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Sodium Chloride Inhalation Solution

DEFINITION

Sodium Chloride Inhalation Solution is a sterile solution of Sodium Chloride in water purified by distillation or by reverse osmosis and rendered sterile. It contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium chloride (NaCl). It contains no antimicrobial agents or other added substances.

IDENTIFICATION

• **A. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*:** Meets the requirements

Delete the following:

▲• **B. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Chloride*:** Meets the requirements▲ (USP 1-Aug-2021)

Add the following:

▲• **B.** The retention time of the chloride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲

(USP 1-Aug-2021)

ASSAY

Change to read:

• **Procedure**

▲Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.

Solution A: 100 mM potassium hydroxide

Solution B: Water

Mobile phase: See *Table 1*. [Note—Alternatively, *Mobile phase* can be generated electrolytically using an automatic eluant generator.]

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	5	95
12	70	30
15	5	95
24	5	95

System suitability solution: 100 µg/mL of USP Sodium Chloride RS and 8 µg/mL of USP Sodium Nitrite RS in water

Standard solution: 100 µg/mL of USP Sodium Chloride RS in water

Sample solution: Nominally 100 µg/mL of sodium chloride from a suitable volume of Inhalation Solution in water

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4.0-mm × 5-cm; 11-µm packing L121. [Note—Alternatively, a 4.0-mm × 0.5-cm column that contains 5.0-µm packing L91 may be used.]

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Analytical: 4.0-mm × 25-cm; 7.5-µm packing L103. [NOTE—Alternatively, a 4.0-mm × 15-cm column that contains 5.0-µm packing L91 may be used.]

Column temperature: 35°

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for the chloride and nitrite peaks are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the chloride and nitrite peaks, *System suitability solution*

Tailing factor: NMT 2.0 for the chloride and nitrite peaks, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

r_S = peak response of 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)

▲ (USP 1-Aug-2021)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Add the following:

▲• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meets the requirements▲ (USP 1-Aug-2021)

SPECIFIC TESTS

• **STERILITY TESTS ⟨71⟩:** Meets the requirements

• **pH ⟨791⟩:** 4.5–7.0

ADDITIONAL REQUIREMENTS

Change to read:

• **PACKAGING AND STORAGE:** Preserve in single-dose containers, ▲and store at controlled room temperature.▲ (USP 1-Aug-2021)

Add the following:

▲• **USP REFERENCE STANDARDS ⟨11⟩**

USP Sodium Chloride RS

USP Sodium Nitrite RS▲ (USP 1-Aug-2021)

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

Topic/Question	Contact	Expert Committee
SODIUM CHLORIDE INHALATION SOLUTION	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

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