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Bacteriostatic Sodium Chloride Injection

DEFINITION

Bacteriostatic Sodium Chloride Injection is a sterile, isotonic solution of Sodium Chloride in Water for Injection, and it contains one or more suitable antimicrobial agents. It contains NLT 0.85% and NMT 0.95% of NaCl.

[NOTE—Use Bacteriostatic Sodium Chloride Injection with due regard for the compatibility of the antimicrobial agent or agents it contains with the particular medicinal substance that is to be dissolved or diluted.]

IDENTIFICATION

- **IDENTIFICATION TESTS—GENERAL**, [Sodium\(191\)](#) and [Chloride\(191\)](#): Meets the requirements

ASSAY

PROCEDURE

Sample solution: Equivalent to 90 mg of sodium chloride from the volume of Injection. 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 NaCl.

Acceptance criteria: 0.85%–0.95%

IMPURITIES

Change to read:

INORGANIC IMPURITIES

- ▲ [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

- **ANTIMICROBIAL AGENT(S):** It meets the requirements under [Antimicrobial Effectiveness Testing \(51\)](#), and meets the labeled claim for content of the antimicrobial agent(s) as determined by the method set forth under [Antimicrobial Agents—Content \(341\)](#), except use the following procedure when methylparaben and propylparaben are used as the antimicrobial agents.

Mobile phase: Methanol and water (7:3)

Standard stock solution: 1.2 mg/mL of [USP Methylparaben RS](#) and 0.12 mg/mL of [USP Propylparaben RS](#) in methanol

Standard solution: Pipet 5 mL of the *Standard stock solution* into a 50-mL volumetric flask, add by pipet 30 mL of methanol, and dilute with water to volume.

Sample solution: Pipet 1 mL of Injection into a 10-mL volumetric flask, add by pipet 7.0 mL of methanol, and dilute with water to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection size: 12 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor: 0.52 for methylparaben and 1.05 for propylparaben

Resolution: NLT 2.0 between the methylparaben and propylparaben peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration, in mg/mL, of methylparaben or propylparaben in the portion of Injection taken:

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

r_U = peak height from the *Sample solution*

r_S = peak height from the *Standard solution*

C_S = concentration of [USP Methylparaben RS](#) or [USP Propylparaben RS](#) in the *Standard solution* (mg/mL)

- **PARTICULATE MATTER IN INJECTIONS** (788): Meets the requirements for small-volume injections
- **pH** (791): 4.5–7.0
- **BACTERIAL ENDOTOXINS TEST** (85): NMT 1.0 USP Endotoxin Unit/mL
- **OTHER REQUIREMENTS**: It meets the requirements under [Injections and Implanted Drug Products](#) (1).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in single-dose or multiple-dose containers, of not larger than 30-mL size, preferably of Type I or Type II glass.
- **LABELING**: Label it to indicate the name(s) and proportion(s) of the added antimicrobial agent(s). Label it also to include the statement: NOT FOR USE IN NEWBORNS, in boldface capital letters, on the label immediately under the official name, printed in a contrasting color, preferably red. Alternatively, the statement may be placed prominently elsewhere on the label if the statement is enclosed within a box. Label it also to include the statement: NOT FOR INHALATION.
- **USP REFERENCE STANDARDS** (11):
[USP Methylparaben RS](#)
[USP Propylparaben RS](#)

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

Topic/Question	Contact	Expert Committee
BACTERIOSTATIC 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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