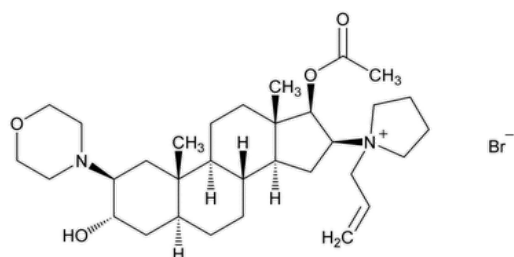


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Rocuronium Bromide

Change to read:



$C_{32}H_{53}BrN_2O_4$ ▲609.69▲ (ERR 1-Dec-2022)

Pyrrolidinium, 1-[(2β,3α,5α,16β,17β)-17-(acetyloxy)-3-hydroxy-2-(4-morpholinyl)androstane-16-yl]-1-(2-propenyl)-, bromide;
 1-Allyl-1-(3α,17β-dihydroxy-2β-morpholino-5α-androstane-16β-yl)pyrrolidinium bromide, 17-acetate CAS RN®: 119302-91-9; UNII: I65MW40FHZ.

DEFINITION

Rocuronium Bromide contains NLT 98.0% and NMT 102.0% of rocuronium bromide ($C_{32}H_{53}BrN_2O_4$), calculated on the anhydrous and 2-propanol-free or acetic acid-free basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197M**
- **B.** The retention time of the rocuronium bromide peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C. IDENTIFICATION TESTS—GENERAL (191), Bromide**
Sample solution: 10 mg/mL
Acceptance criteria: Meets the requirements of test B

ASSAY

PROCEDURE

Diluent: Acetonitrile and water (90:10)
Buffer: 4.53 g/L of tetramethylammonium hydroxide pentahydrate. Adjust the solution with phosphoric acid to a pH of 7.4.
Mobile phase: Acetonitrile and *Buffer* (90:10)
Standard solution: 1 mg/mL of [USP Rocuronium Bromide RS](#) in *Diluent*
Sample solution: 1 mg/mL of Rocuronium Bromide in *Diluent*
Chromatographic system
 (See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: UV 210 nm
Column: 4.6-mm × 25-cm; 5-μm packing L3
Column temperature: 30°
Flow rate: 2 mL/min
Injection volume: 5 μL

System suitability

[NOTE—The system may need equilibration for 4 h.]

Sample: *Standard solution*
Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of rocuronium bromide ($C_{32}H_{53}BrN_2O_4$) in the portion of the sample 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 Rocuronium Bromide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous and 2-propanol-free or acetic acid-free basis

IMPURITIES

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

Change to read:

• ORGANIC IMPURITIES

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

Peak identification solution: 1 mg/mL of [USP Rocuronium Peak Identification Mixture RS](#) in *Diluent*

Standard solution: 0.01 mg/mL of [USP Rocuronium Bromide RS](#) in *Diluent*

Sample solution: 10 mg/mL of Rocuronium Bromide in *Diluent*

Run time: 2.5 times the retention time for rocuronium

System suitability

[NOTE—The system may need equilibration for 4 h.]

Sample: *Peak identification solution*

Suitability requirements

Peak-to-valley ratio: The ratio of the height of the rocuronium related compound H peak to the height of the valley between the rocuronium related compound H peak and the rocuronium peak is NLT 1.5.

Resolution: NLT 3.5 between rocuronium and rocuronium related compound C

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Rocuronium Bromide taken:

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

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

r_S = peak response of rocuronium bromide from the *Standard solution*

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

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

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

Acceptance criteria: See [Table 1](#).

[NOTE—Disregard any peak eluting before rocuronium bromide related compound A, and any peak with an area less than 0.5 times that of the principal peak from the *Standard solution*.]

Table 1