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Amoxicillin for Injectable Suspension

» Amoxicillin for Injectable Suspension is a sterile mixture of Amoxicillin and one or more suitable buffers, preservatives, stabilizers, and suspending agents. It contains not less than 90.0 percent and not more than 120.0 percent of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$).

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

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—

USP Amoxicillin RS

Change to read:

Identification—Prepare a test solution containing the equivalent of 4 mg of amoxicillin per mL by adding 0.1 N hydrochloric acid to Amoxicillin for Injectable Suspension. Allow the solution to stand for 5 minutes before use. ▲Prepare a Standard solution of USP Amoxicillin RS in 0.1 N hydrochloric acid containing 4 mg per mL. Use within 10 minutes after preparation. Apply separately 5 µL of each solution on a thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture (see *Chromatography* ⟨621⟩). Place the plate in a suitable chromatographic chamber, and develop the chromatogram in a solvent system consisting of a mixture of methanol, chloroform, water, and pyridine (90:80:30:10). When the solvent front has moved about three-fourths of the length of the plate, remove the plate from the chamber, and dry with warm air for 10 minutes. Locate the spots on the plate by spraying lightly with a solution of ninhydrin in alcohol containing 3 mg per mL, and dry at 110° for 15 minutes: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.▲ (ERR 1-Nov-2023)

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.25 Endotoxin Unit per mg of amoxicillin.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed 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 containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the amoxicillin in each tube, to use Soybean–Casein Digest Medium containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the amoxicillin in each tube, and to shake the tubes once daily.

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

Water Determination, *Method I* ⟨921⟩: between 11.0% and 14.0%.

Assay—

Diluent, Mobile phase, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Amoxicillin*.

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Amoxicillin for Injectable Suspension as directed in the labeling. Withdraw all of the withdrawable contents, using a hypodermic needle and syringe, and quantitatively dilute with *Diluent* to obtain a solution containing about 1 mg of anhydrous amoxicillin per mL. Pass a portion of this solution through a suitable filter of 1-µm or finer porosity, and use the filtrate as *Assay preparation 1*. Use this solution within 6 hours.

Assay preparation 2 (where the label states the quantity of amoxicillin in a given volume of constituted suspension)—Constitute Amoxicillin for Injectable Suspension as directed in the labeling. Quantitatively dilute an accurately measured volume of the constituted suspension with *Diluent* to obtain a solution containing about 1 mg of anhydrous amoxicillin per mL. Pass a portion of this solution through a suitable filter of 1-µm or finer porosity, and use the filtrate as *Assay preparation 2*. Use this solution within 6 hours.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Amoxicillin*. Calculate the quantity, in mg, of amoxicillin ($C_{16}H_{19}N_3O_5S$) in the container, or in the portion of constituted Suspension taken by the formula:

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

in which L is the labeled quantity, in mg, of anhydrous amoxicillin in the container, or in the volume of constituted suspension taken; D is the concentration, in mg of anhydrous amoxicillin per mL, of *Assay preparation 1* or of *Assay preparation 2* on the basis of the labeled quantity in the container or in the portion of constituted suspension taken, respectively, and the extent of dilution; and the other terms are as defined therein.

Topic/Question	Contact	Expert Committee
AMOXICILLIN FOR INJECTABLE SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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