Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2023
Document Type: USP Monographs
DocId: GUID-403EF7C3-9D36-489E-90C2-4CAE8C6A6A2B_2_en-US
DOI: https://doi.org/10.31003/USPNF_M16685_02_01
DOI Ref: 5tru5

Add the following:

▲Sodium Chloride Compounded Injection

DEFINITION

Sodium Chloride Compounded Injection 234 mg/mL, 23.4%, (4 mEq/mL) contains NLT 95.0% and NMT 105.0% of the labeled amount of sodium chloride (NaCl).

Prepare Sodium Chloride Compounded Injection 234 mg/mL, 23.4%, (4 mEq/mL) as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Sodium chloride powder	7.02 g
Sterile water for Injection, a sufficient quantity to make	30 mL

In a suitable calibrated container, dissolve the *Sodium chloride* in about 27 mL of *Sterile water for Injection*. Add sufficient *Sterile water for Injection* to bring to final volume, and mix well. Pass through a sterile filter of 0.22-µm pore size into sterile single-dose container(s).

ASSAY

• **Procedure**

Mobile phase: 0.52 mL/L of methanesulfonic acid in water

Standard solution: 25 µg/mL of USP Sodium Chloride RS in water. Vortex or shake until well mixed.

Sample solution: Transfer about 2 mL of injection into a polystyrene cup. Pipette a 1.0 mL sample with a micropipette into a 100-mL volumetric flask. Rinse the pipette tip 2 times using water and add contents into the flask. Bring to volume with water. Vortex or shake until well mixed. Transfer 0.7 mL of the solution into a 25-mL volumetric flask. Rinse the pipette tip 2 times and add contents into the volumetric flask. Bring to volume with water. Vortex or shake until well mixed.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Conductivity

Column: 4-mm × 25-cm; packing L77

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for sodium chloride is about 3.21 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium chloride (NaCl) in the portion of Injection taken:

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

r_U = peak response of sodium chloride from the *Sample solution*

r_S = peak response of sodium chloride from the *Standard solution*

C_S = concentration of USP Sodium Chloride RS in the *Standard solution* (μg/mL)

C_U = nominal concentration of sodium chloride in the *Sample solution* (μg/mL)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.5–7.0

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in the *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 3.6 USP Endotoxin units/mL

• **Particulate Matter in Injections ⟨788⟩:** It meets the requirements.

Appearance: Clear, colorless solution with no particulates

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant glass sterile single-dose container(s). Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature.

• **Labeling:** Label to indicate that it is a concentrate, not for direct injection, and must be diluted prior to administration. Label to indicate that the osmolarity is 8.01 mOsm/mL (calc). Label to state single-use. Label to state the *Beyond-Use Date*.

• **USP Reference Standards ⟨11⟩**

USP Sodium Chloride RS▲ (USP 1-Aug-2023)

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

Topic/Question	Contact	Expert Committee
SODIUM CHLORIDE COMPOUNDED INJECTION	Selma Mitiche Associate Scientific Liaison	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 47(6)

Current DocID: GUID-403EF7C3-9D36-489E-90C2-4CAE8C6A6A2B_2_en-US
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