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Hydrochloric Acid Compounded Injection

Change to read:

DEFINITION

Hydrochloric Acid Compounded Injection contains NLT 90% and NMT 110% of the labeled amount of hydrochloric acid (HCl), equivalent to NLT 328 mg and NMT 401 mg of hydrochloric acid (HCl) in 100 mL.

Prepare Hydrochloric Acid Compounded Injection, 0.1 N, as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Hydrochloric Acid, 1.0 N	10 mL
Sodium Chloride Injection, 0.45% or 0.9%, a sufficient quantity to make	100 mL

Prepare *1.0 N Hydrochloric Acid* by adding Hydrochloric Acid to *Purified Water* in an appropriate volumetric flask with continuous stirring. Allow the solution to cool to room temperature, add sufficient *Purified Water* to bring to final volume, and continue mixing for 1 min. Pass through a compatible filter of 0.45-µm pore size to reduce particulate matter load. Accurately measure the nonsterile *1.0 N Hydrochloric Acid* with an appropriate glass or plastic device, and accurately dilute to final volume with *0.45% or 0.9% Sodium Chloride Injection*. Sterilize the solution by passing through a sterile acid-compatible membrane filter of 0.2-µm pore size into a sterile intravenous polypropylene container in an ISO Class 5 environment. ▲[NOTE—This is a high-risk level compounded sterile preparation (CSP) that shall be prepared according to *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*.]▲ (CN 1-May-2020)

ASSAY

• **PROCEDURE**

Sample: 25 mL

Blank: 25 mL of water

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.5 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Place the *Sample* in a conical flask, add methyl red TS, and titrate with *Titrant*.

Calculate the weight of hydrochloric acid in 100 mL:

$$\text{Result} = [(V_S - V_B) \times N \times F] \times D$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 36.46 mg/mEq

D = dilution factor, 4

Acceptance criteria: 328–401 mg in 100 mL

SPECIFIC TESTS

• **pH ⟨791⟩:** 1.0–1.2

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed under *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 1.5 USP Endotoxin Units/mL

Change to read:

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in a single-dose polypropylene container. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** ▲If a sterility test and bacterial endotoxin test is passed, NMT 120 days when stored at controlled room temperature or in a refrigerator. In the absence of passing a sterility test and endotoxin test, the storage periods at controlled room temperature or cold temperature for high-risk level CSPs applies (see *CSP Microbial Contamination Risk Levels* in *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).▲ (CN 1-May-2020)

• **Labeling:** Label it Hydrochloric Acid Compounded Injection, 0.1 N. Label it to state that this is a single-dose container. Label it to state the *Beyond-Use Date*.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
HYDROCHLORIC ACID COMPOUNDED INJECTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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