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Amoxicillin Boluses

» Amoxicillin Boluses contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

Labeling—Label Boluses to indicate that they are for veterinary use only.

USP Reference standards ⟨11⟩—

USP Amoxicillin RS

Change to read:

Identification—

Test solution—To a portion of powdered Boluses add 0.1 N hydrochloric acid to obtain a *Test solution* containing about 4 mg of amoxicillin per mL. Use within 10 minutes after preparation.

▲*Application volume*—5 µL.

Developing solvent system—a mixture of methanol, chloroform, water, and pyridine (90:80:30:10).

Procedure—Proceed as directed in *Thin-Layer Chromatographic Identification Test* ⟨201⟩. Dry the plate with the aid of a current of 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.▲ (ERR 1-Dec-2023)

Disintegration ⟨701⟩: 30 minutes, simulated gastric fluid being used instead of water.

Water Determination, *Method I* ⟨921⟩: not more than 7.5%.

Assay—

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

Assay preparation—Weigh and finely powder not fewer than 5 Boluses. Transfer an accurately weighed portion of the powder, equivalent to about 250 mg of amoxicillin, to a 250-mL volumetric flask, add *Diluent* to volume, and mix. Sonicate if necessary to ensure complete dissolution of the amoxicillin. Pass a portion of this solution through a filter of 1-µm or finer porosity, and use the filtrate as the *Assay preparation*. [Note—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 portion of Boluses taken by the formula:

$$0.25CP(r_U/r_S)$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
AMOXICILLIN BOLUSES	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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