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Anticoagulant Sodium Citrate Solution

DEFINITION

Anticoagulant Sodium Citrate Solution is a sterile solution of Sodium Citrate in Water for Injection. It contains, in each 100 mL, NLT 3.80 g and NMT 4.20 g of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$). It contains no antimicrobial agents.

Prepare Anticoagulant Sodium Citrate Solution as follows.

Sodium Citrate (dihydrate)	40 g
Water for Injection, a sufficient quantity to make	1000 mL

[NOTE—Anhydrous sodium citrate (35.1 g) may be used instead of the dihydrate.]

Dissolve the *Sodium Citrate* in sufficient *Water for Injection* to make 1000 mL, and filter until clear. Place the solution in suitable containers, and sterilize.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Citrate (191):** Meets the requirements when evaporated to a concentration of 1 in 20
- **B. IDENTIFICATION TESTS—GENERAL, Sodium (191):** Meets the requirements when evaporated to a concentration of 1 in 20

ASSAY

• **PROCEDURE**

Mobile phase, Standard preparation 1, and Chromatographic system: Proceed as directed in [Assay for Citric Acid/Citrate and Phosphate \(345\)](#).

Sample solution: Pipet 10 mL of Solution into a suitable volumetric flask, and proceed as directed in [Assay for Citric Acid/Citrate and Phosphate \(345\)](#), [Sample solution \(for the assay of citric acid/citrate\)](#).

Analysis

Samples: *Standard preparation 1* and *Sample solution*

Proceed as directed in [Assay for Citric Acid/Citrate and Phosphate \(345\)](#), [Procedure](#).

Calculate the quantity, in g, of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$) in the volume of Solution taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (M_{r1}/M_{r2}) \times D \times F$$

r_U = peak area of citrate from the *Sample solution*

r_S = peak area of citrate from *Standard preparation 1*

C_S = concentration of citrate in *Standard preparation 1* (µg/mL)

M_{r1} = molecular weight of sodium citrate dihydrate, 294.10

M_{r2} = molecular weight of citrate ($C_6H_5O_7$), 189.10

D = dilution factor

F = conversion factor, 0.000001 g/µg

Acceptance criteria: In each 100 mL, 3.80–4.20 g of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$)

SPECIFIC TESTS

- **pH (791):** 6.4–7.5
- **BACTERIAL ENDOTOXINS TEST (85):** Contains NMT 5.56 USP Endotoxin Units/mL
- **OTHER REQUIREMENTS:** Meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose containers, preferably of Type I or Type II glass.
- **USP REFERENCE STANDARDS (11):**
[USP Citric Acid RS](#)

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

Topic/Question	Contact	Expert Committee
ANTICOAGULANT SODIUM CITRATE SOLUTION	Rebecca C. Potts Associate Scientific Liaison	BIO32020 Biologics Monographs 3 - Complex Biologics and Vaccines

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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