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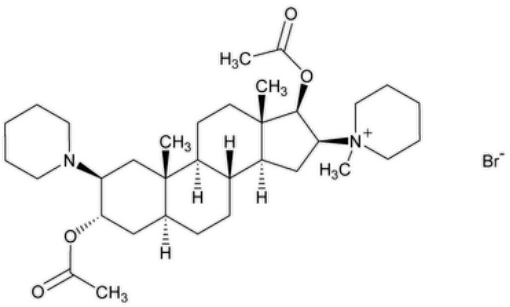
Vecuronium Bromide

Change to read:



$C_{34}H_{57}BrN_2O_4$ ▲637.74▲ (USP 1-May-2021)

Piperidinium, 1-[(2β,3α,5α,16β,17β)-3,17-bis(acetyloxy)-2-(1-piperidinyl)androstan-16-yl]-1-methyl-, bromide;

▲1-(3α,17β-Dihydroxy-2β-piperidino-5α-androstan-16β-yl)-1-methylpiperidinium bromide, diacetate;

1-[3α,17β-Bis(acetyloxy)-2β-(piperidin-1-yl)-5α-androstan-16β-yl]-1-methylpiperidin-1-ium bromide.▲ (USP 1-May-2021) CAS RN®: 50700-72-6; UNII: 7E4PHP5N1D.

DEFINITION

Vecuronium Bromide contains NLT 98.0% and NMT 102.0% of vecuronium bromide ($C_{34}H_{57}BrN_2O_4$), calculated on the dried basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

- **Procedure**

Solution A: Dissolve 8.0 g of sodium perchlorate in 6.0 mL of water, and dilute with acetonitrile to 1 L.

Solution B: Dissolve 1.6 g of ammonium chloride in 8 mL of ammonium hydroxide, and dilute with methanol to 1 L. [Note—Avoid excessive degassing to prevent the loss of ammonium hydroxide.]

Mobile phase: *Solution A* and *Solution B* (60:40)

Diluent: Transfer 1.0 mL of 1 N hydrochloric acid VS into a 1000-mL volumetric flask, and dilute with acetonitrile to volume.

Standard solution: 0.5 mg/mL of USP Vecuronium Bromide RS in *Diluent*

Sample solution: 0.5 mg/mL of Vecuronium Bromide in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Column temperature: 40°

Flow rate: 0.5 mL/min

Injection volume: 20 µL

▲**Run time:** NLT 2.5 times the retention time of vecuronium bromide▲ (USP 1-May-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

▲Tailing factor: NMT 1.5▲ (USP 1-May-2021)

Relative standard deviation: NMT ▲0.73%▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of vecuronium bromide ($C_{34}H_{57}BrN_2O_4$) in the portion of Vecuronium 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 Vecuronium Bromide RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

Change to read:

• **Organic Impurities**

Cation suppressor regeneration solution: 0.02 M tetrabutylammonium hydroxide

Mobile phase: [Note—Filter components before combining. Avoid evaporation of tetrahydrofuran during degassing.] Combine methanol, water, and hydrochloric acid (250:1500:1). Leave at room temperature for a few minutes. Add 45 mL of tetrahydrofuran, and then dilute with water to 2 L.

▲Diluent: 2.5 mM hydrochloric acid▲ (USP 1-May-2021)

[Note—This applies to all of the solution preparations. The addition, with sonication of a small amount of acetonitrile (NMT 0.5 mL per 25 mg) to the weighed quantity of the samples may be used to aid in dissolution. Shaking and sonication may also be used after the addition of the required amount of ▲*Diluent*.▲ (USP 1-May-2021)]

System suitability solution: 5 µg/mL each of USP Vecuronium Bromide RS, USP Pancuronium Bromide RS, USP Vecuronium Bromide Related Compound A RS, USP Vecuronium Bromide Related Compound B RS, USP Vecuronium Bromide Related Compound C RS, and USP Vecuronium Bromide Related Compound F RS in ▲*Diluent* ▲ (USP 1-May-2021)

Standard solution: 0.005 mg/mL of USP Vecuronium Bromide RS in ▲*Diluent*▲ (USP 1-May-2021)

Sample solution: 1 mg/mL of Vecuronium Bromide prepared as follows. To 25 mg of Vecuronium Bromide in a 25-mL volumetric flask add 0.5 mL of acetonitrile, sonicate, and rapidly dilute with ▲*Diluent*.

