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 (C₁₆H₁₉N₃O₅S) and clavulanic acid (C₈H₉NO₅).

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.

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—Tables 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 (C₁₆H₁₉N₃O₅S) and clavulanic acid (C₈H₉NO₅) 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 C₁₆H₁₉N₃O₅S and not less than 80% (Q) of the labeled amount of C₈H₉NO₅ is dissolved in 30 minutes.

FOR TABLETS LABELED AS CHEWABLE—Not less than 80% (Q) of the labeled amounts of C₁₆H₁₉N₃O₅S and C₈H₉NO₅ 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 C₁₆H₁₉N₃O₅S is dissolved in 45 minutes, and not less than 80% (Q) of the labeled amount of C₈H₉NO₅ is dissolved in 30 minutes.

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 (C₁₆H₁₉N₃O₅S) in each Tablet taken by the formula:

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\frac{(L/D)(C/P)(1000)}{r_U / r_S}
\]

where 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 (C₈H₉NO₅) in each Tablet taken by the formula:

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\frac{(L/D)(C/P)(1000)}{r_U / r_S}
\]

where 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.