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Thallous Chloride Tl 201 Injection

» Thallous Chloride Tl 201 Injection is a sterile, isotonic, aqueous solution of radioactive thallium (^{201}Tl) in the form of thallous chloride suitable for intravenous administration. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{201}Tl as chloride, expressed in megabecquerels (microcuries or millicuries) per mL, at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 5.0 percent of the total radioactivity. It may contain a preservative or stabilizer.

Packaging and storage—Preserve in single-dose or multiple-dose containers.

Labeling—Label it to include the following, in addition to the information specified for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*: the time and date of calibration; the amount of ^{201}Tl as labeled thallous chloride expressed as total megabecquerels (microcuries or millicuries) and concentration as megabecquerels (microcuries or millicuries) per mL at the time of calibration; the expiration date and time; and the statement "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of ^{201}Tl is 73.1 hours.

Radionuclide identification (see *Radioactivity ⟨821⟩*)—Its gamma-ray spectrum is identical to that of a specimen of ^{201}Tl of known purity that exhibits a major photopeak at an energy of 167 KeV and a minor photopeak of 135 KeV.

Bacterial Endotoxins Test ⟨85⟩—The limit of endotoxin content is not more than 175/*V* USP Endotoxin Unit per mL of the Injection, when compared with the USP Endotoxin RS, in which *V* is the maximum recommended total dose, in mL, at the expiration date or time.

pH ⟨791⟩: between 4.5 and 7.5.

Radiochemical purity —Soak a 2.5- × 15.0-cm cellulose polyacetate strip in 0.05 M edetate disodium for 45 to 60 minutes. Remove the strip with forceps, taking care to handle the outer edges only. Place the strip between two absorbent pads, and blot to remove excess solution. Apply not less than 5 µL of a previously mixed solution consisting of equal volumes of Injection and 0.05 M edetate disodium to the center of the blotted strip, and mark the point of application. Attach the strip to the support bridge of an electrophoresis chamber containing equal portions of 0.05 M edetate disodium in each side of the chamber. Ensure that each end of the strip is in contact with the 0.05 M edetate disodium. Attach the chamber cover, and perform the electrophoresis at 250 volts for 30 minutes. Remove the strip from the chamber, and allow to air-dry without blotting. Using a suitable scanner and counting assembly, determine the radioactivity. Not less than 95.0% of the radioactivity on the strip migrates toward the cathode as a single peak.

Radionuclidic purity (see *Radioactivity ⟨821⟩*)—Using a suitable counting assembly, determine the radioactivity of each radionuclidic impurity in the Injection by use of a calibrated system. Not less than 95.0% of the total radioactivity is present as thallium 201. In addition, not more than 2.0% of thallium 200 (half-life is 26.1 hours), not more than 0.3% of lead 203 (half-life is 52.02 hours), and not more than 2.7% of thallium 202 (half-life is 12.23 days) are present.

Content of thallium—

Standard thallium solution—Transfer 235 mg of thallous chloride, accurately weighed, to a 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 1.0 mL of the resulting solution to a 100-mL volumetric flask, dilute with saline TS containing 0.9% benzyl alcohol to volume, and mix. This standard solution contains 2 µg of thallium per mL.

Procedure—Transfer 1.0-mL portions of the *Standard thallium solution* and the Injection to separate screw-cap test tubes. To each tube add 2 drops of a solution, prepared by carefully mixing 18 mL of nitric acid and 82 mL of hydrochloric acid, and mix. Then add to each tube 1.0 mL of sulfosalicylic acid solution (1 in 10), and mix. Add 2 drops of 12 N hydrochloric acid to each tube, and mix. To each tube add 4 drops of rhodamine B solution (50 mg of rhodamine B diluted with hydrochloric acid to 100.0 mL), and mix. Add 1.0 mL of diisopropyl ether. Screw the caps on tightly, shake the tubes by hand for 1 minute, accurately timed, releasing any pressure build-up by loosening the caps slightly. Recap the tubes and allow the phases to separate. Transfer 0.5 mL of the diisopropyl ether layer from each tube to clean tubes. Visually compare the ether layers: the color of the ether layer from the Injection is not darker than that from the *Standard thallium solution.*

Change to read:

Iron—Into separate cavities of a spot plate, place 0.1 mL of the Injection and 0.1 mL of *Standard Iron Solution* (see ▲*Iron ⟨241⟩, Procedures, Procedure 1*▲ (CN 1-Jun-2023)) diluted with water to a concentration of 5 µg per mL. Add to each cavity 0.1 mL of hydroxylamine hydrochloride solution (1 in 10), 1 mL of sodium acetate solution (1 in 4), and 0.1 mL of 0.5% dipyridyl solution (0.5 g of 2,2'-dipyridyl dissolved in 100 mL of

water containing 0.15 mL of hydrochloric acid), and mix. After 5 minutes, the color of the specimen of Injection is not darker than that of the *Standard Iron Solution.*

Copper—

Standard copper solution—Dissolve 0.982 g of $CuSO_4 \cdot 5H_2O$ in 1000 mL of 0.1 N hydrochloric acid. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix to obtain a Standard solution containing 5 µg of copper per mL.

Procedure—Into separate cavities of a spot plate, place 0.2 mL of the Injection and 0.2 mL of *Standard copper solution.* Add to each cavity 0.2 mL of water and 0.1 mL of iron thiocyanate solution (1.5 g ferric chloride and 2 g potassium thiocyanate dissolved in water and diluted with water to 100.0 mL). Mix, then add 0.1 mL of sodium thiosulfate solution (1 in 100), and again mix. The time required for the specimen of Thallous Chloride Tl 201 Injection to decolorize is equal to or longer than that observed for the *Standard copper solution.*

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩, except that the Injection may be distributed or dispensed prior to the completion of the test for *Sterility*, the latter test being started on the day of final manufacture, and except that it is not subject to the recommendations on *Container Content*.

Assay for radioactivity (see *Radioactivity*⟨821⟩)—Using a suitable counting assembly, determine the radioactivity in MBq (µCi or mCi) per mL of Injection by use of a calibrated system.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
THALLOUS CHLORIDE TL 201 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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