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Add the following:

^Carboplatin Injection

DEFINITION

Carboplatin Injection is a sterile, nonpyrogenic, and aqueous solution of Carboplatin. It contains NLT 90.0% and NMT 110.0% of the labeled amount of carboplatin ($C_6H_{12}N_2O_4Pt$).

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

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **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

[NOTE—Use the solutions containing carboplatin within 2 h of preparation.]

PROCEDURE

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

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard solution: 1.0 mg/mL of [USP Carboplatin RS](#) in *Diluent*

Sample solution: Nominally 1.0 mg/mL of carboplatin from Injection in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm. For *Identification A*, use a diode array detector in the range of 200–400 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 2.0

Relative standard deviation: NMT 1.2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carboplatin ($C_6H_{12}N_2O_4Pt$) in the portion of Injection taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

LIMIT OF CYCLOBUTANE DICARBOXYLIC ACID

[NOTE—Use the solutions containing carboplatin or cyclobutane dicarboxylic acid within 2 h of preparation.]

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 7.6.

Mobile phase: [Acetonitrile](#), *Solution A*, and [water](#) (10:2:88)

System suitability solution: 1.0 mg/mL of [USP Carboplatin RS](#) and 4.0 μg/mL of cyclobutane dicarboxylic acid in [water](#)

Sensitivity solution: 1.5 μg/mL of cyclobutane dicarboxylic acid in [water](#)

Standard solution: 4.0 µg/mL of cyclobutane dicarboxylic acid in [water](#)

Sample solution: Nominally 1.0 mg/mL of carboplatin in [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

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

Flow rate: 2.0 mL/min

Injection volume: 100 µL

Run time: NLT 2.5 times the retention time of cyclobutane dicarboxylic acid

System suitability

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

[NOTE—The relative retention times of carboplatin and cyclobutane dicarboxylic acid are 1.0 and 3.0, respectively.]

Suitability requirements

Resolution: NLT 2.5 between carboplatin and cyclobutane dicarboxylic acid, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cyclobutane dicarboxylic acid in the portion of Injection taken:

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

r_U = peak response of cyclobutane dicarboxylic acid from the *Sample solution*

r_S = peak response of cyclobutane dicarboxylic acid from *Standard solution*

C_S = concentration of cyclobutane dicarboxylic acid in *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 1.0%

• ORGANIC IMPURITIES

[NOTE—Use the solutions containing carboplatin within 2 h of preparation.]

Mobile phase, Diluent, Sample solution, and Chromatographic system: Proceed as directed in the Assay, except for the *Run time*.

Run time: NLT 2.5 times the retention time of carboplatin

System suitability solution: 1.0 mg/mL of [USP Carboplatin RS](#) and 2.0 µg/mL of [USP Cisplatin RS](#) in *Diluent*

Sensitivity solution: 1.0 µg/mL of [USP Carboplatin RS](#) in *Diluent*

Standard solution: 2.0 µg/mL each of [USP Carboplatin RS](#) and [USP Cisplatin RS](#) in *Diluent*

System suitability

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

Suitability requirements

Resolution: NLT 5.0 between cisplatin and carboplatin, *System suitability solution*

Relative standard deviation: NMT 5.0% for cisplatin and carboplatin, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cisplatin in the portion of 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 carboplatin in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified degradation product in the portion of Injection taken:

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

r_U = peak response of any unspecified degradation product from the *Sample solution*