

Status: Currently Official on 16-Feb-2025  
Official Date: Official as of 01-Aug-2022  
Document Type: USP Monographs  
DocId: GUID-3C7C0757-C7F8-484F-99AF-3096884639CC\_2\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M76110\\_02\\_01](https://doi.org/10.31003/USPNF_M76110_02_01)  
DOI Ref: rj6yd

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# Sodium Chloride Ophthalmic Ointment

**DEFINITION**  
Sodium Chloride Ophthalmic Ointment is Sodium Chloride in a suitable ophthalmic ointment base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium chloride (NaCl). It is sterile.

**IDENTIFICATION**  
• **A.** ~~IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sodium~~

**Sample solution:** Transfer a quantity of Ophthalmic Ointment, equivalent to about 200 mg of sodium chloride, to a separator containing 25 mL of [ether](#), and extract with 5 mL of [water](#). Use the aqueous extract.  
**Acceptance criteria:** Meets the requirements

**Delete the following:**  
▲ **B.** ~~IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride~~  
**Sample solution:** Use the *Sample solution* from *Identification A*.  
**Acceptance criteria:** Meets the requirements▲ (USP 1-Aug-2022)

**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-2022)

**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 by 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 625 µg/mL of sodium chloride prepared as follows. Transfer an appropriate portion of Ophthalmic Ointment to a suitable flask. Add 20 mL each of [water](#) and [methylene chloride](#), and shake well until Ophthalmic Ointment is dispersed. Allow the layers to separate and use the aqueous layer.  
**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 Ophthalmic Ointment taken:

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-2022)

**Acceptance criteria:** 90.0%–110.0%

**SPECIFIC TESTS**  
• **STERILITY TESTS (71):** Meets the requirements  
• **OTHER REQUIREMENTS:** It meets the requirements in [Ophthalmic Products—Quality Tests \(771\)](#), [Drug Product Quality](#), [Universal Tests](#), [Particulate and Foreign Matter](#) and [Container Contents](#).

**ADDITIONAL REQUIREMENTS**  
• **PACKAGING AND STORAGE:** Preserve in collapsible ophthalmic ointment tubes. Store at controlled room temperature. Store away from heat. Protect from freezing.  
**Add the following:**  
▲ • **USP REFERENCE STANDARDS (11).**  
[USP Sodium Chloride RS](#)  
[USP Sodium Nitrite RS](#)▲ (USP 1-Aug-2022)

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

Topic/Question	Contact	Expert Committee
SODIUM CHLORIDE OPHTHALMIC OINTMENT	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM52020 Small Molecules 5

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. 46(5)

**Current DocID: GUID-3C7C0757-C7F8-484F-99AF-3096884639CC\_2\_en-US**

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