Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2024
Document Type: USP Monographs
DocId: GUID-8D4410EF-295B-44A0-8370-DB88C1FCED73_5_en-US
DOI: https://doi.org/10.31003/USPNF_M10963_05_01
DOI Ref: nnoxr

Sodium Bicarbonate Compounded Injection

DEFINITION

Sodium Bicarbonate Compounded Injection contains NLT 95.0% and NMT 105.0% of the labeled amount of sodium bicarbonate ($NaHCO_3$). 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:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 48(4)

Current DocID: GUID-8D4410EF-295B-44A0-8370-DB88C1FCED73_5_en-US

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