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Potassium Acetate Injection

» Potassium Acetate Injection is a sterile solution of Potassium 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 $C_2H_3KO_2$.

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

Labeling—The label states the potassium 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 *Potassium* ⟨191⟩ and for *Acetate* ⟨191⟩.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 8.80 USP Endotoxin Units per mEq.

pH ⟨791⟩: between 5.5 and 8.0, when diluted with water to 1.0% of potassium acetate.

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—

Potassium stock solution—Dissolve 190.7 mg of potassium chloride, previously dried at 105° for 2 hours, in water. Transfer to a 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 100.0 mL of this solution to a 1000-mL volumetric flask, dilute with water to volume, and mix. This solution contains 10 µg of potassium (equivalent to 19.07 µg of potassium chloride) per mL.

Standard preparations—To separate 100-mL volumetric flasks transfer 10.0, 15.0, and 20.0 mL, respectively, of *Potassium stock solution*. To each flask add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix. The *Standard preparations* contain, respectively, 1.0, 1.5, and 2.0 µg of potassium per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 2 g of potassium acetate, to a 500-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the solution to a 250-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the potassium emission line of 766.5 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a potassium hollow-cathode lamp and an air–acetylene flame, using water as the blank. Plot the absorbance of the *Standard preparation* versus concentration, in µg per mL, of potassium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, in µg per mL, of potassium in the *Assay preparation*. Calculate the quantity, in mg, of $C_2H_3KO_2$ in the portion of Injection taken by the formula:

$$500C(2.510)$$

in which C is the concentration, in µg per mL, of potassium in the *Assay preparation*, and 2.510 is the ratio of the molecular weight of potassium acetate to the atomic weight of potassium.

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POTASSIUM ACETATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

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Chromatographic Database Information: Chromatographic Database

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