Ritodrine Hydrochloride Injection

リトドリン塩酸塩注射液

Ritodrine Hydrochloride Injection is an aqueous injection.

It contains not less than 95.0% and not more than 105.0% of the labeled amount of ritodrine hydrochloride ($C_{17}H_{21}NO_3$.HCl: 323.81).

Method of preparation Prepare as directed under Injections, with Ritodrine Hydrochloride.

Manufacture Manufacture according to the formulation and the manufacturing method so that the amounts of related substances do not exceed the specification values of related substances under Ritodrine Hydrochloride.

Description Ritodrine Hydrochloride Injection is a clear and colorless liquid.

Identification To a volume of Ritodrine Hydrochloride Injection, equivalent to 50 mg of Ritodrine Hydrochloride, add 0.01 mol/L hydrochloric acid TS to make 100 mL. To 10 mL of this solution add 0.01 mol/L hydrochloric acid TS to make 100 mL. Determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits a maximum between 272 nm and 276 nm.

pH Being specified separately when the drug is granted approval based on the Law.

Bacterial endotoxins *<4.01>* Less than 25 EU/mg.

Extractable volume *<6.05>* It meets the requirement.

Foreign insoluble matter *<6.06>* Perform the test according to Method 1: it meets the requirement.

Insoluble particulate matter *<6.07>* It meets the requirement.

Sterility *<4.06>* Perform the test according to the Membrane filtration method: it meets the requirement.

Assay Pipet a volume of Ritodrine Hydrochloride Injection, equivalent to about 20 mg of ritodrine hydrochloride ($C_{17}H_{21}NO_3$.HCl), and add a mixture of 0.02 mol/L sodium dihydrogen phosphate dihydrate and methanol (7:3) to make exactly 250 mL, and use this solution as the sample solution. Separately, weigh accurately about 20 mg of Ritodrine Hydrochloride RS, previously dried at 105℃ for 2 hours, dissolve in a mixture of 0.02 mol/L sodium dihydrogen phosphate dihydrate and methanol (7:3) to make exactly 250 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography *<2.01>* according to the following conditions. Determine the peak areas, A_T and A_S, of ritodrine in each solution.

Amount (mg) of ritodrine hydrochloride ($C_{17}H_{21}NO_3$.HCl)
$= M_S \times A_T / A_S$

M_S: Amount (mg) of Ritodrine Hydrochloride RS taken

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 220 nm).

Column: A stainless steel column 6 mm in inside diameter and 15 cm in length, packed with octylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 6.6 g of diammonium hydrogen phosphate and 1.1 g of sodium 1-heptansulfonate in 840 mL of water, add 160 mL of acetonitrile for liquid chromatography, and adjust to pH 3.0 with phosphoric acid.

Flow rate: Adjust so that the retention time of ritodrine is about 19 minutes.

System Suitability —

System performance: Dissolve 10 mg of ritodrine hydrochloride in 50 mL of dilute sulfuric acid. Heat a portion of this solution in a water bath for about 30 minutes, and allow to cool. Measure a portion of this solution, and add the same volume of 2 mol/L sodium hydroxide TS. Dissolve 2 mg of ritodrine hydrochloride in 10 mL of this solution, and add a mixture of 0.02 mol/L sodium dihydrogen phosphate dihydrate and methanol (7:3) to make 25 mL. When the procedure is run with 10 μL of this solution under the above operating conditions, ritodrine and ritodrine threo-isomer are eluted in this order with the resolution between these peaks being not less than 3.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ritodrine is not more than 1.0%.

Containers and storage Containers — Hermetic containers.

Storage — At a temperature of 2 – 8℃.