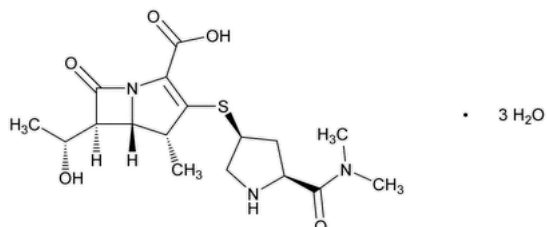


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# Meropenem

## Change to read:



$C_{17}H_{25}N_3O_5S \cdot 3H_2O$  437.51

$C_{17}H_{25}N_3O_5S$  ▲383.46▲ (USP 1-Dec-2019)

1-Azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid, 3-[[5-[(dimethylamino)carbonyl]-3-pyrrolidinyl]thio]-6-(1-hydroxyethyl)-4-methyl-7-oxo, trihydrate, [4R-[3(3S\*,5S\*),4 $\alpha$ ,5 $\beta$ ,6 $\beta$ (R\*)]]-; (4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)pyrrolidin-3-yl]thio]-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid, trihydrate CAS RN®: 119478-56-7; UNII: FV9J3JU8B1.

Anhydrous CAS RN®: 96036-03-2; UNII: YOP6PX0BAO.

## DEFINITION

Meropenem contains NLT 98.0% and NMT 101.0% of meropenem ( $C_{17}H_{25}N_3O_5S$ ), calculated on the anhydrous basis.

## IDENTIFICATION

### Change to read:

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

### Change to read:

- **B.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Dec-2019)

## ASSAY

### Change to read:

#### PROCEDURE

▲**Solution A:** Dilute 15 mL of tetrabutylammonium hydroxide solution (25% in methanol) with [water](#) to 750 mL. Adjust with [10% phosphoric acid TS](#) to a pH of  $7.5 \pm 0.1$ .

**Mobile phase:** [Acetonitrile](#), [methanol](#), and *Solution A* (150:100:750)

**Standard solution:** 0.1 mg/mL of [USP Meropenem RS](#) in *Mobile phase*. Immediately after preparation, store this solution in a refrigerator, and use within 24 h.

**Sample solution:** 0.1 mg/mL of Meropenem in *Mobile phase*. Immediately after preparation, store this solution in a refrigerator, and use within 8 h.

#### 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- $\mu$ m packing [L1](#)

**Flow rate:** 1.5 mL/min

**Injection volume:** 20  $\mu$ L

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Tailing factor:** NMT 1.5

**Relative standard deviation:** NMT 1.0%

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

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

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

$r_U$  = peak response of meropenem from the *Sample solution*

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

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

$C_U$  = concentration of Meropenem in the *Sample solution* (mg/mL)

$P$  = designated potency of [USP Meropenem RS](#) (mg/mg)

▲ (USP 1-Dec-2019)

**Acceptance criteria:** 98.0%–101.0% on the anhydrous basis

## IMPURITIES

**Change to read:**

- [RESIDUE ON IGNITION \(281\)](#)

**Analysis:** Ignite at  $500 \pm 50^\circ$  ▲ (USP 1-Dec-2019)

**Acceptance criteria:** NMT 0.1%

**Change to read:**

- **ORGANIC IMPURITIES**

**Solution A:** Mix 1.0 mL of [triethylamine](#) and 900 mL of [water](#). Adjust with [10% phosphoric acid TS](#) to a pH of  $5.0 \pm 0.1$ , and dilute with [water](#) to 1000 mL.

**Mobile phase:** [Acetonitrile](#) and *Solution A* (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. ▲

(USP 1-Dec-2019)

**Standard solution:** 0.025 mg/mL of [USP Meropenem RS](#) in *Solution A*

▲ Store this solution in a refrigerator and use within 24 h. ▲ (USP 1-Dec-2019)

**Sample solution:** 5 mg/mL of Meropenem in *Solution A*. Use this *Sample solution* immediately.

## Chromatographic system

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

**Mode:** LC

**Detector:** UV 220 nm

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

**Column temperature:**  $40^\circ$

**Flow rate:** 1.6 mL/min

▲ ▲ (USP 1-Dec-2019)

**Injection volume:** 10  $\mu$ L

**Run time:** NLT 3 times the retention time of meropenem

## System suitability

**Sample:** *Standard solution*

## Suitability requirements

▲ ▲ (USP 1-Dec-2019)

**Tailing factor:** NMT 1.5

**Relative standard deviation:** NMT 2.0%

## Analysis

**Samples:** ▲ *Peak identification solution*, *Standard solution*, and *Sample solution*

Chromatograph the *Peak identification solution* and identify the components on the basis of their relative retention times, as shown in

[Table 1](#). ▲ (USP 1-Dec-2019)

Calculate the percentage of each individual impurity in the portion of Meropenem taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100 \text{ ▲ (USP 1-Dec-2019)}$$

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

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