



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

Sodium Benzoate Sterile Concentrate

[General Notices](#)

Sterile Sodium Benzoate Concentrate

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

Action and use

Treatment of hyperammonaemia due to urea cycle disorders; treatment of non-ketotic hyperglycinaemia.

DEFINITION

Sodium Benzoate Sterile Concentrate is a sterile solution of Sodium Benzoate in a suitable vehicle.

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 sodium, Na

95.0 to 105.0% of the stated amount.

Content of sodium benzoate, $C_7H_5NaO_2$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A clear and colourless solution.

IDENTIFICATION

- A. Yields reaction A characteristic of *benzoates*, [Appendix VI](#).
- B. Complies with the Assay for sodium.

TESTS

Acidity or alkalinity

pH, 7.0 to 7.5, [Appendix V L](#).

ASSAY

For Na

Prepare a suitable dilution in [water](#) and determine by *atomic emission spectrophotometry*, [Appendix II D](#), measuring at 589 nm and using *sodium standard solution* (100 ppm Na), suitably diluted with [water](#), for the [standard solutions](#).

For sodium benzoate

Dilute a quantity of the sterile concentrate containing 0.250 g of Sodium Benzoate to 20 mL with [anhydrous acetic acid](#). Titrate with 0.1M [perchloric acid](#) using 0.05 mL of *1-naphtholbenzein* solution as indicator, until a green colour is obtained.

Each mL of 0.1M [perchloric acid](#) is equivalent to 14.41 mg of $C_7H_5NaO_2$.