Sodium Chloride Irrigation

» Sodium Chloride Irrigation is Sodium Chloride Injection that has been suitably packaged, and it contains no antimicrobial agents. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of NaCl.

Packaging and storage—Preserve in single-dose containers.

Identification—It responds to the tests for Sodium (191) and for Chloride (191).

Bacterial endotoxins (85)—It contains not more than 0.5 USP Endotoxin Unit per mL.

Sterility (71): meets the requirements.

Other requirements—It meets the requirements for pH, Iron, Heavy metals, and Assay under Sodium Chloride Injection.

Sodium Chloride Ophthalmic Ointment

» Sodium Chloride Ophthalmic Ointment is Sodium Chloride in a suitable ophthalmic ointment base. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of NaCl. It is sterile.

Packaging and storage—Preserve in collapsible ophthalmic ointment tubes.

Identification—Transfer a quantity of Ophthalmic Ointment, equivalent to about 200 mg of sodium chloride, to a separator containing about 25 mL of ether, and extract with 5 mL of water: the aqueous extract so obtained responds to the tests for Sodium (191), and for Chloride (191).

Sterility (71): meets the requirements.

Minimum fill (755): meets the requirements.

Metal particles (751): meets the requirements.

Assay—Transfer an accurately weighed quantity of Ophthalmic Ointment, equivalent to about 100 mg of sodium chloride, to a separator containing about 50 mL of ether, and extract with four 20-mL portions of water. Combine the aqueous extracts in a conical flask, evaporate to a volume of about 10 mL, and add 10 mL of glacial acetic acid, 75 mL of methanol, and 0.5 mL of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.

Sodium Chloride Inhalation Solution

» Sodium Chloride Inhalation Solution is a sterile solution of Sodium Chloride in water purified by distillation or by reverse osmosis and rendered sterile. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of NaCl. It contains no antimicrobial agents or other added substances.

Packaging and storage—Preserve in single-dose containers.

Identification—It responds to the tests for Sodium (191) and for Chloride (191).

Sterility (71): meets the requirements.

pH (791): between 6.5 and 7.0.

Assay—Pipet a volume of Inhalation Solution, equivalent to about 90 mg of sodium chloride, into a conical flask, and add 10 mL of glacial acetic acid, 75 mL of methanol, and 0.5 mL of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.

Sodium Chloride Ophthalmic Solution

» Sodium Chloride Ophthalmic Solution is a sterile solution of Sodium Chloride. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of sodium chloride. It may contain suitable antimicrobial and stabilizing agents. It contains a buffer.

Packaging and storage—Preserve in tight containers.

Identification—Heat a portion of Ophthalmic Solution to boiling, and filter while hot. After cooling, the filtrate responds to the tests for Sodium (191) and for Chloride (191).

Sterility (71): meets the requirements.

pH (791): between 6.0 and 8.0.

Assay—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 90 mg of sodium chloride, to a conical flask, and add 10 mL of glacial acetic acid, 75 mL of methanol, and 0.5 mL of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.

Sodium Chloride Tablets

» Sodium Chloride Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of NaCl.

Packaging and storage—Preserve in well-closed containers.

Identification—A filtered extract of Tablets responds to the tests for Sodium (191) and for Chloride (191).

Disintegration (701): 30 minutes.

Uniformity of dosage units (905): meet the requirements.