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Sodium Chloride Injection

DEFINITION

Sodium Chloride Injection is a sterile solution of Sodium Chloride in Water for Injection. It contains no antimicrobial agents. It contains NLT 95.0% and NMT 105.0% of the labeled amount of sodium chloride (NaCl).

IDENTIFICATION

- A. [IDENTIFICATION TESTS—GENERAL, Sodium\(191\)andChloride\(191\)](#): Meets the requirements

ASSAY

• PROCEDURE

Sample solution: Transfer a volume of Injection, equivalent to 90 mg of sodium chloride, into a conical flask. Add water, if necessary, to bring the volume to 10 mL, and add 10 mL of glacial acetic acid, 75 mL of methanol, and 3 drops of eosin Y TS.

Analysis: Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of sodium chloride (NaCl).

Acceptance criteria: 95.0%–105.0%

IMPURITIES

Change to read:

- [▲ IRON \(241\), Procedures, Procedure 1](#) ▲ (CN 1-Jun-2023)

Test preparation: Dilute 5.0 mL of Injection with water to 45 mL, and add 2 mL of hydrochloric acid.

Acceptance criteria: NMT 2 ppm

SPECIFIC TESTS

- [pH \(791\)](#): 4.5–7.0
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): NMT 0.5 USP Endotoxin Unit/mL where the labeled amount of sodium chloride in the Injection is between 0.5% and 0.9%, and NMT 3.6 USP Endotoxin Units/mL where the labeled amount of sodium chloride in the Injection is between 3.0% and 24.3%
- **OTHER REQUIREMENTS:** It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.
- **LABELING:** The label states the total osmolar concentration in mOsmol/L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol/mL.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

| Topic/Question | Contact | Expert Committee |
|----------------------------|-----------------------------------------------------------------------------|---------------------------|
| SODIUM CHLORIDE INJECTION | Documentary Standards Support | SM52020 Small Molecules 5 |
| REFERENCE STANDARD SUPPORT | RS Technical Services RSTECH@usp.org | SM52020 Small Molecules 5 |

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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