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Ceftriaxone for Injection

DEFINITION

Ceftriaxone for Injection contains an amount of Ceftriaxone Sodium equivalent to NLT 776 µg/mg of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$), calculated on the anhydrous basis, and the equivalent of NLT 90.0% and NMT 115.0% of the labeled amount of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$).

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Protect solutions containing ceftriaxone sodium from light.

Solution A: 9 g/L of [monobasic potassium phosphate](#) in water

Solution B: 24 g/L of [dibasic sodium phosphate, dodecahydrate](#) in water

Solution C: 20 g/L of [citric acid](#) in water. Adjust with [10 N sodium hydroxide TS](#) to a pH of 5.0 prior to dilution.

Buffer: Combine 389 mL of *Solution A* and 611 mL of *Solution B*. Adjust with [10 N sodium hydroxide TS](#) or [phosphoric acid](#) to a pH of 7.0.

Mobile phase: Dissolve 2.0 g each of [tetradecylammonium bromide](#) and [tetraheptylammonium bromide](#) in a mixture of 440 mL of water, 55 mL of *Buffer*, 5.0 mL of *Solution C*, and 500 mL of acetonitrile.

System suitability solution: 50 µg/mL each of [USP Ceftriaxone Sodium RS](#) and [USP Ceftriaxone Sodium E-Isomer RS](#) in *Mobile phase*

Standard solution: 0.3 mg/mL of [USP Ceftriaxone Sodium RS](#) in *Mobile phase*

Sample solution 1: Nominally 0.3 mg/mL of ceftriaxone from Ceftriaxone for Injection in *Mobile phase*

Sample solution 2 (where it is represented as being in a single-dose container): Nominally 0.3 mg/mL of ceftriaxone in *Mobile phase* prepared as follows. Constitute Ceftriaxone 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 transfer to a suitable volumetric flask. Dilute with *Mobile phase* to volume.

Sample solution 3 (where the label states the quantity of ceftriaxone in a given volume of constituted solution): Nominally 0.3 mg/mL of ceftriaxone in *Mobile phase* prepared as follows. Constitute Ceftriaxone for Injection in a volume of water corresponding to the volume of solvent specified in the labeling, and dilute with *Mobile phase* to final volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for ceftriaxone and ceftriaxone *E*-isomer are 1.0 and 1.4, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the ceftriaxone and ceftriaxone *E*-isomer peaks, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 0.7%, *Standard solution*

Analysis

Samples: *Standard solution*, *Sample solution 1*, and *Sample solution 2* or *Sample solution 3*

Calculate the quantity, in µg/mg, of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$) in the portion of Ceftriaxone for Injection taken:

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

r_U = peak response of ceftriaxone from *Sample solution 1*

r_s = peak response of ceftriaxone from the *Standard solution*

C_s = concentration of [USP Ceftriaxone Sodium RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of ceftriaxone in *Sample solution 1* (mg/mL)

P = potency of ceftriaxone in [USP Ceftriaxone Sodium RS](#) (µg/mg)

Acceptance criteria: NLT 776 µg/mg on the anhydrous basis

Calculate the percentage of the labeled amount of ceftriaxone ($C_{18}H_{18}N_8O_7S_3$) in the portion of Ceftriaxone for Injection withdrawn from the container or in the portion of the constituted solution:

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

r_U = peak response of ceftriaxone from *Sample solution 2* or *Sample solution 3*

r_s = peak response of ceftriaxone from the *Standard solution*

C_s = concentration of [USP Ceftriaxone Sodium RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of ceftriaxone in *Sample solution 2* or *Sample solution 3* (mg/mL)

P = potency of ceftriaxone in [USP Ceftriaxone Sodium RS](#) (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–115.0% of the labeled amount of ceftriaxone

PERFORMANCE TESTS

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

IMPURITIES

• ORGANIC IMPURITIES

Protect solutions containing ceftriaxone sodium from light.

Solution A, Solution B, Solution C, Buffer, Mobile phase, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 3 µg/mL of [USP Ceftriaxone Sodium RS](#) in *Mobile phase*

Sample solution: Nominally 0.3 mg/mL of ceftriaxone from Ceftriaxone for Injection in *Mobile phase*

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ceftriaxone and ceftriaxone *E*-isomer are listed in [Table 1](#).]

Suitability requirements

Resolution: NLT 3.0 between the ceftriaxone and ceftriaxone *E*-isomer

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Ceftriaxone for Injection taken:

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

r_U = peak response of each individual impurity from the *Sample solution*

r_s = peak response of ceftriaxone from the *Standard solution*

C_s = concentration of [USP Ceftriaxone Sodium RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of ceftriaxone in the *Sample solution* (mg/mL)

P = potency of ceftriaxone in [USP Ceftriaxone Sodium RS](#) (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: See [Table 1](#). Disregard any peak below 0.1%.

Table 1