Faropenem Sodium

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**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 (C₁₂H₁₂NO₅S₂: 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** $[\alpha]_{D}^{20}$: $+145^\circ$ to $+150^\circ$ (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.

Amount [µg (potency)] of faropenem (C₁₂H₁₂NO₅S₂) = amount [mg (potency)] of Faropenem Sodium

Reference Standard $\times \frac{Q_T}{Q_S} \times 1000$

**Containers and storage** Containers—Tight containers.
Operating conditions—
Detector: An ultraviolet absorption photometer (wavelength: 305 nm).
Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecylsilaized silica gel for liquid chromatography (5 µm in particle diameter).
Column temperature: A constant temperature of about 40°C.
Mobile phase: Dissolve 4.8 g of potassium dihydrogenphosphate, 5.4 g of disodium hydrogenphosphate 12-water and 1.0 g of tetra n-butyl ammonium bromide in water to make 1000 mL. To 870 mL of this solution add 130 mL of acetonitrile.
Flow rate: Adjust the flow rate so that the retention time of faropenem is about 11 minutes.
System suitability—
System performance: When the procedure is run with 20 µL of the standard solution under the above operating conditions, the internal standard and faropenem are eluted in this order with the resolution between these peaks being not less than 1.5.
System repeatability: When the test is repeated 6 times with 20 µL of the standard solution under the above operating conditions, the relative standard deviation of the ratio of the peak area of faropenem to that of the internal standard is not more than 1.0%.
Containers and storage  Containers—Tight containers.

Fenbufen

フェンブフェン

C_{16}H_{14}O_{2}: 254.28
4-(Biphenyl-4-yl)-4-oxobutanoic acid [36330-85-5]

Fenbufen, when dried, contains not less than 98.0% of C_{16}H_{14}O_{2}.

Description  Fenbufen occurs as a white crystalline powder.
It has a bitter taste.
It is sparingly soluble in acetone, slightly soluble in methanol, in ethanol (95%) and in diethyl ether, and practically insoluble in water.
Melting point: about 188°C (with decomposition).

Identification  (1) Determine the absorption spectrum of a solution of Fenbufen in ethanol (95%) (1 in 200,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.
(2) Determine the infrared absorption spectrum of Fenbufen, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotomet-
ry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

Purity  (1) Heavy metals—Take 2.0 g of Fenbufen, add 2 mL of sulfuric acid, and carbonize by gentle heating, proceed according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).
(2) Arsene—Prepare the test solution with 1.0 g of Fenbufen according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).
(3) Related substances—Dissolve 0.1 g of Fenbufen in 20 mL of acetone, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add acetone to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 µL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of dichloromethane, methanol and water (80:20:3) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying  Not more than 0.3% (1 g, 105°C, 3 hours).
Residue on ignition  Not more than 0.10% (1 g).

Assay  Weigh accurately about 0.2 g of Fenbufen, previously dried, dissolve in 100 mL of ethanol (95%), and titrate with 0.1 mol/L potassium hydroxide-ethanol VS (potentiometric titration). Perform a blank determination, and make any necessary correction.
Each mL of 0.1 mol/L potassium hydroxide-ethanol VS = 25.429 mg of C_{16}H_{14}O_{2}

Containers and storage  Containers—Tight containers.

Fentanyl Citrate

フェンタニル酸フェナチル

C_{22}H_{33}N_{2}O_{2}.C_{6}H_{12}O_{7}: 528.59
N-(1-Phenethylpiperidin-4-yl)-N-phenylpropionamide monocitrate [590-73-8]

Fentanyl Citrate contains not less than 98.0% of C_{22}H_{33}N_{2}O_{2}.C_{6}H_{12}O_{7}, calculated on the dried basis.

Description  Fentanyl Citrate occurs as white crystals or crystalline powder.
It is freely soluble in methanol and in acetic acid (100), sparingly soluble in water and in ethanol (95), and very slightly soluble in diethyl ether.