



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

## Sodium Acetate Sterile Concentrate

### General Notices

Sterile Sodium Acetate Concentrate

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

### Action and use

Used in Parenteral Nutrition Solutions.

## DEFINITION

Sodium Acetate Sterile Concentrate is a sterile solution of Sodium Acetate Trihydrate 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 anhydrous sodium acetate, $C_2H_3NaO_2$

95.0 to 105.0% of the stated amount.

### Content of sodium, Na

95.0 to 105.0% of the stated amount.

## IDENTIFICATION

- A. Yields the reactions characteristic [of sodium salts, Appendix VI](#).
- B. Yields reaction A characteristic [of acetates, Appendix VI](#).

## TESTS

### Alkalinity

pH of the concentrate, diluted if necessary to produce a solution containing the equivalent of 5% w/v of anhydrous sodium acetate, 7.5 to 9.0, [Appendix V L](#).

## ASSAY

### For [sodium acetate](#)

Evaporate a volume of the concentrate containing the equivalent of 0.15 g of anhydrous sodium acetate to dryness; add 50 mL of [anhydrous acetic acid](#) and 10 mL of [acetic anhydride](#) and carry out Method I for non-aqueous titration, [Appendix VIII A](#), using [1-naphtholbenzein solution](#) as indicator. Each mL of [0.1M perchloric acid VS](#) is equivalent to 8.20 mg of  $C_2H_3NaO_2$ .

Prepare a suitable dilution in [water](#) and determine by *atomic emission spectrophotometry*, [Appendix II D](#), measuring at 589 nm and using [sodium standard solution \(200 ppm Na\)](#), suitably diluted with [water](#), for the [standard solutions](#).

## **LABELLING**

The quantity of active ingredient is stated in terms of the equivalent amount of anhydrous sodium acetate and in terms of the concentration of sodium ions ( $\text{Na}^+$ ) in millimoles per mL.