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Tigecycline for Injection

DEFINITION

Tigecycline for Injection contains NLT 96.0% and NMT 116.0% of the labeled amount of tigecycline ($C_{29}H_{39}N_5O_8$). It may contain suitable stabilizers and buffers.

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

IDENTIFICATION

• **A.** 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:

▲ • **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-2020)

ASSAY

Change to read:

• 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](#). Adjust 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: Nominally 0.1 mg/mL of tigecycline from Tigecycline for Injection in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 248 nm. ▲ For *Identification B*, use a diode array detector in the range of 190–400 nm. ▲ (USP 1-Dec-2020)

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Temperatures

Autosampler: 10°

Column: 30°

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 1.1%, *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 for Injection taken:

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

r_U = peak response of tigecycline from the *Sample solution*

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

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

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

Acceptance criteria: 96.0%–116.0%

PERFORMANCE TESTS

- **UNIFORMITY OF DOSAGE UNITS (905):** Meets the requirements

IMPURITIES

Change to read:

• 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](#). Adjust 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*

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

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

Sample solution: Nominally 0.5 mg/mL of tigecycline in *Diluent* from the combined contents of NLT 5 vials ▲ of Tigecycline for Injection ▲ (USP 1-Dec-2020)

Chromatographic system

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

Mode: LC

Detector: UV 248 nm

Column: 4.6-mm × 15-cm; 3-µm packing [L1](#)

Temperatures

Autosampler: 10°

Column: 30°