Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-50F68016-920D-458F-A8B7-3134CBD8854C_3_en-US
DOI: https://doi.org/10.31003/USPNF_M89585_03_01
DOI Ref: mw523

Zinc Chloride Injection

DEFINITION

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

IDENTIFICATION

• **A.** The *Sample solution*, prepared as directed in the *Assay*, exhibits an absorption maximum at 213.8 nm, when determined as directed in the *Assay*.

ASSAY

• **Procedure**

[Note—The *Standard solutions* and the *Sample solution* may be diluted quantitatively with water, if necessary, to obtain solutions of suitable concentrations adaptable to the linear or working range of the instrument.]

Sodium chloride solution: 0.9 mg/mL of sodium chloride in water

Standard stock solution A: 10 mg/mL of zinc in water prepared as follows. Transfer 3.11 g of zinc oxide to a 250-mL volumetric flask. Add 80 mL of 1 N sulfuric acid, warm to dissolve, and cool. Dilute with water to volume.

Standard stock solution B: 125 µg/mL of zinc in water from *Standard stock solution A*

Standard solution A: Transfer 2.0 mL of *Standard stock solution B* and 5 mL of *Sodium chloride solution* into a 500-mL volumetric flask, and dilute with water (0.50 µg/mL of zinc).

Standard solution B: Transfer 3.0 mL of *Standard stock solution B* and 5 mL of *Sodium chloride solution* into a 500-mL volumetric flask, and dilute with water (0.75 µg/mL of zinc).

Standard solution C: Transfer 4.0 mL of *Standard stock solution B* and 5 mL of *Sodium chloride solution* into a 500-mL volumetric flask, and dilute with water (1.0 µg/mL of zinc).

Sample solution: Transfer a volume of Injection, equivalent to 5 mg of zinc, to a 500-mL volumetric flask. Dilute with water to volume. Transfer 10.0 mL of this solution to 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 10.0-mL portion, and add a sufficient amount of *Sodium chloride solution* to bring the total sodium chloride content of the 100-mL volumetric flask to 0.9 mg. Dilute with water to volume.

Blank: Water

Instrumental conditions

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

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Zinc emission line at 213.8 nm

Lamp: Zinc hollow-cathode

Flame: Air–acetylene

Analysis

Samples: *Standard solutions* and *Sample solution*

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

Calculate the percentage of the labeled amount of zinc (Zn) in the portion of Injection taken:

$$\text{Result} = (C_O/C_U) \times 100$$

C_O = concentration of zinc in the *Sample solution* as determined from the standard curve (observed concentration, µg/mL)

C_U = nominal concentration of the *Sample solution*, based on the label claim of the Injection and the dilution factor (calculated concentration, µg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

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

SPECIFIC TESTS

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 25.0 USP Endotoxin Units/mg of zinc.

• **pH** ⟨791⟩**:** 1.5–2.5

• **Other Requirements:** It 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 with Water for Injection or other suitable fluid to appropriate strength before administration.

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

Topic/Question	Contact	Expert Committee
ZINC CHLORIDE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 32(5)

Current DocID: GUID-50F68016-920D-458F-A8B7-3134CBD8854C_3_en-US
Previous DocID: GUID-50F68016-920D-458F-A8B7-3134CBD8854C_1_en-US
DOI: https://doi.org/10.31003/USPNF_M89585_03_01
DOI ref: mw523