Rocuronium Injection

Rocuronium Bromide Injection

Rocuronium Injection is a sterile solution of Rocuronium Bromide in Water for Injections.

Rocuronium Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of rocuronium bromide, $C_{32}H_{53}BrN_2O_4$.

Usual strength. 10 mg per ml.

Description. A clear colourless solution.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

pH (2.4.24). 3.0 to 4.5.

Related substances. Determine byliquid chromatography (2.4.14).

Solvent mixture. 90 volumes of *acetonitrile* and 10 volumes of *water.*

Test solution. Dilute a suitable volume of the injection with the solvent mixture to obtain a solution containing 0.1 per cent w/v of Rocuronium Bromide.

Reference solution (a). A 0.001 per cent w/v solution of *rocuronium bromide IPRS* in the solvent mixture.

Reference solution (b). A 0.1 per cent w/v solution of *rocuronium for peak identification IPRS* (containing impurities A, B, C, F, G and H) in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with porous silica (5 µm),
- mobile phase: a mixture of 10 volumes of a buffer solution prepared by dissolving 4.53 g of *tetramethyl ammonium hydroxide* in 1000 ml of *water*, adjusted to pH 7.4 with *orthophosphoric acid* and 90 volumes of *acetonitrile*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 10 µl.

Name	Relative retention time	Correction factor
Rocuronium impurity A[1]	0.2	0.5
Rocuronium impurity G[2]	0.4	0.4
Rocuronium impurity F[3]	0.75	1.3
Rocuronium impurity B[4]	0.8	--
Rocuronium impurity H[5]	0.95	0.4
Rocuronium (retention time is about 9 minutes)	1.0	--
Rocuronium impurity C[6]	1.2	--

[1]3α-hydroxy-2β-(morpholin-4-yl)-16β-(pyrrolidin-1-yl)-5α-androstan-17β-yl acetate,
[2]β-(morpholin-4-yl)-16β-(pyrrolidin-1-yl)-5α-androstane-3α,17β-diol,
[3]1-[3α,17β-acetoxy-2β-(pyrrolidin-1-yl)-5α-androstan-16β-yl]-1-(prop-2-enyl)pyrrolidinium,
[4]1-[3α,17β-diacetoxy-2β-(morpholin-4-yl)-5α-androstan-16β-yl]-1-(prop-2-enyl)pyrrolidinium,
[5]1-[17β-acetoxy-2-(morpholin-4-yl)-3-oxo-5α-androst-1-en-16β-yl]-1-(prop-2-enyl)pyrrolidinium,
[6]1-[3α,17β-dihydroxy-2β-(morpholin-4-yl)-5α-androstan-16β-yl]-1-(prop-2-enyl)pyrrolidinium.

NOTE – Equilibrate the column at least for 4 hours.

Inject reference solution (a) and (b). The test is not valid unless the peak-to-valley ratio is not less than 3.0, where Hp is the height above the baseline of the peak due to impurity H and Hv is the height above the baseline of the lowest point of the curve separating this peak from the peak due to rocuroniumin the chromatogram obtained with reference solution (b) and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to rocuronium impurity A, B, C, F, G, H, each of, is not more than 0.5 the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent), the area of any other secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per

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cent) and the sum of the areas of all the secondary peaks is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (3.0 per cent). Ignore any peak eluting before impurity A and with an area less than 0.05 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Other tests. Comply with the tests stated under Parenteral preparations (Injections).

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances with the following modifications.

Reference solution. A 0.1 per cent w/v solution of *rocuronium bromide IPRS* in the solvent mixture.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 5000 theoretical plates, the tailing factor is more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solutionand the test solution.

Calculate the content of $C_{32}H_{53}BrN_2O_4$ in the injection.

Storage. Store at a temperature between 2° to 8°.

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