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Piperacillin for Injection

DEFINITION

Piperacillin for Injection contains an amount of Piperacillin Sodium equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of piperacillin ($C_{23}H_{27}N_5O_7S$).

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Sample: Dissolve 250 mg in water. Add 0.5 mL of 2 N hydrochloric acid and 5 mL of ethyl acetate. Stir, and allow to stand for 10 min in ice water. Pass through a suitable sintered-glass filter, applying suction. Wash the crystals with 5 mL of water and 5 mL of ethyl acetate, then dry in an oven at 60° for 60 min.

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Methanol, 0.2 M monobasic sodium phosphate, 0.4 M tetrabutylammonium hydroxide, and water (450:100:3:447). Adjust with phosphoric acid to a pH of 5.50.

System suitability solution: 0.1 mg/mL of [USP Ampicillin RS](#) and 0.2 mg/mL of [USP Piperacillin RS](#) in *Mobile phase*

Standard solution: 0.4 mg/mL of [USP Piperacillin RS](#) in *Mobile phase*. Dissolve in a few drops of methanol, and dilute with *Mobile phase* to volume. Use this solution within 1 h.

Sample solution 1 (where it is labeled for use as a single-dose container): Equivalent to 0.4 mg/mL of piperacillin from Piperacillin for Injection constituted as directed below.

Constitute Piperacillin for Injection in a volume of water corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents using a suitable hypodermic needle and syringe, and dilute with *Mobile phase*.

Sample solution 2 (where the label states the quantity of piperacillin in a given volume of the constituted solution): Equivalent to 0.4 mg/mL of piperacillin from Piperacillin for Injection constituted as directed below.

Constitute Piperacillin for Injection in a volume of water corresponding to the volume of solvent specified in the labeling. Dilute an aliquot of the constituted solution with *Mobile phase*.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 16 between ampicillin and piperacillin, *System suitability solution*

Tailing factor: NMT 1.2 for the piperacillin peak, *System suitability solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution 1* or *Sample solution 2*

Calculate the percentage of the labeled amount of piperacillin ($C_{23}H_{27}N_5O_7S$) in the container or in the portion of constituted solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Piperacillin RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of piperacillin in *Sample solution 1* or *Sample solution 2* (mg/mL)

P = potency of piperacillin in [USP Piperacillin RS](#) (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase, System suitability solution, Sample solution 1, Sample solution 2, Chromatographic system, and System

suitability: Proceed as directed in the Assay. Evaluate the *Relative standard deviation* using the *Standard solution* prepared in the Assay.

Standard solution: 40 µg/mL of [USP Piperacillin RS](#) in *Mobile phase*. Dissolve in a few drops of methanol, and dilute with *Mobile phase* to volume. Use this solution within 1 h.

Analysis

Samples: *Sample solution 1* or *Sample solution 2* and *Standard solution*

Calculate the percentage of piperacillin penicilloic acid and acetylated penicilloic acid of piperacillin in the portion of Piperacillin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times (1/F_1) \times F_2 \times 100$$

r_U = peak response of piperacillin penicilloic acid or acetylated penicilloic acid of piperacillin from *Sample solution 1* or *Sample solution 2*

r_S = peak response of piperacillin from the *Standard solution*

C_S = concentration of [USP Piperacillin RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of piperacillin in *Sample solution 1* or *Sample solution 2* (mg/mL)

P = potency of piperacillin in [USP Piperacillin RS](#) (µg/mg)

F_1 = relative response factor (see [Table 1](#))

F_2 = conversion factor, 0.001 mg/µg

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Piperacillin related compound E a, b	0.24	—	—
Ampicillin ^a	0.31	—	—



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