Cefoperazone Sodium for Injection

注射用セフォペラゾンナトリウム

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

It contains not less than 93.0% and not more than 107.0% of the labeled potency of cefoperazone ($C_{25}H_{27}N_9O_8S_2$: 645.67).

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

Description Cefoperazone Sodium for Injection occurs as a white to yellowish white, crystalline powder or masses.

Identification Determine the absorption spectrum of a solution of Cefoperazone Sodium for Injection (1 in 50,000) as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits maxima between 226 nm and 230 nm, and between 263 nm and 267 nm.

pH *<2.54>* The pH of a solution dissolved an amount of Cefoperazone Sodium for Injection, equivalent to 1.0 g (potency) of Cefoperazone Sodium, in 4 mL of water is 4.5 to 6.5.

Purity **(1)** Clarity and color of solution－Dissolve an amount of Cefoperazone Sodium for Injection, equivalent to 1.0 g (potency) of Cefoperazone Sodium, in 10 mL of water: the solution is clear, and its absorbance at 400 nm, measured as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, is not more than 0.22.

(2) Related substances － Dissolve an amount of Cefoperazone Sodium for Injection, equivalent to 0.1 g (potency) of Cefoperazone Sodium, in 100 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 25 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 of related substance I, having a relative retention time of about 0.8 to cefoperazone, from the sample solution is not larger than 2.5 times the peak area of cefoperazone from the standard solution, the area of the peak of related substance II having a relative retention time of about 1.7 to cefoperazone, from the sample solution are not larger than 3/4 times the peak area of cefoperazone from the standard solution. Furthermore, the total area of the peaks other than cefoperazone from the sample solution is not larger than 3.5 times the peak area of cefoperazone from the standard solution. For this calculation use the peak areas of the related substances I and II after multiplying by their relative response factors, 0.90 and 0.75, respectively.

Operating conditions－

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

Time span of measurement: About 3 times as long as the retention time of cefoperazone, beginning after the solvent peak.

System suitability－

Proceed as directed in the system suitability in the Purity (4) Related substances under Cefoperazone Sodium.

Water *<2.48>* Not more than 1.0% (3 g, volumetric titration, direct titration).

Bacterial endotoxins *<4.01>* Less than 0.05 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 Cefoperazone Sodium for Injection. Weigh accurately a portion of the content, equivalent to about 0.1 g (potency) of Cefoperazone Sodium, dissolve in water to make exactly 100 mL, and 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 an amount of Cefoperazone RS, equivalent to about 20 mg (potency), dissolve in 1 mL of 0.1 mol/L phosphate buffer solution (pH 7.0), and add water to make exactly 20 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, and use this solution as the standard solution. Then, proceed as directed in the Assay under Cefoperazone Sodium.

Amount [mg (potency)] of cefoperazone ($C_{25}H_{27}N_9O_8S_2$)
$= M_S \times Q_T / Q_S$

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

Internal standard solution－A solution of acetanilide in a mixture of water and acetonitrile (43:7) (3 in 8000).

Containers and storage Containers－Hermetic containers.

Storage－In a cold place.

95 **Expiration date** 24 months after preparation.