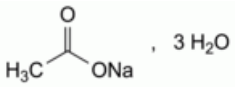
Edition: BP 2025 (Ph. Eur. 11.6 update)

Sodium Acetate Trihydrate

General Notices

(Ph. Eur. monograph 0411)



$C_2H_3NaO_2,3H_2O$ 136.1 *6131-90-4*

Action and use

Used in solutions for dialysis; excipient.

Preparation

Sodium Acetate Sterile Concentrate

Ph Eur

DEFINITION

Sodium acetate trihydrate (sodium ethanoate trihydrate).

Content

99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder or colourless crystals.

Solubility

Very soluble in water, soluble in ethanol (96 per cent).

IDENTIFICATION

A. 1 mL of solution S (see Tests) gives reaction (b) of acetates (*2.3.1*).
B. 1 mL of solution S gives reaction (a) of sodium (*2.3.1*).
C. Loss on drying (see Tests).

TESTS

Solution S

Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100 mL with the same solvent.

Appearance of solution

Solution S is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

pH (*2.2.3*)

7.5 to 9.0.

Dilute 5 mL of solution S to 10 mL with *carbon dioxide-free water R*.

Reducing substances

Dissolve 5.0 g in 50 mL of *water R*, then add 5 mL of *dilute sulfuric acid R* and 0.5 mL of a 0.32 g/L solution of *potassium permanganate R*. The pink colour persists for at least 1 h. Prepare a blank in the same manner but without the substance to be examined.

Chlorides (*2.4.4*)

Maximum 200 ppm.

Dilute 2.5 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*)

Maximum 200 ppm.

Dilute 7.5 mL of solution S to 15 mL with *distilled water R*.

Aluminium (*2.4.17*)

Maximum 0.2 ppm, if intended for use in the manufacture of dialysis solutions.

Prescribed solution Dissolve 20 g in 100 mL of *water R* and adjust to pH 6.0 with a 103 g/L solution of *hydrochloric acid R* (about 10 mL).

Reference solution Mix 2 mL of *aluminium standard solution (2 ppm Al) R*, 10 mL of *acetate buffer solution pH 6.0 R* and 98 mL of *water R*.

Blank solution Mix 10 mL of *acetate buffer solution pH 6.0 R* and 100 mL of *water R*.

Calcium and magnesium

Maximum 50 ppm, calculated as Ca.

To 200 mL of *water R* add 10 mL of *ammonium chloride buffer solution pH 10.0 R*, 0.1 g of *mordant black 11 triturate R*, 2.0 mL of *0.05 M zinc chloride* and, dropwise, *0.02 M sodium edetate* until the colour changes from violet to blue. Add to the solution 10.0 g of the substance to be examined and shake to dissolve. Titrate with *0.02 M sodium edetate* until the blue colour is restored. Not more than 0.65 mL of *0.02 M sodium edetate* is required.

Iron (*2.4.9*)

Maximum 10 ppm, determined on solution S.

Loss on drying (*2.2.32*)

39.0 per cent to 40.5 per cent, determined on 1.000 g by drying in an oven at 130 °C. Introduce the substance to be examined into the oven while the latter is cold.

ASSAY

Dissolve 0.250 g in 50 mL of *anhydrous acetic acid R*, add 5 mL of *acetic anhydride R*, mix and allow to stand for 30 min. Using 0.3 mL of *naphtholbenzein solution R* as indicator, titrate with *0.1 M perchloric acid* until a green colour is obtained.

1 mL of *0.1 M perchloric acid* is equivalent to 8.20 mg of $C_2H_3NaO_2$.

STORAGE

In an airtight container.

LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of dialysis solutions.

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