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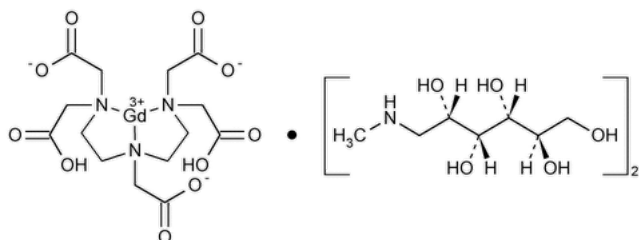
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Gadopentetate Dimeglumine Injection



DEFINITION

Gadopentetate Dimeglumine Injection is a sterile solution of gadopentetate dimeglumine in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of gadopentetate dimeglumine ($C_{14}H_{20}GdN_3O_{10} \cdot 2C_7H_{17}NO_5$). It may contain small amounts of Meglumine and Pentetic Acid as stabilizers, and it may contain suitable buffers. Gadopentetate Dimeglumine Injection intended for intravascular use contains no antimicrobial agents.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy:** 197U

Standard solution: 74 mg/mL of [USP Gadopentetate Monomeglumine RS](#)

Sample solution: 94 mg/mL of gadopentetate dimeglumine

- **B.** The absorption of the gadolinium emission line at 368.4 nm by the *Sample solution* in the test for *Content of Gadolinium* confirms the presence of gadolinium.
- **C.** 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: Dissolve 1.37 g of tetrabutylammonium perchlorate in 1 L of a mixture of [acetonitrile](#) and [water](#) (12:88).

Standard solution: 1.85 mg/mL of [USP Gadopentetate Monomeglumine RS](#) prepared as follows. Transfer a suitable quantity to a suitable volumetric flask containing 50% of the flask volume of 0.1% meglumine solution. Dilute with [water](#) to volume.

Sample solution: Nominally 2.35 mg/mL of gadopentetate dimeglumine from Injection in [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 195 nm

Column: 4.6-mm × 12.5-cm; 5-μm packing [L7](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 800 theoretical plates

Tailing factor: NMT 3.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of gadopentetate dimeglumine ($C_{14}H_{20}GdN_3O_{10} \cdot 2C_7H_{17}NO_5$) in the portion of Injection taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_s = concentration of [USP Gadopentetate Monomeglumine RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of gadopentetate dimeglumine, 938.02

M_{r2} = molecular weight of gadopentetate monomeglumine, 742.80

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• CONTENT OF MEGGLUMINE

Sample solution: Use the Injection.

Instrumental conditions

Mode: Polarimetry (see [Optical Rotation \(781\)](#))

Light source: Sodium lamp

Analytical wavelength: 589 nm

Cell: 10 cm

Analysis: Determine the angular rotation (see [Optical Rotation \(781\)](#)) of the *Sample solution*.

Calculate the amount of meglumine as a percentage of the labeled amount of gadopentetate dimeglumine ($C_{14}H_{20}GdN_3O_{10} \cdot 2C_7H_{17}NO_5$) in the portion of the Injection taken:

$$\text{Result} = [(100a/\alpha) \times (1/L)] \times F \times 100$$

a = observed angular rotation corrected for the *Blank* (degrees)

α = average specific rotation of meglumine, 24.9 deg.dL/g

L = label claim of Injection (mg/mL)

F = unit conversion factor from g/dL to mg/mL, 10

Acceptance criteria: Meglumine content is 37.4%–45.8% of the labeled amount of gadopentetate dimeglumine.

• CONTENT OF GADOLINIUM

Cesium chloride solution: 100 mg/mL of [cesium chloride](#) in [water](#)

Blank solution: *Cesium chloride solution*, hydrochloric acid (spectrophotometric grade), and [water](#) (10:1:89)

Standard stock solution: Transfer 1.15 g of gadolinium (III) oxide to a 100-mL volumetric flask, add 2.0 mL of [hydrochloric acid](#) to dissolve, and dilute with [water](#) to volume.

Standard solution A: 600 µg/mL of gadolinium prepared as follows. Transfer 3.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, add 5.0 mL of *Cesium chloride solution* and 0.5 mL of hydrochloric acid (spectrophotometric grade), and dilute with [water](#) to volume.

Standard solution B: 800 µg/mL of gadolinium prepared as follows. Transfer 4.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, add 5.0 mL of *Cesium chloride solution* and 5.0 mL of hydrochloric acid (spectroscopic grade), and dilute with [water](#) to volume.

Standard solution C: 1000 µg/mL of gadolinium prepared as follows. Transfer 5.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, add 5.0 mL of *Cesium chloride solution* and 5.0 mL of hydrochloric acid (spectroscopic grade), and dilute with [water](#) to volume.

Sample solution: Treat a volume of Injection, equivalent to 469 mg of gadopentetate dimeglumine, with 0.2 mL of [nitric acid](#) in a porcelain crucible, concentrate on a hot plate, char with a burner, and ignite in a muffle furnace at 800° until all black particles disappear (approximately 1 h). Allow the residue to cool on a refractory surface for 5 min, then equilibrate to room temperature in a desiccator. Dissolve the white residue so obtained in a mixture of 1.0 mL of [water](#) and 1.0 mL of hydrochloric acid (spectrophotometric grade) with heating. Transfer this solution to a 100-mL volumetric flask, add 10.0 mL of *Cesium chloride solution*, and dilute with [water](#) to volume.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectroscopy

Analytical wavelength: 368.4 nm at the gadolinium emission line

Lamp: Gadolinium hollow-cathode

Flame: Nitrous oxide–acetylene

Analysis

Samples: *Blank solution*, *Standard solutions*, and *Sample solution*

Blank the instrument with the *Blank solution*. Determine the absorbances of the *Standard solutions* and *Sample solution*. Plot the absorbances of the *Standard solutions* versus their concentrations, in µg/mL, of gadolinium, and draw the straight line best fitting the three plotted points. From the graph so obtained and the absorbance of the *Sample solution*, determine the concentration, in µg/mL, of gadolinium in the *Sample solution*.

Calculate the amount of gadolinium as a percentage of the labeled amount of gadopentetate dimeglumine ($C_{14}H_{20}GdN_3O_{10} \cdot 2C_7H_{17}NO_5$) in the portion of the Injection taken:

$$\text{Result} = [(C \times D)/(V \times L)] \times F \times 100$$