Quality standards

Edition: BP 2025 (Ph. Eur. 11.6 update)

Dipotassium Hydrogen Phosphate Injection

General Notices

Dipotassium Phosphate Injection

DEFINITION

Dipotassium Hydrogen Phosphate Injection is a sterile solution of Dipotassium Hydrogen Phosphate in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of dipotassium hydrogen phosphate, K2HPO4

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Yields the reactions characteristic of potassium salts and reaction B characteristic of phosphates, Appendix VI.

TESTS

Alkalinity

pH, 9.0 to 10.0, Appendix V L.

ASSAY

Dilute, if necessary, a volume of the injection with sufficient <u>carbon dioxide-free water</u> to produce a solution containing 8.71% w/v (1 millimole of potassium ion per mL) of dipotassium hydrogen phosphate. Titrate 20 mL with <u>0.5m hydrochloric acid VS</u> using a mixture of 4 volumes of <u>bromocresol green solution</u> and 1 volume of <u>methyl red solution</u> as indicator. Each mL of <u>0.5m hydrochloric acid VS</u> is equivalent to 87.1 mg of K_2HPO_4 .

LABELLING

The label states (1) the percentage w/v of Dipotassium Phosphate; (2) the concentration of the potassium ion in millimoles.

