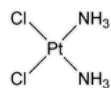


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-69CFF339-676B-407F-A520-3FFF585B3C51_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M17910_02_01
 DOI Ref: v66xr

© 2025 USPC
 Do not distribute

Cisplatin



$\text{Cl}_2\text{H}_6\text{N}_2\text{Pt}$ 300.05

Platinum, diamminedichloro-, (SP-4-2)-;

cis-Diamminedichloroplatinum CAS RN®: 15663-27-1; UNII: Q20Q21Q62J.

DEFINITION

Cisplatin contains NLT 98.0% and NMT 102.0% of cisplatin ($\text{Cl}_2\text{H}_6\text{N}_2\text{Pt}$), calculated on the anhydrous basis.

[CAUTION—Cisplatin is potentially cytotoxic. Great care should be taken to prevent inhaling particles and exposing the skin to it.]

IDENTIFICATION

Change to read:

- A. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- B. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K ▲ (CN 1-May-2020)

ASSAY

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

Chromatographic system

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

Mode: LC

Detector: UV 310 nm

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 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cisplatin ($\text{Cl}_2\text{H}_6\text{N}_2\text{Pt}$) in the portion of Cisplatin 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 Cisplatin RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES**• LIMIT OF TRICHLOROAMMINEPLATINATE**

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 Trichloroamineplatinate RS](#) in [saline TS](#). Protect the solution from light. Use the solution within 4 h.

Sample solution: 0.5 mg/mL of Cisplatin in [saline TS](#). Completely dissolve by stirring by mechanical means for 30 min. 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 trichloroamineplatinate are about 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the saline and trichloroamineplatinate peaks

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trichloroamineplatinate in the portion of Cisplatin taken:

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

r_U = peak area of trichloroamineplatinate from the *Sample solution*

r_S = peak area of trichloroamineplatinate from the *Standard solution*

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

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

M_{r1} = molecular weight of trichloroamineplatinate, 318.48

M_{r2} = molecular weight of potassium trichloroamineplatinate, 357.58

Acceptance criteria: NMT 1.0%

• LIMIT OF TRANSPLATIN

Mobile phase: 0.18 M [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.2.

Standard stock solution A: 0.05 mg/mL of [USP Transplatin RS](#) in [saline TS](#). Dissolve by stirring by mechanical means for 30 min.

Standard stock solution B: Transfer 5 mL of *Standard stock solution A* to a 25-mL volumetric flask containing 12 mg of [USP Cisplatin RS](#). Dilute with [saline TS](#) to volume, and stir by mechanical means for 30 min to dissolve.

System suitability stock solution: 0.05 mg/mL of [USP Cisplatin RS](#) in [saline TS](#). Dissolve by stirring by mechanical means for 30 min.

System suitability solution: Transfer 10 mL each of *System suitability stock solution* and *Standard stock solution A* to a 50-mL volumetric flask. Add 5.0 mL of a solution (5 mg/mL) of [thiourea](#) (prepared fresh daily) and 5.0 mL of [1 N hydrochloric acid](#), and dilute with [saline TS](#) to volume. Place 10 mL of this solution in a suitable serum vial, seal with a polytetrafluoroethylene-lined closure, and heat in a heating block at 60 ± 0.5° for 60 min. Remove, and cool to room temperature.

Standard solution: Transfer 10 mL of *Standard stock solution B* to a 50-mL volumetric flask. Add 5.0 mL of a solution (5 mg/mL) of [thiourea](#) (prepared fresh daily) and 5.0 mL of [1 N hydrochloric acid](#), and dilute with [saline TS](#) to volume. Place 10 mL of this solution in a suitable serum vial, seal with a polytetrafluoroethylene-lined closure, and heat in a heating block at 60 ± 0.5° for 60 min. Remove, and cool to room temperature.

Sample stock solution: 0.5 mg/mL of Cisplatin in [saline TS](#). Dissolve by stirring by mechanical means for 30 min.

Sample solution: Transfer 10 mL of *Sample stock solution* to a 50-mL volumetric flask. Add 5.0 mL of a solution (5 mg/mL) of [thiourea](#) (prepared fresh daily) and 5.0 mL of [1 N hydrochloric acid](#), and dilute with [saline TS](#) to volume. Place 10 mL of this solution in a suitable serum vial, seal with a polytetrafluoroethylene-lined closure, and heat in a heating block at 60 ± 0.5° for 60 min. Remove, and cool to room temperature.

Chromatographic system

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