Blank: *Diluent*▲ (USP 1-May-2021)

Chromatographic system

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

Mode: LC

Detector: Conductivity with 4-mm cation suppressor

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

Flow rates

Column: 1.5 mL/min

Cation suppressor: 2 mL/min

Injection volume: 25 µL

System suitability

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

[Note—The system may need equilibration for 4 h. Rinse and store the column in acetonitrile and water (50:50).]

Suitability requirements

Peak-to-valley ratio: NLT 2.0 between the vecuronium bromide related compound F peak and the height of the trough between the vecuronium bromide related compound F and pancuronium peaks, *System suitability solution*

Relative standard deviation: NMT 10.0% for 3 replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Vecuronium 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 USP Vecuronium Bromide RS from the *Standard solution*

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

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

F = relative response factor ▲▲ (USP 1-May-2021) (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Pancuronium bromide	0.5	1.1	0.5
Vecuronium bromide related compound F▲▲ (USP 1-May-2021)	0.6	1.3	0.5
Vecuronium bromide related compound C▲▲ (USP 1-May-2021)	0.9	1.4	0.5
Vecuronium bromide	1.0	—	—
Vecuronium bromide related compound A▲▲ (USP 1-May-2021)	1.8	0.4	0.3
Vecuronium bromide related compound B▲▲ (USP 1-May-2021)	2.2	1.0	0.5
Any other individual unspecified impurity	—	1.0	0.1
Total impurities	—	—	1.0

SPECIFIC TESTS

Change to read:

• **Optical Rotation** ⟨781S⟩, *Procedures, Specific Rotation*

Sample solution: 10 mg/mL ▲of Vecuronium Bromide▲ (USP 1-May-2021) in dehydrated alcohol

Acceptance criteria: −16° to −20° at 20°

Change to read:

• **Bacterial Endotoxins Test** ⟨85⟩**:** ▲Where the label states that vecuronium bromide must be subjected to further processing during the

preparation of injectable dosage forms, the level of bacterial endotoxin is such that the requirement under the relevant dosage form monograph(s) in which vecuronium bromide is used can be met.▲ (USP 1-May-2021)

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 2.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at room temperature.

Add the following:

▲• **Labeling:** Where Vecuronium Bromide must be subjected to further processing during the preparation of injectable dosage forms, the label states that it is sterile or must be subjected to further processing, to ensure acceptable levels of bacterial endotoxins, it is so labeled.▲ (USP 1-May-2021)

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Pancuronium Bromide RS

▲▲ (USP 1-May-2021)

USP Vecuronium Bromide RS

USP Vecuronium Bromide Related Compound A RS

3α,17β-diacetyl-oxy-2β,16β-bispiperidinyl-5α-androstan;

▲Also known as 2β,16β-Di(piperidin-1-yl)-5α-androstane-3α,17β-diyl diacetate.▲ (USP 1-May-2021)

$C_{33}H_{54}N_2O_4$ ▲542.81▲ (USP 1-May-2021)

USP Vecuronium Bromide Related Compound B RS

Piperidinium, 1-[(2β,3α,5α,16β,17β)-3-acetyloxy-17-hydroxy-2-(1-piperidinyl) androstan-16-yl]-1-methyl bromide;

▲Also known as 1-[3α-(Acetyloxy)-17β-hydroxy-2β-(piperidin-1-yl)-5α-androstan-16β-yl]-1-methylpiperidin-1-ium bromide.▲ (USP 1-May-2021)

$C_{32}H_{55}BrN_2O_3$ ▲595.71▲ (USP 1-May-2021)

USP Vecuronium Bromide Related Compound C RS

Piperidinium, 1-[(2β,3α,5α,16β,17β)-3,17-dihydroxy-2-(1-piperidinyl) androstan-16-yl]-1-methyl bromide;

▲Also known as 1-[3α,17β-Dihydroxy-2β-(piperidin-1-yl)-5α-androstan-16β-yl]-1-methylpiperidin-1-ium bromide.▲ (USP 1-May-2021)

$C_{30}H_{53}BrN_2O_2$ ▲553.67▲ (USP 1-May-2021)

USP Vecuronium Bromide Related Compound F RS

Piperidinium, 1-[(2β,3α,5α,16β,17β)-17-acetyloxy-3-hydroxy-2-(1-piperidinyl) androstan-16-yl]-1-methyl bromide;

▲Also known as 1-[17α-(Acetyloxy)-3β-hydroxy-2β-(piperidin-1-yl)-5α-androstan-16β-yl]-1-methylpiperidin-1-ium bromide.▲ (USP 1-May-2021)

$C_{32}H_{55}BrN_2O_3$ ▲595.71▲ (USP 1-May-2021)

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

Topic/Question	Contact	Expert Committee
VECURONIUM BROMIDE	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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