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Sodium Acetate Injection

» Sodium Acetate Injection is a sterile solution of Sodium Acetate in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of CH_3COONa .

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass.

Labeling—The label states the sodium acetate content in terms of weight and of milliequivalents in a given volume. Label the Injection to indicate that it is to be diluted to appropriate strength with water or other suitable fluid prior to administration. The label states also 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 [Acetate <191>](#).

[BACTERIAL ENDOTOXINS TEST <85>](#)—It contains not more than 3.90 USP Endotoxin Units per mEq.

[pH <791>](#): between 6.0 and 7.0.

[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—

Standard stock solution—Dissolve 570.0 mg of sodium chloride, previously dried at 105° for 2 hours, in 100 mL of water, transfer to a 1000-mL volumetric flask, dilute with water to volume, and mix. Each mL of this solution contains 224 µg of sodium, equivalent to 800 µg of anhydrous sodium acetate.

Standard preparations—Transfer to each of four 100-mL volumetric flasks 10 mL of a nonionic wetting agent (1 in 500). Dilute the contents of one of the flasks with water to volume to provide a blank. To the remaining flasks add, respectively, 5.0, 10.0, and 15.0 mL of *Standard stock solution*, dilute with water to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 800 mg of anhydrous sodium acetate, to a 1000-mL volumetric flask, dilute with water to volume, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask containing 10 mL of a nonionic wetting agent (1 in 500), dilute with water to volume, and mix.

Standard graph—Set a flame photometer for maximum transmittance at a wavelength of about 589 nm. Adjust the instrument to zero transmittance with the blank, and to 100% transmittance with the most concentrated of the *Standard preparations*. Read the transmittances of the other *Standard preparations*, and plot transmittances versus equivalent concentration of sodium acetate.

Procedure—Adjust the instrument as directed under *Standard graph*, read the transmittance of the *Assay preparation*, and calculate the sodium acetate content, in mg per mL, of Injection.

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

Topic/Question	Contact	Expert Committee
SODIUM ACETATE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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