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Sodium Chloride Tablets

DEFINITION
Sodium Chloride Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of sodium chloride (NaCl).

IDENTIFICATION

Change to read:

• ▲**A.**▲ (USP 1-MAY-2021) **IDENTIFICATION TESTS—GENERAL** ⟨191⟩, *Chemical Identification Tests, Sodium*

Sample solution: A filtered extract of Tablets

Acceptance criteria: Meet the requirements

Change to read:

• ▲**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-May-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 stock solution: Nominally 5 mg/mL of sodium chloride prepared as follows. Finely powder NLT 30 Tablets and transfer an appropriate portion of the powder to a suitable volumetric flask. Dissolve in about 50% of the final volume of water. Dilute with water to volume.

Sample solution: Nominally 100 µg/mL of sodium chloride in water from the *Sample stock solution*

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; 5.0-µm packing L91 column may be used.]

Analytical: 4.0-mm × 25-cm; 7.5-µm packing L103. [NOTE—Alternatively, a 4.0-mm × 15-cm; 5.0-µm packing L91 column 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 Tablets 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)

Acceptance criteria: 95.0%–105.0%▲ (USP 1-May-2021)

PERFORMANCE TESTS

• **DISINTEGRATION ⟨701⟩**

Time: 30 min

Acceptance criteria: Meet the requirements

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

IMPURITIES

• **IODIDE OR BROMIDE**

Sample: 2.0 g of powdered Tablets

Sample solution: Digest the *Sample* with 25 mL of warm alcohol for 3 h, cool, and filter. Use the filtrate.

Analysis: Evaporate the *Sample solution* to dryness, dissolve the residue in 5 mL of water, filter if necessary, and add 1 mL of chloroform. Cautiously introduce, dropwise and with constant agitation, 5 drops of 33% (v/v) chlorine TS in water.

Acceptance criteria: The chloroform does not acquire a violet, yellow, or orange color.

• **BARIUM**

Sample: 4.0 g of powdered Tablets

Sample solution: Digest the *Sample* with 20 mL of water, and filter. Use the filtrate.

Analysis: Divide the *Sample solution* into two equal portions. To one portion add 2 mL of 2 N sulfuric acid and to the other portion add 2 mL of water, and stand for 2 h.

Acceptance criteria: The solutions are equally clear.

• **CALCIUM AND MAGNESIUM**

Sample: 1 g of powdered Tablets

Sample solution: Digest the *Sample* with 50 mL of water, and filter. Use the filtrate.

Analysis: Add 4 mL of 6 N ammonium hydroxide to the *Sample solution*, and divide the mixture into two equal portions. Treat one portion with 1 mL of ammonium oxalate TS and the other portion with 1 mL of dibasic sodium phosphate TS.

Acceptance criteria: Neither mixture becomes turbid within 5 min.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Add the following:

▲• **USP REFERENCE STANDARDS ⟨11⟩**

USP Sodium Chloride RS

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

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

Topic/Question	Contact	Expert Committee
SODIUM CHLORIDE TABLETS	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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