

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Mar-2019
 Document Type: USP Monographs
 DocId: GUID-78E81F31-73C0-40F3-9EAD-D152DDC292B5_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M1428_05_01
 DOI Ref: fei59

© 2025 USPC
 Do not distribute

Oxaliplatin for Injection

DEFINITION

Oxaliplatin for Injection is a sterile, lyophilized mixture of Oxaliplatin and Lactose Monohydrate. It contains NLT 90.0% and NMT 110.0% of the labeled amount of oxaliplatin ($C_8H_{14}N_2O_4Pt$).

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.▲_{2S}
 (USP41)

ASSAY

Change to read:

• PROCEDURE

[NOTE—Use vigorous shaking and very brief sonication to dissolve the substance to be examined. Inject the *Sample solution* within 20 min of preparation. Use polypropylene HPLC autosampler vials.]

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 each of [USP Oxaliplatin RS](#) and [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 equivalent to 0.1 mg/mL of oxaliplatin obtained by constituting a suitable number of vials of Oxaliplatin for Injection with the appropriate amount of [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 210 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲_{2S} (USP41)

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

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

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

Suitability requirements

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

Tailing factor: NMT 2.0 for the oxaliplatin peak, *System suitability solution*

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

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 Oxaliplatin for 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%

PERFORMANCE TESTS

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

IMPURITIES

Change to read:

- **LIMIT OF OXALIC ACID**

[NOTE—Use vigorous shaking and very brief sonication to dissolve the substance to be examined. Inject the *Sample solution* within 20 min of preparation. Use polypropylene HPLC autosampler vials.]

Buffer: Add 1.36 g of ▲[monobasic potassium phosphate](#) ▲_{2S} (USP41) to 10 mL of 10% [tetrabutylammonium hydroxide](#) in [water](#), and dilute with [water](#) to 1000 mL. Adjust with [phosphoric acid](#) to a pH of 6.0.

Mobile phase: Acetonitrile and *Buffer* (1:4)

Standard stock solution: 0.06 mg/mL of [USP Oxaliplatin Related Compound A RS](#) in [water](#). [NOTE—[USP Oxaliplatin Related Compound A RS](#) is available as oxalic acid dihydrate.]

Standard solution: 15 µg/mL of [USP Oxaliplatin Related Compound A RS](#) in [water](#), from the *Standard stock solution*

System suitability stock solution: 0.05 mg/mL of [sodium nitrate](#) in [water](#)

System suitability solution: 1.0 µg/mL of [sodium nitrate](#) and 15 µg/mL of oxaliplatin related compound A in [water](#), from the *System suitability stock solution* and *Standard stock solution*, respectively

Sensitivity solution: ▲1.5 µg/mL of [USP Oxaliplatin Related Compound A RS](#) in [water](#), from the *Standard solution* ▲_{2S} (USP41)

Sample solution: Nominally equivalent to 2.0 mg/mL of oxaliplatin in [water](#) from Oxaliplatin for Injection

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

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

Column temperature: 40°

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for the sodium nitrate and oxalic acid peaks are about 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the oxalic acid and sodium nitrate peaks, *System suitability solution*

Relative standard deviation: NMT 3.0% for the oxalic acid peak, *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 Oxaliplatin for 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)