Pazufloxacin Mesilate Injection

パズフロキサシンメシル酸塩注射液

Pazufloxacin Mesilate Injection is an aqueous injection.

It contains not less than 95.0% and not more than 105.0% of the labeled amount of pazufloxacin mesilate ($C_{16}H_{15}FN_2O_4.CH_4O_3S$: 414.41).

Method of preparation Prepare as directed under Injections, with Pazufloxacin Mesilate.

Description Pazufloxacin Mesilate Injection is a clear, colorless liquid.

Identification To a volume of Pazufloxacin Mesilate Injection, equivalent to 20 mg of Pazufloxacin Mesilate, add a mixture of methanol and 1 mol/L hydrochloric acid VS (49:1) to make 100 mL. To 5 mL of this solution add a mixture of methanol and 1 mol/L hydrochloric acid VS (49:1) to make 100 mL. Determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits maxima between 237 nm and 241 nm, between 314 nm and 324 nm, between 328 nm and 332 nm, and between 343 nm and 347 nm.

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

Bacterial endotoxins *<4.01>* Less than 0.3 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 Pazufloxacin Mesilate Injection, equivalent to about 12 mg of pazufloxacin mesilate ($C_{16}H_{15}FN_2O_4.CH_4O_3S$), and add water to make exactly 50 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, and use this solution as the sample solution. Separately, weigh accurately about 23 mg of Pazufloxacin Mesilate RS, previously dried at 105℃ for 3 hours, and add water to make exactly 100 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, and use this solution as the standard solution. Perform the test with 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography *<2.01>* according to the following conditions, and calculate the ratios, Q_T and Q_S of the peak area of pazufloxacin to that of the internal standard.

Amount (mg) of pazufloxacin mesilate ($C_{16}H_{15}FN_2O_4.CH_4O_3S$)
$= M_S \times Q_T / Q_S \times 1/2$

M_S: Amount (mg) of Pazufloxacin Mesilate RS taken

Internal standard solution－A solution of acetanilide in the mobile phase (3 in 10,000).

Operating conditions－

Proceed as directed in the operating conditions in the Assay under Pazufloxacin Mesilate.

System Suitability－

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, pazufloxacin and acetanilide 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 ratio of the peak area of pazufloxacin to that of the internal standard is not more than 1.0%.

Containers and storage Containers－Hermetic containers. Plastic containers for aqueous injections may be used.

Storage－Light-resistant.

Add the following to 9.01 Reference Standards (1):

Pazufloxacin Mesilate RS