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Amoxicillin Intramammary Infusion

» Amoxicillin Intramammary Infusion is a suspension of Amoxicillin in a suitable vegetable oil vehicle. It contains not less than 90.0 percent and not more than 120.0 percent of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$). It contains a suitable dispersing agent and preservative.

Packaging and storage—Preserve in well-closed disposable syringes.

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

USP Reference standards ⟨11⟩—
USP Amoxicillin RS

Change to read:

Identification—Transfer a quantity of Intramammary Infusion, equivalent to about 60 mg of amoxicillin, to a 50-mL centrifuge tube, add 25 mL of toluene, mix, and centrifuge. Decant and discard the toluene. Wash the residue with four 25-mL portions of toluene, sonicating for about 30 seconds after each addition of toluene. Dry the residue in vacuum over silica gel. Add 15 mL of 0.1 N hydrochloric acid to the residue, and mix.

▲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-Dec-2023)

Water Determination, *Method I* ⟨921⟩**:** not more than 1.0%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay—Proceed as directed for amoxicillin under *Antibiotics—Microbial Assays* ⟨81⟩. Expel the contents of 1 syringe of Intramammary Infusion into a high-speed glass blender jar containing 499.0 mL of *Buffer B.3* and 1.0 mL of polysorbate 80, and blend for 3 to 5 minutes. Allow to stand for about 10 minutes, and dilute an accurately measured volume of the aqueous phase quantitatively and stepwise with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
AMOXICILLIN INTRAMAMMARY INFUSION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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