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Sodium Benzoate Oral Solution

General Notices

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 Oral Solution is a solution of Sodium Benzoate in a suitable vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral solution 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.

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 weighed quantity of the oral solution 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.

Determine the *weight per mL* of the oral solution, Appendix V G, and calculate the content of $C_7H_5NaO_2$, weight in volume.

Each mL of 0.1M *perchloric acid* is equivalent to 14.41 mg of $C_7H_5NaO_2$.