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Potassium Acetate Sterile Concentrate

General Notices

NOTE: This monograph has been developed to cover unlicensed formulations.

Details for the public consultation of this monograph are as follows:

<i>Expert Advisory Group ULM:</i>	<i>Unlicensed Medicines</i>
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<i>Notes:</i>	Revised monograph

Action and use

Used in Parenteral Nutrition Solutions.

DEFINITION

Potassium Acetate Sterile Concentrate is a sterile solution of Potassium Acetate in a suitable solvent.

The concentrate complies with the requirements for Concentrates for Injections or Infusions stated under Parenteral Preparations and with the following requirements. Where appropriate, the concentrate also complies with the requirements stated under Unlicensed Medicines.

Content of potassium acetate, C₂H₃KO₂

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Yields reaction A characteristic of *potassium salts* and reaction A characteristic of *acetates*, [Appendix VI](#).

TESTS

Acidity or alkalinity

pH of the concentrate, diluted to contain 1% w/v of Potassium Acetate, 6.5 to 8.5, [Appendix V L](#).

Sodium

Not more than 0.5%, calculated with respect to the content of potassium acetate, when determined by the following method.

Carry out the method for *atomic emission spectrophotometry*, [Appendix II D](#), Method II, using the following solutions and measuring at 589 nm.

- (1) Dilute the concentrate with [water](#) to produce a solution containing 1% w/v of Potassium Acetate.
- (2) Prepare the [standard solutions](#) using [sodium standard solution \(200 ppm Na\)](#), diluted as necessary with [water](#).

ASSAY

Dilute a quantity of the concentrate with sufficient [water](#) to produce a solution containing 1% w/v of Potassium Acetate. Evaporate a volume of the resulting solution containing 80 mg of Potassium Acetate to dryness, dissolve the residue in 20 mL of [anhydrous acetic acid](#) and carry out Method I for non-aqueous titration, [Appendix VIII A](#), using 0.2 mL of [1-naphtholbenzein solution](#) as indicator. Carry out a blank titration using [water](#) in place of the preparation being examined.

Each mL of 0.1M [perchloric acid](#) is equivalent to 9.81 mg of $C_2H_3KO_2$.

LABELLING

The strength is stated as the percentage w/v of Potassium Acetate and as the approximate concentration of potassium ions, in mmol, in a suitable volume.