Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2021
Document Type: USP Monographs
DocId: GUID-D824FB38-4D6B-49B5-8232-CF72FCA07C70_2_en-US
DOI: https://doi.org/10.31003/USPNF_M76140_02_01
DOI Ref: u91dr

Sodium Chloride Tablets for Solution

DEFINITION

Sodium Chloride Tablets for Solution are composed of Sodium Chloride in compressed form, containing no added substance. Sodium Chloride Tablets for Solution 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 for Solution

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 for Solution 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 for 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)

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 for Solution

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 for Solution

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 for Solution

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 FOR 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(1)

Current DocID: GUID-D824FB38-4D6B-49B5-8232-CF72FCA07C70_2_en-US

DOI: https://doi.org/10.31003/USPNF_M76140_02_01

DOI ref: u91dr