

Sodium Bicarbonate Compounded Injection

DEFINITION
Sodium Bicarbonate Compounded Injection contains NLT 95.0% and NMT 105.0% of the labeled amount of sodium bicarbonate (NaHCO₃). It contains no bacteriostat or other preservatives.
Prepare Sodium Bicarbonate Compounded Injection 8.4% (1 mEq/mL) as follows (see [Pharmaceutical Compounding—Sterile Preparations \(797\)](#)).

Sodium Bicarbonate	8.4 g
Sterile Water for Injection, a sufficient quantity to make	100 mL

Dissolve the Sodium Bicarbonate in sufficient Sterile Water for Injection and bring to final volume. Pass through a sterile filter of 0.22-µm pore size into a sterile container.

ASSAY
Change to read:
• **PROCEDURE FOR SODIUM**
Mobile phase: 8 mM methanesulfonic acid
Standard solution: 0.025 mg/mL of sodium prepared with [USP Sodium Chloride RS](#) and water
Sample solution: Transfer 1 mL of Injection into a 100-mL volumetric flask, and dilute with water to volume.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: Conductivity
Column: ▲4.0▲ (USP 1-May-2024) -mm × 25-cm; packing L97
Column temperature: 30°
Flow rate: 1.0 mL/min
Injection volume: 10 µL
System suitability
Sample: Standard solution
[NOTE—The retention time for sodium is about 3.6 min.]
Suitability requirements
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0% for replicate injections
Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of the labeled amount of sodium (Na) in the portion of Injection taken:

Result = (r_U/r_S) × (C_S/C_U) × 100

r_U = peak response of sodium from the Sample solution
r_S = peak response of sodium from the Standard solution
C_S = concentration of sodium in the Standard solution (mg/mL)

C_U = nominal concentration of sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

• **PROCEDURE FOR SODIUM BICARBONATE**

Sample solution: A volume of Injection, equivalent to about 3 g of sodium bicarbonate

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 1 N hydrochloric acid VS

Endpoint detection: Visual

Analysis: Add methyl red TS to the *Sample solution*. Add *Titrant* slowly, with constant stirring, until the solution becomes faintly pink. Heat the solution to boiling, cool, and continue the titration until the faint pink color no longer fades after boiling. Perform a blank determination, and make any necessary correction.

Calculate the percentage of the labeled amount of sodium bicarbonate (NaHCO_3) in the portion of Injection taken:

$$\text{Result} = [(V_S - V_B) \times N_A \times F \times 100] / W$$

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

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

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

F = equivalency factor, 84.01 mg/mEq

W = sample weight (mg)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **pH (791):** 7.0–8.5
- **STERILITY TESTS (71):** Meets the requirements
- **BACTERIAL ENDOTOXINS TEST (85):** NMT 5.0 USP Endotoxin Units/mEq of sodium bicarbonate
- **PARTICULATE MATTER IN INJECTIONS (788):** Meets the requirements for small-volume injections

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in single-dose glass containers. Store at controlled room temperature.
- **BEYOND-USE DATE:** In the absence of passing a sterility and endotoxin test, the storage conditions for high-risk compounded sterile preparations (CSPs) in [Pharmaceutical Compounding—Sterile Preparations \(797\)](#), apply. After successful completion of sterility and endotoxin testing, NMT 120 days after the date on which it was compounded when stored at controlled room temperature.
- **LABELING:** Label it to state the *Beyond-Use Date*. The label states the total osmolar concentration in mOsmol/mL.
- **USP REFERENCE STANDARDS (11):**
[USP Sodium Chloride RS](#)

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

Topic/Question	Contact	Expert Committee
SODIUM BICARBONATE COMPOUNDED INJECTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

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