

# 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:

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

$r_U$  = 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-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<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** [Chromatographic Database](#)