

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 octadecylsilanized silica gel for liquid chromatography (5 μ m 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—

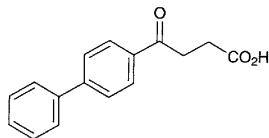
System performance: When the procedure is run with 20 μ L of the standard solution under the above operating conditions, the internal standard and faropenem are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated 6 times with 20 μ L of the standard solution under the above operating conditions, the relative standard deviation of the ratios 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



$C_{16}H_{14}O_3$: 254.28

4-(Biphenyl-4-yl)-4-oxobutanoic acid [36330-85-5]

Fenbufen, when dried, contains not less than 98.0% of $C_{16}H_{14}O_3$.

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 Spectrophotometry,

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) **Arsenic—**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 μ L 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).

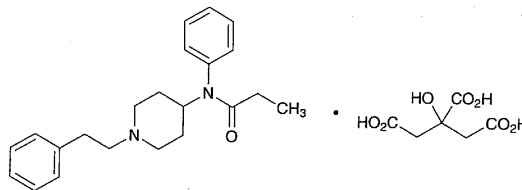
Assay Weigh accurately about 0.2 g of Fenbufen, previously dried, dissolve in 100 mL of ethanol (99.5), and titrate with 0.1 mol/L potassium hydroxide-ethanol VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L potassium hydroxide-ethanol VS = 25.429 mg of $C_{16}H_{14}O_3$

Containers and storage Containers—Tight containers.

Fentanyl Citrate

クエン酸フェンタニル



$C_{22}H_{28}N_2O \cdot C_6H_8O_7$: 528.59

N-(1-Phenethylpiperidin-4-yl)-*N*-phenylpropionamide monocitrate [990-73-8]

Fentanyl Citrate contains not less than 98.0% of $C_{22}H_{28}N_2O \cdot C_6H_8O_7$, 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.