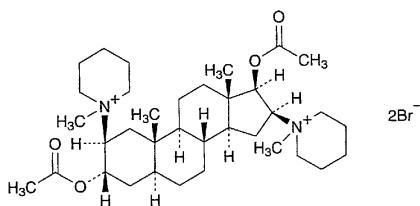


Pancuronium Bromide

臭化パンクロニウム



$C_{35}H_{60}Br_2N_2O_4$: 732.67

1,1'-(3 α ,17 β -Diacetoxy-5 α -androstan-2 β ,16 β -diyl)bis(1-methylpiperidinium) dibromide [15500-66-0]

Pancuronium Bromide contains not less than 98.0% and not more than 102.0% of $C_{35}H_{60}Br_2N_2O_4$, calculated on the dehydrated basis.

Description Pancuronium Bromide occurs as a white crystalline powder.

It is very soluble in water, and freely soluble in ethanol (95) and in acetic anhydride.

It is hygroscopic.

Identification (1) Determine the infrared absorption spectrum of Pancuronium Bromide 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.

(2) A solution of Pancuronium Bromide (1 in 100) responds to the Qualitative Tests (1) for bromide.

Optical rotation $[\alpha]_D^{20}$: +38 – +42° (0.75 g calculated on the dehydrated basis, water, 25 mL, 100 mm).

pH The pH of a solution of Pancuronium Bromide (1 in 100) is between 4.5 and 6.5.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Pancuronium Bromide in 10 mL of water: the solution is clear and colorless.

(2) Related substances—Dissolve 0.050 g of Pancuronium Bromide in 5 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of this solution, add ethanol (95) to make exactly 100 mL, and use this solution as the standard solution (1). Separately, weigh exactly 5 mg of dacrurium bromide for thin-layer chromatography, add ethanol (95) to make exactly 25 mL, and use this solution as the standard solution (2). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 2 μ L each of the sample solution, the standard solution (1) and the standard solution (2) on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 2-propanol, acetonitrile and a solution of sodium iodide (1 in 5) (17:2:1) to a distance of about 12 cm, and air-dry the plate. Spray evenly a solution of sodium nitrite in methanol (1 in 100) on the plate, allow to stand for 2 minutes, and spray evenly potassium bismuth iodide TS on the plate: a spot from the sample solution, corresponding to

that from the standard solution (2), has no more color than that from the standard solution (2), and the spots other than the principal spot and the above mentioned spot from the sample solution have no more color than the spot from the standard solution (1).

Water Not more than 8.0% (0.3 g, volumetric titration, direct titration).

Residue on ignition Not more than 0.10% (1 g).

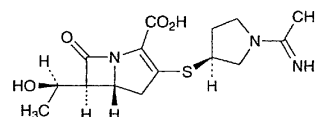
Assay Weigh accurately about 0.2 g of Pancuronium Bromide, dissolve in 50 mL of acetic anhydride by warming, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 36.634 mg of $C_{35}H_{60}Br_2N_2O_4$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Panipenem

パニペネム



$C_{15}H_{21}N_3O_4S$: 339.41

(5*R*,6*S*)-6-[(1*R*)-1-Hydroxyethyl]-3-[(3*S*)-1-(1-iminoethyl)pyrrolidin-3-ylsulfanyl]-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid [87726-17-8]

Panipenem contains not less than 900 μ g (potency) per mg, calculated on the anhydrous and desolvent basis. The potency of Panipenem is expressed as mass (potency) of panipenem ($C_{15}H_{21}N_3O_4S$).

Description Panipenem occurs as a white to light yellow, crystalline powder or mass.

It is very soluble in water, freely soluble in methanol, and slightly soluble in ethanol (99.5).

It is hygroscopic.

It deliquesces in the presence of moisture.

Identification (1) Dissolve 0.02 g of Panipenem in 2 mL of water, add 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 color develops.

(2) Determine the absorption spectrum of a solution of Panipenem in 0.02 mol/L 3-(*N*-morpholino)propanesulfonic acid buffer solution, pH 7.0 (1 in 50,000) as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 296 nm and 300 nm.

(3) Determine the infrared absorption spectrum of Panipenem as directed in the potassium bromide disk