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Cisplatin for Injection

DEFINITION

Cisplatin for Injection is a sterile, lyophilized mixture of Cisplatin, Mannitol, and Sodium Chloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of cisplatin ($\text{Cl}_2\text{H}_6\text{N}_2\text{Pt}$).

[CAUTION—Cisplatin is potentially cytotoxic. Great care should be taken in handling the powder and preparing solutions.]

IDENTIFICATION

Delete the following:

▲ • A. THIN-LAYER CHROMATOGRAPHY

Solution A: 5.6 g of [stannous chloride](#) in 10 mL of [hydrochloric acid](#). Stir for 5 min. [NOTE—It is not necessary that all of the solids dissolve.]

Solution B: 0.2 g of [potassium iodide](#) in 90 mL of [water](#)

Standard solution: 1.0 mg/mL of [USP Cisplatin RS](#), 9 mg/mL of [sodium chloride](#), and 10 mg/mL of D-mannitol in [water](#)

Sample solution: Nominally equivalent to 1.0 mg/mL of cisplatin by dissolving the contents of 1 container of Cisplatin for Injection in [water](#), based on the label claim

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: [Acetone](#) and [1 N nitric acid](#) (9:1)

Spray reagent A: Mix *Solution A* and *Solution B* together. Disregard any precipitate that is formed. Store in the dark. [NOTE—The solution is usable for at least 1 week.]

Spray reagent B: 20 mg/mL of [potassium iodide](#) in water

Analysis

Samples: *Standard solution* and *Sample solution*

Develop with *Developing solvent system*, in a suitable chromatographic chamber containing a filter paper lining and equilibrated for 30 min with the *Developing solvent system*, for a distance of about 8 cm from the origin, followed by air drying. Complete the drying by heating in a forced-air oven at about 100° for 1 min. Spray with *Spray reagent A*, heat in an oven at about 100° for 5 min, cool, and spray with *Spray reagent B* to bring out the full color of the spots.

Acceptance criteria: The principal spot from the *Sample solution* corresponds in appearance and R_f value to that produced by the *Standard solution*. ▲ (USP 1-Dec-2021)

Add the following:

▲ • A. 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-2021)

• 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

Change to read:

• PROCEDURE

Mobile phase: [Ethyl acetate](#), [methanol](#), [dimethylformamide](#), and degassed [water](#) (25:16:5:5)

Standard solution: 1 mg/mL of [USP Cisplatin RS](#) in [dimethylformamide](#). Use within 1 h.

Sample solution: Nominally 1.0 mg/mL of cisplatin in [dimethylformamide](#), prepared as follows. Quantitatively dissolve 1 container of Cisplatin for Injection in [dimethylformamide](#) by sonicating for 5 min. Pass 5 mL of this solution through a suitable filter and collect the filtrate after discarding the first milliliters of the filtrate. Use within 1 h.

Chromatographic system

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

Mode: LC

Detector: UV 310 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Dec-2021)

Column: 4.0-mm × 30-cm; packing [L8](#)

Flow rate: 2.0 mL/min

Injection volume: 40 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cisplatin ($\text{Cl}_2\text{H}_6\text{N}_2\text{Pt}$) in the portion of Cisplatin for Injection taken:

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

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

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

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

C_U = nominal concentration of cisplatin 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 ▲AMINOTRICHLOROPLATINUM▲** (USP 1-Dec-2021)

Mobile phase: 0.4 g/L of [ammonium sulfate](#) in water. Adjust with [6 N ammonium hydroxide](#) to a pH of 5.9.

Standard solution: 6 µg/mL of [USP Potassium Trichloroammineplatinate RS](#) in [saline TS](#). Protect the solution from light. Use the solution within 4 h.

Sample solution: Nominally 0.5 mg/mL of cisplatin, prepared as follows. Quantitatively dissolve the contents of 1 container of Cisplatin for Injection in [water](#). Protect the solution from light. Use the solution within 4 h.

Chromatographic system

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

Mode: LC

Detector: UV 209 nm

Column: 4.6-mm × 25-cm; packing [L14](#)

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for saline and ▲aminotrichloroplatinum▲ (USP 1-Dec-2021) are about 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between saline and ▲aminotrichloroplatinum▲ (USP 1-Dec-2021)

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲aminotrichloroplatinum▲ (USP 1-Dec-2021) in the portion of Cisplatin for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$