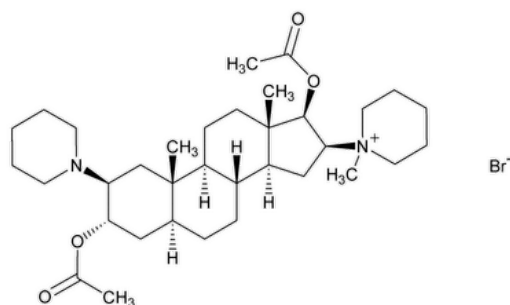


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Vecuronium Bromide

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-piperidiny)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