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Cephapirin for Injection

» Cephapirin for Injection contains an amount of Cephapirin Sodium equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of cephapirin.

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

USP Reference standards ⟨11⟩—
USP Cephapirin Sodium RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 0.17 USP Endotoxin Unit per mg of cephapirin.

Sterility Tests ⟨71⟩—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It responds to the *Identification* tests and meets the requirements for *Crystallinity, pH,* and *Water* under *Cephapirin Sodium*. It meets also the requirements for *Uniformity of Dosage Units ⟨905⟩* and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water, dimethylformamide, glacial acetic acid, and 11.7 N potassium hydroxide (1834:160:4:2). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*). Increase the proportion of dimethylformamide to decrease the retention time of cephapirin.

Resolution solution—Prepare a solution of Cephapirin Sodium in pH 2.0 hydrochloric acid buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*) containing about 1 mg per mL. Place 10 mL of this solution in a test tube, and heat at 95° for 10 minutes, accurately timed. Promptly cool the tube in an ice water bath. Dilute 5 mL of the cooled solution with *Mobile phase* to obtain 50 mL of *Resolution solution.*

Standard preparation—Transfer about 21 mg of USP Cephapirin Sodium RS, accurately weighed, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. This solution contains about 0.2 mg of cephapirin per mL.

Assay preparation 1 (where it is packaged for dispensing and is represented as being in a single-dose container)—Constitute Cephapirin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution containing the equivalent of about 0.2 mg of cephapirin per mL.

Assay preparation 2 (where the label states the quantity of cephapirin in a given volume of constituted solution)—Constitute Cephapirin for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution containing the equivalent of about 0.2 mg of cephapirin per mL. [Note—Use the *Standard preparation* and the *Assay preparation* within 1 hour.]

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between the cephapirin peak and the peak having a retention time of about 0.9 relative to that of cephapirin is not less than 0.9. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.9 for cephapirin lactone and 1.0 for cephapirin; the column efficiency determined from the cephapirin peak is not less than 1200 theoretical plates; the tailing factor for the cephapirin peak is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the appropriate *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of cephapirin ($C_{17}H_{17}N_3O_6S_2$) withdrawn from the container, or in the portion of constituted solution taken by the formula:

$$(L/D)(CP/1000)(r_U/r_S)$$

in which L is the labeled quantity, in mg, of cephapirin in the single-dose container, or in the volume of constituted solution taken; D is the concentration, in mg per mL, of cephapirin in *Assay preparation 1* or in *Assay preparation 2,* on the basis of the labeled quantity in the container, or in the portion of constituted solution taken, respectively, and the extent of dilution; C is the concentration, in mg per mL, of USP Cephapirin Sodium RS in the *Standard preparation; P* is the potency, in µg of cephapirin per mg, of USP Cephapirin Sodium RS; and r_U and r_S are the cephapirin peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CEPHAPIRIN FOR INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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