Bacampicillin Hydrochloride Tablets

Bacampicillin Hydrochloride Tablets contain the equivalent of not less than 90.0 per cent and not more than 125.0 percent of the labeled amount of ampicillin (C16H19N3O4S).

Packaging and storage—Preserve in tight containers.

USP Reference standards (11)—
USP Ampicillin RS
USP Bacampicillin Hydrochloride RS

Identification—To a portion of powdered Tablets add alcohol containing an equivalent of 2 mg of ampicillin per mL to obtain a solution containing the equivalent of 0.3 mg per mL: the solution so obtained responds to the Identification test under Bacampicillin Hydrochloride.

Dissolution (711)—

Medium: water; 900 mL.
Apparatus 2: 75 rpm.
Time: 30 minutes.

Standard preparation—Dissolve an accurately weighed quantity of USP Ampicillin RS in water to obtain a solution having a known concentration of about 0.3 mg per mL.

Procedure—Determine the amount of ampicillin (C16H19N3O4S) dissolved as directed for Procedure in the section Antibiotics—Hydroxylamine Assay under Automated Methods of Analysis (16).

Tolerances—Not less than 85% (Q) of the labeled amount of C16H19N3O4S is dissolved in 30 minutes.

Uniformity of dosage units (905): meet the requirements.

Water, Method I (921): not more than 2.5%.

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Proced as directed in the Assay under Bacampicillin Hydrochloride.

Assay preparation—Weigh and finely powder not fewer than 20 tablets. Transfer an accurately weighed portion of the powder, equivalent to about 56 mg of ampicillin (C16H19N3O4S), to a 100-mL volumetric flask, add 90 mL of water, and sonicate for about 20 minutes. Dilute with water to volume, mix, and filter through a filter of 0.5-µm or finer porosity.

Procedure—Proceed as directed for Procedure in the Assay under Bacampicillin Hydrochloride. Calculate the quantity, in mg, of ampicillin (C16H19N3O4S) equivalent to the portion of Tablets taken by the formula:

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\frac{(0.0625)V(8-I)}{V} - B = I
\]

in which V is the volume, in mL, of constituted Bacampicillin Hydrochloride for Oral Suspension taken, and the other terms are as defined therein.

Bacitracin

Bacitracin [1405-87-4].

Bacitracin is a mixture of polypeptides produced by the growth of an organism of the licheniformis group of Bacillus subtilis (Fam. Bacil-lacea), the main components being bacitracins A, B1, B2, and B3. It has a potency of not less than 65 Bacitracin Units per mg, calculated on the dried basis.

Packaging and storage—Preserve in tight containers, and store in a cool place.

Labeling—Where it is packaged for prescription compounding, label it to indicate that it is not sterile and that the potency cannot be assured for longer than 60 days after opening, and to state the number of Bacitracin Units per milligram. Where it is intended for use in preparing injectable or other sterile dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable or other sterile dosage forms.

USP Reference standards (11)—
USP Bacitracin Zinc RS
USP Endotoxin RS

Identification—

A: Thin-Layer Chromatographic Identification Test (201BNP): meets the requirements.

B: It meets the requirements of the liquid chromatographic procedure in the test for Composition.

pH (791): between 5.5 and 7.5, in a solution containing 10,000 Bacitracin Units per mL.

Loss on drying (731):—Dissolve about 100 mg in a capillary y-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours; it loses not more than 5.0% of its weight.

Residue on ignition (281):—not more than 0.5%.

Composition—

Buffer—Dissolve 34.8 g of dibasic potassium phosphate in 1 L of water. Adjust with 27.2 g of monobasic potassium phosphate dissolved in 1 L of water to a pH of 6.0.

Mobile phase—Prepare a mixture of methanol, water, Buffer, and acetonitrile (26:15:5:2), mix well, and degas.

System suitability solution—Dissolve an accurately weighed quantity of USP Bacitracin Zinc RS in water, add diluted hydrochloric acid, using about 2% of the final volume, and dilute with water to obtain a solution with a nominal concentration of about 2.0 mg per mL.

Reporting threshold solution—Dilute quantitatively, with Mobile phase, a suitable volume of System suitability solution to obtain a solution having a known concentration of 0.01 mg per mL. This solution is used to determine the reporting threshold.

Peak identification solution—Dissolve a suitable quantity of USP Bacitracin Zinc RS in a suitable volume of a 40 g per L solution of edetate disodium (pH adjusted to 7.0 with dilute sodium hydroxide), to obtain a solution having a nominal con-