Cefotiam Hydrochloride for Injection

Cefotiam Hydrochloride 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 amount of cefotiam \((\text{C}_{18}\text{H}_{23}\text{N}_{9}\text{O}_{4}\text{S}_{3}: 525.63)\).

Method of Preparation
Prepare as directed under Injection, with Cefotiam Hydrochloride.

Identification
Determine the absorption spectrum of a solution of Cefotiam Hydrochloride for Injection (1 in 50,000) as directed under Ultraviolet-visible Spectrophotometry. It exhibits a maximum between 257 nm and 261 nm.

Chromatographic purity
Dissolve 50 mg of Cefotiam Hydrochloride for Injection in 0.5 mL of heavy water for nuclear magnetic resonance spectroscopy, and determine the spectrum of this solution as directed under Nuclear Magnetic Resonance Spectroscopy. Using sodium 3-trimethylsilyl-propanesulfonate for nuclear magnetic resonance spectroscopy as an internal reference compound, it exhibits a single signal \(A\) between \(\delta 2.77\) ppm and \(\delta 3.00\) ppm, and a single signal \(B\) at around \(\delta 6.55\) ppm. The ratio of the integrated intensity of each signal, \(A: B\), is about 6:1.

pH
The pH of a solution prepared by dissolving an amount of Cefotiam Hydrochloride for Injection, equivalent to 0.5 g (potency) according to the labeled amount, in 5 mL of water is between 5.7 and 7.2.

Purity
Clarity and color of solution—Dissolve an amount of Cefotiam Hydrochloride for Injection, equivalent to 1.0 g (potency) of Cefotiam Hydrochloride according to the labeled potency, in 10 mL of water: the solution is clear, and the absorbance of this solution, determined at 450 nm 10 minutes after dissolving as directed under Ultraviolet-visible Spectrophotometry, is not more than 0.20.

Loss on drying
Not more than 6.0% (0.5 g, in vacuum, 60°C, 3 hours).

Bacterial endotoxins
Less than 0.125 EU/mg (potency).

Uniformity of dosage units
It meets the requirement of the Mass variation test.

Foreign insoluble matter
Perform the test according to Method 2: it meets the requirement.

Insoluble particulate matter
Perform the test according to Method 1: it meets the requirement.

Sterility
Perform the test according to the Membrane filtration method: it meets the requirement.

Assay
Weigh accurately the contents of not less than 10 Cefotiam Hydrochloride for Injection. Weigh accurately an amount of the content, equivalent to about 50 mg (potency) of Cefotiam Hydrochloride according to the labeled amount, dissolve in the mobile phase to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 50 mg (potency) of Cefotiam Hydrochloride RS, dissolve in the mobile phase to make exactly 50 mL, and use this solution as the standard solution. Proceed as directed in the Assay under Cefotiam Hydrochloride.

Amount \([\text{mg (potency)}]\) of cefotiam \((\text{C}_{18}\text{H}_{23}\text{N}_{9}\text{O}_{4}\text{S}_{3})\)

\[M_S = \frac{M_{S: \text{Amount [mg (potency)] of cefotiam (C}_{18}\text{H}_{23}\text{N}_{9}\text{O}_{4}\text{S}_{3})}}{A_S} \times 1000\]

\(M_S: \text{Amount [mg (potency)] of Cefotiam Hydrochloride RS}\)

System Suitability
— Proceed as directed in the Assay under Cefotiam Hydrochloride.

Containers and storage
Containers—Hermetic containers.

Cefozopran Hydrochloride

Cefozopran Hydrochloride occurs as a white to light yellow powder.

Description
Cefozopran Hydrochloride contains not less than 860 \(\mu\)g (potency) and not more than 960 \(\mu\)g (potency) per mg, calculated on the anhydrous basis. The potency of Cefozopran Hydrochloride is expressed as mass (potency) of cefozopran \((\text{C}_{19}\text{H}_{17}\text{N}_{9}\text{O}_{5}\text{S}_{2}: 551.99)\).

Cefozopran Hydrochloride occurs as a white to pale yellow, crystals or crystalline powder. It is freely soluble in dimethylsulfoxide and in formamide, slightly soluble in water, in methanol and in ethanol (95), and practically insoluble in acetonitrile and diethyleter.