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Meropenem for Injection

DEFINITION

Meropenem for Injection is a sterile dry mixture of Meropenem and Sodium Carbonate. It contains NLT 90.0% and NMT 120.0% of the labeled amount of meropenem ($C_{17}H_{25}N_3O_5S$).

IDENTIFICATION

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

ASSAY

Change to read:

PROCEDURE

Buffer: Dilute 15 mL of tetrabutylammonium hydroxide solution (25% in water) with [water](#) to 750 mL. Adjust with [10% phosphoric acid TS](#) to a pH of 7.5 ± 0.1 .

Mobile phase: [Acetonitrile](#), [methanol](#), and Δ [Buffer](#)▲ (ERR 1-Feb-2020) (150:100:750)

Standard solution: 0.11 mg/mL of [USP Meropenem RS](#) in *Mobile phase*. Immediately after preparation, store this solution in a refrigerator, and use within 24 h.

Sample stock solution 1 (where it is represented as being a single-dose container): Nominally 1 mg/mL of meropenem, prepared as follows. Constitute a container of Meropenem for Injection with a volume of [water](#) corresponding to the quantity 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 [water](#) to volume, and mix.

Sample solution 1: Nominally 0.1 mg/mL of meropenem in *Mobile phase* from *Sample stock solution 1*. Hold this *Sample solution 1* for 2 h at $25 \pm 1^\circ$ before testing.

Sample stock solution 2 (where the label states the quantity of meropenem in a given volume of constituted solution): Nominally 1 mg/mL of meropenem, prepared as follows. Constitute a container of Meropenem for Injection with a volume of water corresponding to the quantity of solvent specified in the labeling, and dilute with water.

Sample solution 2: Nominally 0.1 mg/mL of meropenem in *Mobile phase* from *Sample stock solution 2*. Hold this *Sample solution 2* for 2 h at $25 \pm 1^\circ$ before testing.

Chromatographic system

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

Mode: LC

Detector: UV 300 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

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 1* or *Sample solution 2*

Calculate the percentage of the labeled amount of meropenem ($C_{17}H_{25}N_3O_5S$) in the portion of Meropenem for Injection taken:

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

r_U = peak response of meropenem from *Sample solution 1* or *Sample solution 2*

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

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

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

P = potency of meropenem in [USP Meropenem RS](#) (mg/mg)

Acceptance criteria: 90.0%–120.0%

OTHER COMPONENTS

• CONTENT OF SODIUM

Solution A: 38.1 g/L of [potassium chloride](#) in [water](#)

Standard stock solution: 25.42 µg/mL of [sodium chloride](#) (previously dried at 105° for 2 h) in [water](#)

Standard solution: 2.5 µg/mL of [sodium chloride](#) from the *Standard stock solution* mixed first with *Solution A* to 10% of the final volume and diluted with [water](#) to volume

Sample stock solution 1 (where it is represented as being a single-dose container): Nominally 0.125 mg/mL of meropenem, prepared as follows. Constitute a container of Meropenem for Injection with a volume of [water](#) corresponding to the quantity 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 [water](#) to volume.

Sample stock solution 2 (where the label states the quantity of meropenem in a given volume of constituted solution): Nominally 0.125 mg/mL of meropenem, prepared as follows. Constitute a container of Meropenem for Injection with a volume of [water](#), corresponding to the quantity of solvent specified in the labeling. Transfer the constituted solution to a suitable volumetric flask, and dilute with [water](#) to volume.

Sample solution: Nominally 0.0125 mg/mL of meropenem from *Sample stock solution 1* or *Sample stock solution 2* mixed first with *Solution A* to 10% of the final volume, and dilute with [water](#) to volume

Blank: *Solution A* and [water](#) (1:10)

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectroscopy

Analytical wavelength: 589.6 nm sodium emission line

Burner: Single-slot

Flame: Air–acetylene

Lamp: Sodium hollow-cathode

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of sodium (Na) in the portion of Meropenem for Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of sodium chloride in the *Standard solution* (µg/mL)

C_U = nominal concentration of meropenem in the *Sample solution* (µg/mL)

M_{r1} = atomic weight of sodium, 22.99

M_{r2} = molecular weight of sodium chloride, 58.44

Acceptance criteria: 80%–120% of the labeled amount of sodium

PERFORMANCE TESTS

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

IMPURITIES

• ORGANIC IMPURITIES

Buffer: Mix 1.0 mL of [triethylamine](#) and 900 mL of [water](#). Adjust with [10% phosphoric acid TS](#) to a pH of 5.0 ± 0.1 , and dilute with [water](#) to 1000 mL.

Mobile phase: Acetonitrile and *Buffer* (70:1000)

Peak identification solution: 5 mg/mL of [USP Meropenem RS](#) in *Mobile phase*. Use this solution between 1 and 24 h from preparation.

Standard solution: 0.029 mg/mL of [USP Meropenem RS](#) in *Buffer*. Store this solution in a refrigerator immediately after preparation, and use within 24 h.

Sample solution: Nominally prepare 5 mg/mL of meropenem in *Buffer* from Meropenem for Injection. This solution has to be prepared fresh and used immediately.

Chromatographic system

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