https://trungtamthuoc.com/

Cupric Chloride Injection

DEFINITION

Cupric Chloride Injection is a sterile solution of Cupric Chloride in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of copper (Cu).

IDENTIFICATION

• **A.** The *Sample solution* exhibits an absorption maximum at about 325 nm when prepared and tested as directed in the *Assay*.

ASSAY

Change to read:

• PROCEDURE

Sodium chloride solution: 1.35 g/L of sodium chloride

Standard stock solution: Transfer 1.000 g of copper to a 1000-mL volumetric flask, dissolve in 20 mL of nitric acid, and dilute with 0.2 N nitric acid to volume. This solution contains 1000 µg/mL of copper. Store in a polyethylene bottle.

Standard solutions: Pipet 15 mL of *Standard stock solution* into a 250-mL volumetric flask, dilute with water to volume, and mix. Transfer 4.0, 5.0, and 6.0 mL of this solution to separate 100-mL volumetric flasks containing 10 mL of *Sodium chloride solution*, dilute the contents of each flask with water to volume, and mix. These *Standard solutions* contain 2.4, 3.0, and 3.6 µg of copper per mL, respectively.

Sample stock solution: Transfer a volume of Injection, equivalent to 2 mg of copper, into 100 mL of water.

Sample solution: Pipet 15 mL of the *Sample stock solution* into a 100-mL volumetric flask. From the labeled amount of sodium chloride, if any, in the Injection, calculate the amount, in mg, of sodium chloride in the initial dilution, and add sufficient *Sodium chloride solution* to bring the total ▲sodium chloride▲ (ERR 1-Dec-2018) content of this flask to 13.5 mg. Dilute with water to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption

Analytical wavelength: 324.8 nm (copper emission line)

Lamp: Copper hollow-cathode

Flame: Air−acetylene

Blank: *Sodium chloride solution* and water (1 in 10)

Analysis

Samples: *Standard solutions* and *Sample solution*

Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, of copper, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, *C*, in µg/mL, of copper in the *Sample solution*.

Calculate the percentage of copper in the portion of Injection taken:

$$\text{Result} = [(C/V) \times F \times V_1 \times D] \times (100/L)$$

C = concentration of copper in the *Sample solution* (µg/mL)

V = volume of Injection (mL)

F = conversion factor from µg to mg, 1/1000

V_1 = volume of the *Sample stock solution*, 100 mL

D = dilution factor from the *Sample solution*, 100/15

L = label claim (mg/mL)

Acceptance criteria: 90.0%−110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 1.5–2.5

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 250.0 USP Endotoxin Units/mg of copper.

• **Particulate Matter in Injections** ⟨788⟩**:** Meets the requirements for small-volume injections

• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I or Type II glass.

• **Labeling:** Label the Injection to indicate that it is to be diluted to the appropriate strength with Sterile Water for Injection or other suitable fluid before administration.

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

Topic/Question	Contact	Expert Committee
CUPRIC CHLORIDE INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

---

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-8E0443BD-7C36-4BAA-A044-EFDBB39BB9C1_4_en-US

DOI: https://doi.org/10.31003/USPNF_M20690_04_01

DOI ref: 9a7cu