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Sodium Bicarbonate Injection

» Sodium Bicarbonate Injection is a sterile solution of Sodium Bicarbonate in Water for Injection, the pH of which may be adjusted by means of added Carbon Dioxide. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of NaHCO_3 .

[**NOTE**—Do not use the Injection if it contains a precipitate.]

Packaging and storage—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I glass. Store at controlled room temperature.

Labeling—The label states the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.

Identification—It responds to the tests for [Sodium \(191\)](#) and for [Bicarbonate \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 5.0 USP Endotoxin Units per mEq.

pH (791): between 7.0 and 8.5.

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

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

Assay—Measure accurately a volume of Injection, equivalent to about 3 g of sodium bicarbonate, add methyl red TS, and titrate with 1 N hydrochloric acid VS. Add the acid 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. Each mL of 1 N hydrochloric acid is equivalent to 84.01 mg of NaHCO_3 .

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

Topic/Question	Contact	Expert Committee
SODIUM BICARBONATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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