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Potassium Phosphates Injection

» Potassium Phosphates Injection is a sterile solution of Monobasic Potassium Phosphate and Dibasic Potassium Phosphate in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amounts of monobasic potassium phosphate (KH_2PO_4) and dibasic potassium phosphate (K_2HPO_4). It contains no bacteriostat or other preservative.

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

Labeling—The label states the potassium content in terms of milliequivalents in a given volume, and states also the elemental phosphorus content in terms of millimoles 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, and that once opened any unused portion is to be discarded. 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 *Phosphate* ⟨191⟩.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.10 USP Endotoxin Units per mg of potassium phosphates.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume Injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay for monobasic potassium phosphate—Transfer an accurately measured volume of Injection, equivalent to about 300 mg of monobasic potassium phosphate, to a 100-mL beaker, and dilute with water to about 50 mL. Place the electrodes of a suitable pH meter in the solution, and titrate with 0.1 N sodium hydroxide VS to the inflection point to a pH of about 9.1. Each mL of 0.1 N sodium hydroxide is equivalent to 13.61 mg of KH_2PO_4.

Assay for dibasic potassium phosphate—Transfer an accurately measured volume of Injection, equivalent to about 300 mg of dibasic potassium phosphate, to a 100-mL beaker, and dilute with water to about 50 mL. Place the electrodes of a suitable pH meter in the solution, and titrate with 0.1 N hydrochloric acid VS to the inflection point to a pH of about 4.2. Each mL of 0.1 N hydrochloric acid is equivalent to 17.42 mg of K_2HPO_4.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
POTASSIUM PHOSPHATES 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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