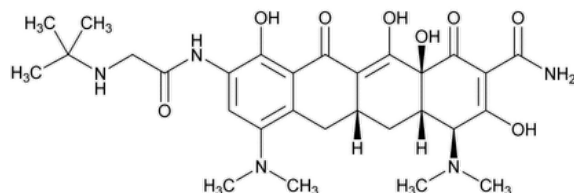


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Tigecycline



$C_{29}H_{39}N_5O_8$ 585.65

2-Naphthacene-1-carboxamide, 4,7-bis(dimethylamino)-9-[[[1,1-dimethylethyl]amino]acetyl]amino]-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-, (4S,4aS,5aR,12aS)-;

(4S,4aS,5aR,12aS)-9-[2-(*tert*-Butylamino)acetamido]-4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-2-naphthacene-1-carboxamide CAS RN®: 220620-09-7; UNII: 70JE2N95KR.

DEFINITION

Tigecycline contains NLT 97.0% and NMT 102.0% of tigecycline ($C_{29}H_{39}N_5O_8$), calculated on the anhydrous and solvent-free basis.

[NOTE—Handle Standards and samples under moisture-controlled conditions to prevent degradation in quantitative applications where degradation could impact results.]

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 tigecycline from light using low-actinic glassware. Store these solutions at 10° immediately after preparation and during analysis.

Buffer: 4.35 g/L of dibasic potassium phosphate and 0.93 g/L of edetate disodium, adjusted with phosphoric acid to a pH of 6.2

Mobile phase: Acetonitrile and *Buffer* (140:860)

Diluent: 4.35 g/L of dibasic potassium phosphate and 0.5 g/L of sodium bisulfite, adjusted with 1 N potassium hydroxide to a pH of 8.0

System suitability stock solution: Dissolve 10 mg of [USP Tigecycline RS](#) in 10.0 mL of water. Add 1 or 2 drops of trifluoroacetic acid, heat at about 65° for 15 min, and cool.

System suitability solution: Dilute 5.0 mL of the *System suitability stock solution* with water to 50.0 mL.

Standard solution: 0.1 mg/mL of [USP Tigecycline RS](#) in *Diluent*

Sample solution: 0.1 mg/mL of Tigecycline in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 248 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Temperatures

Column: 30°

Autosampler: 10°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—The relative retention times for the tigecycline epimer and tigecycline are about 0.67 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the tigecycline epimer and tigecycline, *System suitability solution*

Tailing factor: 0.7–1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tigecycline ($C_{29}H_{39}N_5O_8$) in the portion of Tigecycline taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 97.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

Protect solutions containing tigecycline from light using low-actinic glassware. Store these solutions at 10° immediately after preparation and during analysis.

Solution A: Dissolve 4.35 g of dibasic potassium phosphate and 0.93 g of edetate disodium in 950 mL of water. Adjust with phosphoric acid to a pH of 6.4 ± 0.05 , and add 50 mL of acetonitrile.

Solution B: Dissolve 4.35 g of dibasic potassium phosphate and 0.93 g of edetate disodium in 500 mL of water. Adjust with phosphoric acid to a pH of 6.4 ± 0.05 , and add 500 mL of acetonitrile.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	85	15
40	57	43
55	0	100
58	0	100
59	85	15
66	85	15

Diluent: 4.35 g/L of dibasic potassium phosphate and 0.5 g/L of sodium bisulfite, adjusted with 1 N potassium hydroxide to a pH of 8.0

System suitability solution: 0.5 mg/mL of [USP Tigecycline RS](#) and 2.4 µg/mL of [USP Tigecycline Related Compound B RS](#) in *Diluent*

Standard solution: 0.005 mg/mL of [USP Tigecycline RS](#) in *Diluent*

Sensitivity solution: 0.25 µg/mL of [USP Tigecycline RS](#) in *Diluent*

Sample solution: 0.5 mg/mL of Tigecycline in *Diluent*

Chromatographic system

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

Mode: LC

Detector: 248 nm