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Pancuronium Bromide Injection

DEFINITION

Pancuronium Bromide Injection is a sterile solution containing NLT 92.0% and NMT 105.0% of the labeled amount of pancuronium bromide ($C_{35}H_{60}Br_2N_2O_4$) in Water for Injection. It contains a suitable tonicity-adjusting agent.

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, methanol, and 0.024 M hydrochloric acid (125:220:655)

Diluent: 0.0024 M hydrochloric acid

Standard stock solution: 1.0 mg/mL of USP Pancuronium Bromide RS 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. Sonicate for 3 min.

Standard solution: 0.1 mg/mL of USP Pancuronium Bromide RS from the *Standard stock solution* and *Diluent*

Sample solution: Nominally 0.1 mg/mL of pancuronium bromide from a suitable volume of Injection in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Conductivity with suppression

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

Temperatures

Detector: 40°

Column: 35°

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 the labeled amount of pancuronium bromide ($C_{35}H_{60}Br_2N_2O_4$) in the portion of Injection 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 = nominal concentration of pancuronium bromide in the *Sample solution* (mg/mL)

Acceptance criteria: 92.0%–105.0%

IMPURITIES

• **Organic Impurities**

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

Mobile phase: Acetonitrile, methanol, and 0.024 M hydrochloric acid (125:180:695)

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, and dilute with *Diluent* to volume. Sonicate for 3 min.

Standard solution: 0.02 mg/mL of USP Pancuronium Bromide RS from the *Standard stock solution* and *Diluent*

Sample solution: Nominally 1.0 mg/mL of pancuronium bromide from a suitable volume of Injection in *Diluent*

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; NLT 1.5 between 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 as well as any unspecified impurity in the portion of Injection taken:

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

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

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

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

C_U = nominal concentration of pancuronium bromide in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Pancuronium related compound B	0.70	3.0
Pancuronium related compound A	0.78	0.4
Vecuronium related compound F[a]	0.90	—
Pancuronium	1.0	—
Pancuronium related compound C	1.47	2.0

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Vecuronium[b]	1.69	—
Any individual unspecified degradation product	—	0.2
Total degradation products	—	5.0

[a] Piperidinium, 1-[(2,3,5,16,17)-17-acetyloxy-3-hydroxy-2-(1-piperidinyl)androstan-16-yl]-1-methyl. This impurity is the acid degradation product of vecuronium bromide and may be present only in the *System suitability solution*.

[b] This process impurity is included for peak identification purposes only and is controlled in the drug substance. This is not included in the total impurities.

SPECIFIC TESTS

- **pH ⟨791⟩:** 3.8–4.2
- **Particulate Matter in Injections ⟨788⟩:** It meets the requirements for small-volume injections.
- **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 50 USP Endotoxin Units/mg of pancuronium bromide.
- **Injections and Implanted Drug Products ⟨1⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, single-dose or multiple-dose containers for injections, as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*, preferably of Type 1 glass. Store in a refrigerator between 2° and 8°, protected from light.
- **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 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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