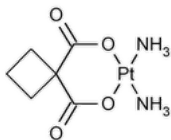


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Jan-2022
 Document Type: USP Monographs
 DocId: GUID-41CBABD3-0760-4473-A9D9-A9995ED177AD_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M13120_03_01
 DOI Ref: 4uy7z

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Carboplatin



$C_6H_{12}N_2O_4Pt$ 371.25

Platinum, diammine[1,1-cyclobutanedicarboxylato(2-)-O,O'], (SP-4-2);

cis-Diammine(1,1-cyclobutanedicarboxylato)platinum CAS RN®: 41575-94-4; UNII: BG3F62OND5.

DEFINITION

Carboplatin contains NLT 98.0% and NMT 102.0% of carboplatin ($C_6H_{12}N_2O_4Pt$), calculated on the dried basis.

[CAUTION—Great care should be taken in handling Carboplatin because it is a suspected carcinogen.]

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197K
- **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

Mobile phase: [Acetonitrile](#) and [water](#) (87:13)

Standard solution: 1 mg/mL of [USP Carboplatin RS](#) in [water](#). Use it within 2 h.

Sample solution: 1 mg/mL of Carboplatin in [water](#). Use it within 2 h.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L8](#)

Flow rate: 2.0 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 1.2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carboplatin ($C_6H_{12}N_2O_4Pt$) in the portion of Carboplatin 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 Carboplatin RS](#) in the *Standard solution* (mg/mL)

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

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

OTHER COMPONENTS

PLATINUM CONTENT

Sample: 0.2 g of Carboplatin, from *Loss on Drying*

Analysis: Ignite the *Sample* to constant weight at $800 \pm 50^\circ$, and weigh the residue. The residue is platinum.
Calculate the platinum content in the portion of Carboplatin taken:

$$\text{Result} = (W_U/W_S) \times 100$$

W_U = weight of platinum

W_S = weight of *Sample*

Acceptance criteria: 52.0%–53.0% on the dried basis

IMPURITIES

Change to read:

• LIMIT OF 1,1-CYCLOBUTANEDICARBOXYLIC ACID

Solution A: Dissolve 8.5 g of [tetrabutylammonium hydrogen sulfate](#) in 80 mL of [water](#). Add 3.4 mL of [phosphoric acid](#), and adjust with [10 N sodium hydroxide](#) to a pH of 7.55.

Mobile phase: [Acetonitrile](#), *Solution A*, and [water](#) (100:20:880)

Standard solution: 5 µg/mL of 1,1-cyclobutanedicarboxylic acid in *Mobile phase*

System suitability solution: 2.5 µg/mL of 1,1-cyclobutanedicarboxylic acid and 0.5 mg/mL of Carboplatin in *Mobile phase* prepared as follows. Mix 1.0 mL of *Standard solution* with 1.0 mL of *Standard solution* in the *Assay*.

Sample solution: 1 mg/mL of Carboplatin in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: ▲3.9-mm▲ (ERR 1-Jan-2022) × 30-cm; packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 100 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for carboplatin and 1,1-cyclobutanedicarboxylic acid are 0.65 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.5 between the carboplatin and 1,1-cyclobutanedicarboxylic acid peaks

Relative standard deviation: NMT 10%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 1,1-cyclobutanedicarboxylic acid in the portion of Carboplatin taken:

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

r_U = peak response of 1,1-cyclobutanedicarboxylic acid from the *Sample solution*

r_S = peak response of 1,1-cyclobutanedicarboxylic acid from the *Standard solution*

C_S = concentration of 1,1-cyclobutanedicarboxylic acid in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.5%

• ORGANIC IMPURITIES

Mobile phase, Standard solution, Sample solution, and System suitability: Proceed as directed in the *Assay*.

Diluted standard solution: 2.5 µg/mL of [USP Carboplatin RS](#) in [water](#), from the *Standard solution*

Chromatographic system: Proceed as directed in the *Assay*, and the run time is at least 2.5 times the retention time of the carboplatin peak.

Analysis

Samples: *Sample solution* and *Diluted standard solution*

Calculate the percentage of each impurity in the portion of Carboplatin 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 carboplatin from the *Diluted standard solution*

C_S = concentration of [USP Carboplatin RS](#) in the *Diluted standard solution* (mg/mL)