

Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-62E70669-6A68-44D5-9EC6-918331F2DC67_3_en-US
DOI: https://doi.org/10.31003/USPNF_M3720_03_01
DOI Ref: 1pm8d

© 2025 USPC
Do not distribute

Ammonium Chloride Injection

» Ammonium Chloride Injection is a sterile solution of Ammonium Chloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of NH_4Cl . Hydrochloric acid may be added to adjust the pH.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I or Type II glass.

Labeling—The label states the content of ammonium chloride in terms of weight and of milliequivalents in a given volume. The label states also the total osmolar concentration in mOsmol per L or per mL. The label states that the Injection is not for direct injection but is to be diluted with Sodium Chloride Injection to the appropriate strength before use.

Identification—It responds to the tests for [Ammonium \(191\)](#), and for [Chloride \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85) —It contains not more than 1.72 USP Endotoxin Units per mEq of chloride.

pH (791): between 4.0 and 6.0, in a concentration of not more than 100 mg of ammonium chloride per mL.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections.

Chloride content—Transfer an accurately measured volume of Injection, evaporated, if necessary, equivalent to about 2 g of ammonium chloride, to a 200-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a conical flask, 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 3.545 mg of Cl. The content of Cl is between 63.0% and 70.3% of the labeled amount of ammonium chloride.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Transfer an accurately measured volume of Injection, equivalent to about 200 mg of ammonium chloride, to a 500-mL Kjeldahl flask, dilute with water to 200 mL, mix, and add 50 mL of sodium hydroxide solution (2 in 5). Immediately connect the flask by means of a distillation trap to a well-cooled condenser, the delivery tube of which dips into 40 mL of boric acid solution (1 in 25) contained in a suitable receiver. Heat to boiling, and distill about 200 mL. Cool the liquid in the receiver, if necessary, then add methyl red TS, and titrate with 0.1 N sulfuric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N sulfuric acid is equivalent to 5.349 mg of NH_4Cl .

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

Topic/Question	Contact	Expert Committee
AMMONIUM CHLORIDE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: [GUID-62E70669-6A68-44D5-9EC6-918331F2DC67_3_en-US](#)

Previous DocID: [GUID-62E70669-6A68-44D5-9EC6-918331F2DC67_1_en-US](#)

DOI: https://doi.org/10.31003/USPNF_M3720_03_01

DOI ref: [1pm8d](#)