Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2021
Document Type: USP Monographs
DocId: GUID-C6962C62-4D93-48FF-A700-7915F3AE9972_2_en-US
DOI: https://doi.org/10.31003/USPNF_M76120_02_01
DOI Ref: kg03o

Sodium Chloride Ophthalmic Solution

DEFINITION

Sodium Chloride Ophthalmic Solution is a sterile solution of Sodium Chloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium chloride (NaCl). It may contain suitable antimicrobial and stabilizing agents. It contains a buffer.

IDENTIFICATION

• **A.** [Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*]

Sample solution: Heat a portion of Ophthalmic Solution to boiling, and filter while hot. Use the filtrate after cooling.

Acceptance criteria: Meets the requirements

Delete the following:

▲• **B.** [Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Chloride*]

Sample solution: Heat a portion of Ophthalmic Solution to boiling, and filter while hot. Use the filtrate after cooling.

Acceptance criteria: 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 Ophthalmic 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.]

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 Ophthalmic 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: 90.0%–110.0%▲ (USP 1-Aug-2021)

SPECIFIC TESTS

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

• **pH ⟨791⟩:** 6.0–8.0

Add the following:

▲• **OTHER REQUIREMENTS:** It meets the requirements in *Ophthalmic Products—Quality Tests ⟨771⟩*.▲ (USP 1-Aug-2021)

ADDITIONAL REQUIREMENTS

Change to read:

• **PACKAGING AND STORAGE:** Preserve in tight 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 OPHTHALMIC 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(2)
Current DocID: GUID-C6962C62-4D93-48FF-A700-7915F3AE9972_2_en-US
DOI: https://doi.org/10.31003/USPNF_M76120_02_01
DOI ref: kg03o