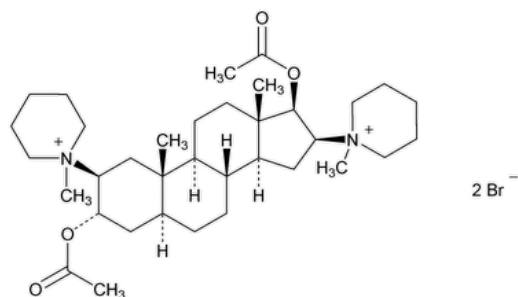


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Pancuronium Bromide



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

Piperidinium, 1,1'-[(2 β ,3 α ,5 α ,16 β ,17 β)-3,17-bis(acetyl oxy)androstane-2,16-diyl]bis[1-methyl]-, dibromide;

1,1'-(3 α ,17 β -Dihydroxy-5 α -androstane-2 β ,16 β -ylene)bis[1-methylpiperidinium] dibromide diacetate;

2 β ,16 β -Dipiperidino-5 α -androstane-3 α ,17 β -diol diacetate dimethobromide CAS RN[®]: 15500-66-0; UNII: U9LY9Y75X2.

DEFINITION

Pancuronium Bromide contains NLT 98.0% and NMT 102.0% of pancuronium bromide ($C_{35}H_{60}Br_2N_2O_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\), Bromide](#): A solution (1 in 10) meets the requirements of test *B*.

ASSAY

PROCEDURE

Diluent: 0.0024 M hydrochloric acid

Mobile phase: Acetonitrile, methanol, and 0.024 M hydrochloric acid (125:200:675)

Standard stock solution: 1.0 mg/mL prepared as follows. Transfer the required quantity of [USP Pancuronium Bromide RS](#) to a suitable volumetric flask. Dissolve in 2% of the flask volume of acetonitrile, dilute with *Diluent* to volume, and sonicate for 3 min.

Standard solution: 0.1 mg/mL of [USP Pancuronium Bromide RS](#) in *Diluent*, from the *Standard stock solution*

Sample stock solution: 1.0 mg/mL prepared as follows. Transfer the required quantity of Pancuronium Bromide to a suitable volumetric flask. Dissolve in 2% of the flask volume of acetonitrile, dilute with *Diluent* to volume, and sonicate for 3 min.

Sample solution: 0.1 mg/mL of Pancuronium Bromide in *Diluent*, from the *Sample stock solution*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Conductivity with suppression

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

Temperatures

Column: 35°

Detector: 40°

Suppressor: 4-mm cationic membrane suppressor or equivalent

Suppression solution: 0.15 M tetrabutylammonium hydroxide

Suppressor flow rate: 1 mL/min

Flow rate: 0.75 mL/min

Injection volume: 25 µL

Run time: 2 times the retention time of pancuronium

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pancuronium bromide ($C_{35}H_{60}Br_2N_2O_4$) in the portion of Pancuronium Bromide 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 Pancuronium Bromide RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Pancuronium Bromide in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

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

System suitability solution: 1 mg/mL of [USP Pancuronium Bromide RS](#) and 0.02 mg/mL each of [USP Pancuronium Bromide Related Compound A RS](#), [USP Pancuronium Bromide Related Compound B RS](#), [USP Pancuronium Bromide Related Compound C RS](#), and [USP Vecuronium Bromide RS](#), prepared as follows. Transfer the required amounts of the individual components to a suitable volumetric flask. Dissolve in 2% of the flask volume of acetonitrile, dilute with *Diluent* to volume, and sonicate for 3 min.

Standard solution: 0.01 mg/mL of [USP Pancuronium Bromide RS](#) in *Diluent*, from the *Standard stock solution*

Sample solution: 1.0 mg/mL prepared as follows. Transfer the required quantity of Pancuronium Bromide to a suitable volumetric flask. Dissolve in 2% of the flask volume of acetonitrile, dilute with *Diluent* to volume, and sonicate for 3 min.

System suitability

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

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between pancuronium related compound B and pancuronium related compound A, and NLT 1.5 between the pancuronium related compound C and vecuronium peaks, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity, including any unspecified impurity, in the portion of Pancuronium Bromide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of pancuronium from the *Standard solution*

C_S = concentration of [USP Pancuronium Bromide RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Pancuronium Bromide in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 1](#))