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Oxaliplatin Injection

DEFINITION

Oxaliplatin Injection is a sterile solution of Oxaliplatin in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of oxaliplatin ($C_8H_{14}N_2O_4Pt$).

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (OFFICIAL 1-MAY-2020)

Sample solution: 100 µg/mL

Medium: [Water](#)

Acceptance criteria: Meets the requirements

- **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

[NOTE—All HPLC autosampler vials should be made of polypropylene.]

Acidified water: Adjust water with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Acidified water* (1:99)

System suitability solution: 0.1 mg/mL of [USP Oxaliplatin RS](#) and 0.1 mg/mL of [USP Oxaliplatin System Suitability RS](#) in [water](#). [NOTE—[USP Oxaliplatin System Suitability RS](#) is [SP-4-2-(1*R-trans*)]-(1,2-cyclohexanediamine-*N,N'*) dichloridoplatinum(II).]

Standard solution: 0.1 mg/mL of [USP Oxaliplatin RS](#) in [water](#)

Sample solution: Nominally 0.1 mg/mL of oxaliplatin in [water](#) from the combined contents of NLT 3 vials of Injection

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

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

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for [SP-4-2-(1*R-trans*)]-(1,2-cyclohexanediamine-*N,N'*) dichloridoplatinum(II) and oxaliplatin are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between [SP-4-2-(1*R-trans*)]-(1,2-cyclohexanediamine-*N,N'*) dichloridoplatinum(II) and oxaliplatin

Tailing factor: NMT 2.0 for the oxaliplatin peak

Relative standard deviation: NMT 1.0% for the oxaliplatin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxaliplatin ($C_8H_{14}N_2O_4Pt$) in the portion of Injection 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 Oxaliplatin RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of oxaliplatin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• LIMIT OF OXALIC ACID

[NOTE—All HPLC autosampler vials should be made of polypropylene.]

Mobile phase: 0.43 g/L of [sodium carbonate](#) and 0.04 g/L of [sodium bicarbonate](#) in [water](#)

Standard stock solution: 0.32 mg/mL of [USP Oxaliplatin Related Compound A RS](#) in [water](#). [NOTE—[USP Oxaliplatin Related Compound A RS](#) is available as dihydrate oxalic acid.]

Tartaric acid standard stock solution: 0.25 mg/mL of [tartaric acid](#) in [water](#)

System suitability solution: 23 µg/mL of [USP Oxaliplatin Related Compound A RS](#) and 12.5 µg/mL of tartaric acid in [water](#) from *Standard stock solution* and *Tartaric acid standard stock solution*.

Standard solution: 16.2 µg/mL of [USP Oxaliplatin Related Compound A RS](#) in [water](#) from *Standard stock solution*

Sensitivity solution: 1.94 µg/mL [USP Oxaliplatin Related Compound A RS](#) in [water](#) from *Standard solution*

Sample solution: Nominally equivalent to 2 mg/mL of oxaliplatin in [water](#) from Injection

Chromatographic system

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

Mode: LC

Detector: Conductivity with anion suppression. [NOTE—A recycle mode may be used.]

Column: 4.0-mm × 25-cm; packing [L81](#)

Autosampler temperature: 5°

Flow rate: 2.0 mL/min

Injection volume: 40 µL

System suitability

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

[NOTE—The relative retention times for tartaric acid and oxalic acid are 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8 between tartaric acid and oxalic acid, *System suitability solution*

Tailing factor: 0.5–1.5 for the oxalic acid peak, *Standard solution*

Relative standard deviation: NMT 3.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxalic acid in the portion of Injection taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (M_{r1}/M_{r2}) \times 100$$

r_u = peak response of oxalic acid from the *Sample solution*

r_s = peak response of oxalic acid from the *Standard solution*

C_s = concentration of [USP Oxaliplatin Related Compound A RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of oxaliplatin in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of anhydrous oxalic acid, 90.03

M_{r2} = molecular weight of oxaliplatin related compound A, 126.07

Acceptance criteria: NMT 0.6%

• LIMIT OF (SP-4-2)-DIAQUA[(1R,2R)-CYCLOHEXANE-1,2-DIAMINE-N,N']PLATINUM AND UNSPECIFIED IMPURITIES

[NOTE—All HPLC autosampler vials should be made of polypropylene.]

Solution A: Dissolve 1.36 g of [monobasic potassium](#) phosphate and 0.55 g of [sodium heptanesulfonate](#) in 1 L of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.