipentahydrate [*122547-49-3*, anhydride]

Faropenem Sodium contains not less than 870 μg (potency) per mg, calculated on the anhydrous basis. The potency of Faropenem Sodium is expressed as mass (potency) of faropenem ($C_{12}H_{15}NO_5S$: 285.32).

Description Faropenem Sodium occurs as white to light yellow, crystals or crystalline powder.

It is freely soluble in water and in methanol, and slightly soluble in ethanol (95).

Identification **(1)** Dissolve 5 mg of Faropenem Sodium in 1 mL of hydroxylammonium chloride-ethanol TS, allow to stand for 3 minutes, add 1 mL of acidic ammonium iron (III) sulfate TS, and shake: a red-brown to brown color develops.

(2) Determine the absorption spectra of solutions of Faropenem Sodium and Faropenem Sodium Reference Standard (1 in 20,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectra: both spectra exhibit similar intensities of absorption at the same wavelengths.

(3) Determine the infrared absorption spectra of Faropenem Sodium and Faropenem Sodium Reference Standard as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectra: both spectra exhibit similar intensities of absorption at the same wave numbers.

Optical rotation $[\alpha]_D^{20}$: +145 – +150° (0.5 g calculated as the anhydrous basis, water, 50 mL, 100 mm).

Purity **(1)** Clarity and color of solution—Being specified separately.

(2) Heavy metals—Proceed with 2.0 g of Faropenem Sodium according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Related substances—Being specified separately.

Water Not less than 12.6% and not more than 13.1% (0.02 g, coulometric titration).

Assay Weigh accurately an amount of Faropenem Sodium and Faropenem Sodium Reference Standard, equivalent to about 0.1 g (potency), dissolve separately in water to make exactly 50 mL. Pipet 5 mL each of these solutions, add exactly 4 mL each of the internal standard solution, add water to make 20 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with 20 μL of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak area of faropenem to that of the internal standard.

$$\text{Amount [μg (potency)] of faropenem } (C_{12}H_{15}NO_5S) = \text{amount [mg (potency)] of Faropenem Sodium Reference Standard} \times \frac{Q_T}{Q_S} \times 1000$$

Internal standard solution—Dissolve 0.5 g of *m*-hydroxyacetophenone in 20 mL of acetonitrile, and add water to make 200 mL.