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## 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.▲<sub>2S</sub>  
(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.▲<sub>2S</sub> (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](#) ▲<sub>2S</sub> (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* ▲<sub>2S</sub> (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)

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

$M_{r2}$  = molecular weight of [USP Oxaliplatin Related Compound A RS](#), 126.07

**Acceptance criteria:** NMT 0.5%

**Change to read:**

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

[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:** Dissolve 1.36 g of ▲[monobasic potassium phosphate](#)▲<sub>2S</sub> (USP41) and 1 g of [sodium 1-heptanesulfonate](#) in 1 L of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

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

**System suitability solution:** 2 mg/mL of [USP Oxaliplatin RS](#) in 0.005 M [sodium hydroxide](#). Allow this solution to stand at room temperature for at least 5 days. [NOTE—Sonicate if necessary.] Transfer 5 mL of this solution into a 50-mL volumetric flask, and dilute with [water](#) to volume. [NOTE—The preparation of the *System suitability solution* forms diaquodiaminocyclohexaneplatinum dimer and (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum.]

**Standard solution:** 0.0125 mg/mL of [USP Oxaliplatin Related Compound B RS](#) prepared as follows. Transfer [USP Oxaliplatin Related Compound B RS](#) to a suitable volumetric flask, add 25% of the final volume of methanol, and sonicate for approximately 30 min to dissolve. Allow to cool, if necessary, and dilute with [water](#) to volume. [NOTE—When preparing the solution, [USP Oxaliplatin Related Compound B RS](#) is converted to (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N'] platinum.]

**Sample solution:** Use the *Sample solution* from the test for *Limit of Oxalic Acid*.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 215 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:** *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum and diaquodiaminocyclohexaneplatinum dimer are about 1.0 and 1.5, respectively.]

**Suitability requirements**

**Resolution:** NLT 2.0 between (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum and diaquodiaminocyclohexaneplatinum dimer, *System suitability solution*

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

**Analysis**

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

Calculate the percentage of (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum 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 (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum from the *Sample solution*

$r_S$  = peak response of (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum from the *Standard solution*

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

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

$M_{r1}$  = molecular weight of (SP-4-2)-diaqua[(1R,2R)-cyclohexane-1,2-diamine-N,N']platinum, 345.30

$M_{r2}$  = molecular weight of [USP Oxaliplatin Related Compound B RS](#), 433.28

**Acceptance criteria:** NMT 0.5%

**Change to read:**

• **LIMIT OF RELATED COMPOUND C AND UNSPECIFIED IMPURITIES**

[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.]

**Mobile phase:** Prepare as directed in the Assay.

**Standard stock solution:** 0.1 mg/mL each of [USP Oxaliplatin RS](#) and [USP Oxaliplatin Related Compound C RS](#) in [water](#)

**Standard solution:** 0.01 mg/mL each of [USP Oxaliplatin RS](#) and [USP Oxaliplatin Related Compound C RS](#) in [water](#), from the *Standard stock solution*

**System suitability stock solution:** 0.1 mg/mL of [USP Oxaliplatin System Suitability RS](#) in methanol. Sonicate for approximately 10 min to aid the dissolution.

**System suitability solution:** Transfer 10 mL each of the *Standard stock solution* and the *System suitability stock solution* into a 100-mL volumetric flask, and dilute with [water](#) to volume.

**Sample solution:** Use the *Sample solution* from the test for *Limit of Oxalic Acid*.

**Chromatographic system:** Proceed as directed in the Assay, except for the *Injection volume*.

**Injection volume:** 10 µL

**System suitability**

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

**Suitability requirements**

**Resolution:** NLT 2.0 between [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 3.0% each for the oxaliplatin and oxaliplatin related compound C peaks, *Standard solution*

**Analysis**

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

Calculate the percentage of oxaliplatin related compound C 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 of oxaliplatin related compound C from the *Sample solution*

$r_S$  = peak response of oxaliplatin related compound C from the *Standard solution*

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

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

Calculate the percentage of each unspecified impurity 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 of each impurity from the *Sample solution*

$r_S$  = peak response of oxaliplatin 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:** See [Table 1](#).

**Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Oxaliplatin related compound C <sup>▲</sup> <sub>2S</sub> (USP41)	0.6	0.3

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
[SP-4-2-(1 <i>R-trans</i> )]-(1,2-Cyclohexanediamine- <i>N,N'</i> ) dichloridoplatinum(II) <sup>a</sup>	0.8	—
Oxaliplatin	1.0	—
Any individual unspecified impurity	—	0.2
Total impurities <sup>b</sup>	—	1.5



▲2S (USP41)

<sup>a</sup> The relative retention time is included for system suitability purposes only.<sup>b</sup> Includes oxalic acid, (SP-4-2)-diaqua[(1*R,2R*)-cyclohexane-1,2-diamine-*N,N'*]platinum, oxaliplatin related compound C, and the total of the individual unspecified impurities.**SPECIFIC TESTS**

- **pH (791):** 4.0–7.0 using a polymer combination electrode, determined in a solution constituted as directed in the labeling
- **PARTICULATE MATTER IN INJECTIONS (788):** It meets the requirements for small-volume injections.
- **CONSTITUTED SOLUTION:** At the time of use, it meets the requirements in [Injections and Implanted Drug Products \(1\)](#), [Product Quality Tests Common to Parenteral Dosage Forms, Specific Tests, Completeness and Clarity of Solutions](#).
- **BACTERIAL ENDOTOXINS TEST (85):** NMT 1.0 USP Endotoxin Unit/mg of oxaliplatin
- **STERILITY TESTS (71):** Meets the requirements
- **WATER DETERMINATION (921), Method I:** NMT 4.0%
- **OTHER REQUIREMENTS:** It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging, Packaging for Constitution](#). Store at controlled room temperature.
- **LABELING:** Label it to indicate that it is to be diluted with a suitable parenteral vehicle before intravenous infusion.

**Change to read:**

- **USP REFERENCE STANDARDS (11).**



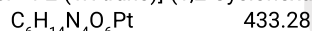
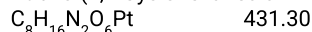
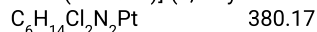
▲ (CN 1-May-2018)

[USP Oxaliplatin RS](#)

▲2S (USP41)

[USP Oxaliplatin Related Compound A RS](#)

Oxalic acid dihydrate.

[USP Oxaliplatin Related Compound B RS](#)[SP-4-2-(1*R-trans*)]-(1,2-Cyclohexanediamine-*N,N'*) dinitratoplatinum(II).[USP Oxaliplatin Related Compound C RS](#)[1*R-trans*-(1,2-Cyclohexanediamine-*N,N'*)]-*trans*-dihydroxido-[oxalato(2-)-*O,O'*]platinum(IV).[USP Oxaliplatin System Suitability RS](#)[SP-4-2-(1*R-trans*)]-(1,2-Cyclohexanediamine-*N,N'*) dichloridoplatinum(II).**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
OXALIPLATIN FOR INJECTION	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

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