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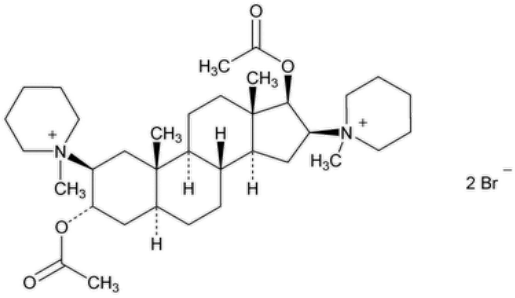
Pancuronium Bromide



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

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

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

2β,16β-Dipiperidino-5α-androstane-3α,17β-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-µm 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*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Pancuronium related compound B	0.73	1.0	0.1
Pancuronium related compound A	0.81	1.0	0.1
Vecuronium related compound F[a]	0.9	—	—
Pancuronium	1.0	—	—
Pancuronium related compound C	1.39	1.0	0.1
Vecuronium	1.53	0.48	1.0
Any individual unspecified impurity	—	1.0	0.10
Total impurities	—	—	1.0

[a] Piperidinium, 1-[(2,3,5,16,17)-17-acetyloxy-3-hydroxy-2-(1-piperidinyl)androstan-16-yl]-1-methyl. This impurity is an acid degradation product of vecuronium bromide and not that of pancuronium bromide.

SPECIFIC TESTS

- **Optical Rotation,** *Specific Rotation* ⟨781S⟩
  Sample solution: 30 mg/mL in water
  Acceptance criteria: +39° to +43°
- **Water Determination,** *Method I* ⟨921⟩**:** NMT 8.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, protected from light and moisture.
- **USP Reference Standards** ⟨11⟩

USP Pancuronium Bromide RS

USP Pancuronium Bromide Related Compound A RS

1,1'-(3α,17β-Dihydroxy-5α-androstan-2β,16β-ylene) bis(1-methylpiperidinium) dibromide.

$C_{31}H_{56}Br_2N_2O_2$ 648.60

USP Pancuronium Bromide Related Compound B RS

1,1'-(17β-Acetoxy-3α-hydroxy-5α-androstan-2β,16β-ylene) bis(1-methylpiperidinium) dibromide.

$C_{33}H_{58}Br_2N_2O_3$ 690.63

USP Pancuronium Bromide Related Compound C RS

1,1'-(3α-Acetoxy-17β-hydroxy-5α-androstan-2β,16β-ylene) bis(1-methylpiperidinium) dibromide.

$C_{33}H_{58}Br_2N_2O_3$ 690.63

USP Vecuronium Bromide RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PANCURONIUM BROMIDE	Documentary Standards Support	SM42020 Small Molecules 4

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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