Amoxicillin and Clavulanate Potassium Tablets

» Amoxicillin and Clavulanate Potassium Tablets contain the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amounts of amoxicillin ($C_{16}H_{19}N_3O_5S$) and clavulanic acid ($C_8H_9NO_5$).

Packaging and storage—Preserve in tight containers.

Change to read:

Labeling—Label chewable Tablets to include the word "chewable" in juxtaposition to the official name. The labeling indicates that chewable Tablets may be chewed before being swallowed or may be swallowed whole. Tablets intended for veterinary use only are so labeled. When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used. (RB 1-Mar-2009)

USP Reference standards ⟨11⟩**—***USP Amoxicillin RS*. *USP Clavulanate Lithium RS*.

Identification—The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Disintegration ⟨701⟩**:** Tablets labeled for veterinary use only; 30 minutes, simulated gastric fluid TS being substituted for water in the test.

Change to read:

Dissolution ⟨711⟩**—**[NOTE—Tablets labeled for veterinary use only are exempt from this requirement.]

TEST 1— (RB 1-Mar-2009)

Medium: water; 900 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes; or 45 minutes where the Tablets are labeled as chewable.

Procedure—Determine the amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) and clavulanic acid ($C_8H_9NO_5$) dissolved, employing the procedure set forth in the *Assay*, making any necessary volumetric adjustments.

Tolerances—Not less than 85% *(Q)* of the labeled amount of $C_{16}H_{19}N_3O_5S$ and not less than 80% *(Q)* of the labeled amount of $C_8H_9NO_5$ are dissolved in 30 minutes.

FOR TABLETS LABELED AS CHEWABLE—Not less than 80% *(Q)* of the labeled amounts of $C_{16}H_{19}N_3O_5S$ and $C_8H_9NO_5$ is dissolved in 45 minutes.

TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium, Apparatus 2, and *Procedure*—Proceed as directed in *Test 1*.

Times: 45 minutes for amoxicillin, and 30 minutes for clavulanic acid.

Tolerances—Not less than 85% (*Q*) of the labeled amount of $C_{16}H_{19}N_3O_5S$ is dissolved in 45 minutes, and not less than 80% *(Q)* of the labeled amount of $C_8H_9NO_5$ is dissolved in 30 minutes. (RB 1-Mar-2009)

Uniformity of dosage units ⟨905⟩**:** meet the requirements for *Weight Variation* with respect to amoxicillin and for *Content Uniformity* with respect to clavulanic acid.

Water, *Method I* ⟨921⟩**:** not more than 7.5% where the labeled amount of amoxicillin in each Tablet is 250 mg or less; not more than 10.0% where the labeled amount of amoxicillin in each Tablet is more than 250 mg but less than or equal to 500 mg; not more than 11.0% where the labeled amount of amoxicillin in each Tablet is more than 500 mg. Where Tablets are labeled as chewable, not more than 6.0% where the labeled amount of amoxicillin in each Tablet is 125 mg or less; not more than 8.0% where the labeled amount of amoxicillin in each Tablet is more than 125 mg. Where the Tablets are labeled for veterinary use only, not more than 10.0%.

Assay—

pH 4.4 Sodium phosphate buffer, Mobile phase, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Amoxicillin and Clavulanate Potassium for Oral Suspension*.

Assay preparation—Dissolve not fewer than 10 Tablets, accurately counted, in water with the aid of mechanical stirring, transfer to a suitable volumetric flask, dilute with water to volume, and mix. Filter a portion of this solution, discarding the first 10 mL of the filtrate. Dilute an accurately measured volume of the filtrate quantitatively and stepwise with water to obtain a solution containing about 0.5 mg of amoxicillin per mL. Use this *Assay preparation* within 1 hour.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Amoxicillin and Clavulanate Potassium for Oral Suspension*. Calculate the quantity, in mg, of amoxicillin ($C_{16}H_{19}N_3O_5S$) in each Tablet taken by the formula:

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

in which L is the labeled quantity, in mg, of amoxicillin in each Tablet; D is the concentration, in mg per mL, of amoxicillin in the *Assay preparation* on the basis of the number of Tablets taken, the labeled quantity of amoxicillin in each Tablet, and the extent of dilution; C is the concentration, in mg per mL, of USP Amoxicillin RS in the *Standard preparation; P* is the potency, in µg of amoxicillin per mg, of USP Amoxicillin RS, and r_U and r_S are the amoxicillin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively. Calculate the quantity, in mg, of clavulanic acid ($C_8H_9NO_5$) in each Tablet taken by the formula:

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

in which L is the labeled quantity, in mg, of clavulanic acid in each Tablet; D is the concentration, in mg per mL, of clavulanic acid in the *Assay preparation*, on the basis of the number of Tablets taken, the labeled quantity of clavulanic acid in each Tablet, and the extent of dilution; C is the concentration, in mg per mL, of USP Clavulanate Lithium RS in the *Standard preparation; P* is the designated potency, in µg of clavulanic acid per mg, of USP Clavulanate Lithium RS; and r_U and r_S are the clavulanic acid peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.