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Cefepime for Injection

DEFINITION

Cefepime for Injection is a sterile mixture of Cefepime Hydrochloride and Arginine. It contains the equivalent of NLT 90.0% and NMT 115.0% of the labeled amount of cefepime ($C_{19}H_{24}N_6O_5S_2$).

IDENTIFICATION

- **A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).**

Standard solution: 20 mg/mL of arginine

Sample solution: 40 mg/mL of Cefepime for Injection

Developing solvent system: [n-Propyl alcohol](#), [ammonium hydroxide](#), and [water](#) (7:4:5)

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in [\(201\)](#), except to spray the plate with [ninhydrin](#) TS.

Acceptance criteria: Arginine appears as a dark red spot. The intensity and the R_f value of the spot from the *Sample solution* correspond to those from the *Standard solution*.

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

- ▲ **C.** The UV spectrum of the cefepime peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲

(USP 1-May-2021)

ASSAY

Change to read:

- **PROCEDURE**

Solution A: 0.68 mg/mL of [monobasic potassium phosphate](#) in [water](#)

Solution B: [Acetonitrile](#) and *Solution A* (1:9), adjusted with 2% [phosphoric acid](#) or 2% [potassium hydroxide](#) to a pH of 5.0

Solution C: [Acetonitrile](#) and *Solution A* (1:1), adjusted with 2% [phosphoric acid](#) or 2% [potassium hydroxide](#) to a pH of 5.0

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	100	0
10	100	0
30	50	50
35	50	50
36	100	0
45	100	0

Standard solution: 1.4 mg/mL of [USP Cefepime Hydrochloride RS](#) in *Solution B*. ▲Sonicate if necessary. Store this solution in a refrigerator and use within 12 h.▲ (USP 1-May-2021)

Sample solution: Constitute one container of Cefepime for Injection as directed on the label, and dilute using *Solution B* to 1 mg/mL of cefepime. [NOTE—For products that are designed for administration with a syringe, withdraw the entire withdrawable contents of the vial and transfer to a suitable volumetric flask. Dilute with *Solution B* to volume. For all other types, transfer the contents of the reconstituted vial quantitatively to a suitable volumetric flask, and dilute with *Solution B* to volume.]

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. ▲For *Identification C*, use a diode array detector in the range of 200–400 nm. ▲ (USP 1-May-2021)

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

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲the labeled amount of cefepime▲ (USP 1-May-2021) ($C_{19}H_{24}N_6O_5S_2$) in the portion of Cefepime for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F \times 100 \quad (\text{USP 1-May-2021})$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

▲ P = potency of cefepime in [USP Cefepime Hydrochloride RS](#) (μg/mg)

F = conversion factor, 0.001 mg/μg▲ (USP 1-May-2021)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

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

IMPURITIES

Change to read:

- ▲ (USP 1-May-2021) **LIMIT OF *N*-METHYLPYRROLIDINE**

Mobile phase: [Acetonitrile](#) and [0.01 N nitric acid](#) (1:19)

Standard solution: 0.05 mg/mL of [N-methylpyrrolidine](#) in 0.002 N [nitric acid](#)

Sample solution: Equivalent to 5 mg/mL of cefepime hydrochloride in 0.002 N [nitric acid](#).

[NOTE—Inject this solution immediately.]

Chromatographic system

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

Mode: LC

Detector: Conductivity

Column: 4.0-mm × 25-cm; 5-μm packing [L76](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

▲**Run time:** About 6 times the retention time of the *N*-methylpyrrolidine peak from the *Sample solution*▲ (USP 1-May-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 4.0%

Analysis

Samples: *Standard solution* and *Sample solution*▲ (USP 1-May-2021)

Calculate the percentage of *N*-methylpyrrolidine in the portion of Cefepime for Injection taken:

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

r_U = peak response of *N*-methylpyrrolidine from the *Sample solution*

r_S = peak response of *N*-methylpyrrolidine from the *Standard solution*