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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:

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

 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	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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