Cefalotin Sodium for Injection

注射用セファロチンナトリウム

Cefalotin Sodium for Injection is a preparation for injection, which is dissolved before use.

It contains not less than 90.0% and not more than 110.0% of the labeled potency of cefalotin ($C_{16}H_{16}N_2O_6S_2$: 396.44).

Method of preparation Prepare as directed under Injections, with Cefalotin Sodium.

Description Cefalotin Sodium for Injection occurs as white to light yellow-white, crystals or crystalline powder.

Identification Determine the infrared absorption spectrum of Cefalotin Sodium for Injection as directed in the potassium bromide disk method under Infrared Spectrophotometry *<2.25>*, and compare the spectrum with the Reference Spectrum of Cefalotin Sodium or the spectrum of Cefalotin Sodium RS: both spectra exhibit similar intensities of absorption at the same wave numbers.

pH *<2.54>* Dissolve an amount of Cefalotin Sodium for Injection, equivalent to 0.5 g (potency) of Cefalotin Sodium, in 5 mL of water: the pH of the solution is between 4.5 and 7.0.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Cefalotin Sodium for Injection in 10 mL of water: the solution is clear. Perform the test with this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: the absorbance at 450 nm is not more than 0.20.

(2) Related substances—Dissolve an amount of Cefalotin Sodium for Injection, equivalent to 25 mg (potency), in the mobile phase to make 25 mL, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add the mobile phase to make exactly 100 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, and determine each peak area by the automatic integration method: the area of the peak other than cefalotin obtained from the sample solution is not larger than the peak area of cefalotin from the standard solution, and the total area of the peaks other than cefalotin from the sample solution is not larger than 3 times the peak area of cefalotin from the standard solution.

Operating conditions —

Detector, column, column temperature, mobile phase and flow rate: Proceed as directed in the operating conditions in the Assay under Cefalotin Sodium.

Time span of measurement: About 4 times as long as the retention time of cefalotin.

System suitability —

Proceed as directed in the system suitability in the Purity (4) under Cefalotin Sodium.

Water *<2.48>* Not more than 1.0% (0.5 g, volumetric titration, direct titration).

Bacterial endotoxins *<4.01>* Less than 0.2 EU/mg (potency).

Uniformity of dosage units *<6.02>* It meets the requirement of the Mass variation test.

Foreign insoluble matter *<6.06>* Perform the test according to Method 2: 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 Weigh accurately the mass of the contents of not less than 10 containers of Cefalotin Sodium for Injection. Weigh accurately an amount of the contents, equivalent to about 25 mg (potency) of Cefalotin Sodium, dissolve in the mobile phase to make exactly 25 mL, and use this solution as the sample solution. Separately, weigh accurately about 25 mg (potency) of Cefalotin Sodium RS, and dissolve in the mobile phase to make exactly 25 mL, and use this solution as the standard solution. Then, proceed as directed in the Assay under Cefalotin Sodium.

Amount [μg(potency)] of cefalotin ($C_{16}H_{16}N_2O_6S_2$)
$= M_S \times A_T / A_S \times 1000$

M_S: Amount [mg(potency)] of Cefalotin Sodium RS taken

Containers and storage Containers — Hermetic containers.