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Ampicillin for Injectable Suspension

» Ampicillin for Injectable Suspension is a dry mixture of ampicillin trihydrate and one or more suitable buffers, preservatives, stabilizers, and suspending agents. It contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of ampicillin ($C_{16}H_{19}N_3O_4S$).

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

USP Reference standards ⟨11⟩—
USP Ampicillin RS

Identification—Dissolve a quantity in a mixture of acetone and 0.1 N hydrochloric acid (4:1) to obtain a solution containing 5 mg of ampicillin per mL: the resulting solution responds to the *Identification* test under *Ampicillin Capsules*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 0.15 Endotoxin Unit per mg of ampicillin.

pH ⟨791⟩: between 5.0 and 7.0, in the suspension constituted as directed in the labeling.

Water Determination, *Method I* ⟨921⟩: between 11.4% and 14.0%.

Sterility Tests ⟨71⟩—It meets the requirements when tested as directed for *Antibiotic Solids, Bulks, and Blends* in the section *Membrane Filtration* under *Test for Sterility of the Product to be Examined,* except to use *Fluid D,* to which has been added sufficient sterile penicillinase to inactivate the ampicillin and to swirl the vessel until solution is complete before filtering. If it does not dissolve completely, proceed as directed for *Solids* in the section *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined,* except to use Fluid Thioglycollate Medium and Soybean–Casein Digest Medium containing sufficient penicillinase to inactivate the ampicillin in each vessel.

Other requirements—It meets the requirements for *Uniformity of Dosage Units ⟨905⟩*, and for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay—

Phosphate buffer solution—Accurately weigh 68 g of monobasic potassium phosphate, and transfer to a 500-mL volumetric flask. Dissolve in and dilute with water to volume.

Mobile phase—Prepare a suitable mixture of water, acetonitrile, *Phosphate buffer solution*, and glacial acetic acid (3600:360:40:4). Pass through a 0.45-µm nylon filter, and degas.

Standard preparation—Dissolve, with sonication, an accurately weighed quantity of USP Ampicillin RS in water to prepare a solution having 0.5 mg per mL. Pass through a 0.45-µm PTFE filter, discarding the first 3 mL of the filtrate.

Caffeine solution—Transfer about 30 mg of caffeine, accurately weighed, to a 50-mL volumetric flask. Add 25 mL of water, sonicate to dissolve, and dilute with water to volume. Pass through a 0.45-µm PTFE filter, discarding the first 3 mL of the filtrate.

System suitability solution—Prepare a solution of 1.0 mL of *Caffeine solution* and 9.0 mL of *Standard preparation*, and mix.

Assay preparation—Quantitatively dilute an accurately measured volume of Ampicillin for Injectable Suspension, constituted as directed in the labeling, with water to obtain a solution containing about 0.5 mg per mL. Pass through a 0.45-µm PTFE filter, discarding the first 3 mL of the filtrate.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm analytical column that contains 10-µm packing L1. The flow rate is about 2.0 mL per minute. The column temperature is maintained at 40°. Chromatograph the *System suitability solution* and the *Standard preparation*, and record the peak responses as directed for *Procedure:* the order of elution is ampicillin followed by caffeine; the resolution, *R,* between ampicillin and caffeine is greater than 2; the column efficiency is not less than 2000 theoretical plates for the ampicillin peak; the tailing factor is not greater than 1.4; and the relative standard deviation for replicate injections of the *Standard preparation* is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas of the major peaks. Calculate the quantity, in mg, of ampicillin ($C_{16}H_{19}N_3O_4S$) in each mL of the constituted solution of Ampicillin for Injectable Suspension taken by the formula:

$$CD(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Ampicillin RS in the *Standard preparation; D* is the dilution factor used in preparing the *Assay preparation;* and r_U and r_S are the average peak responses of the ampicillin peaks obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
AMPICILLIN FOR INJECTABLE SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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