Quality standards

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Sodium Bicarbonate Infusion

General Notices

Sodium Bicarbonate Injection; Sodium Bicarbonate Intravenous Infusion

DEFINITION

Sodium Bicarbonate Infusion is a sterile solution containing Sodium Bicarbonate. It is supplied as a ready-to-use solution.

The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of sodium bicarbonate, NaHCO₃

94.0 to 106.0% of the stated amount.

IDENTIFICATION

- A. The residue on evaporation, when moistened with <u>hydrochloric acid</u> and introduced on a platinum wire into a flame, imparts a yellow colour to the flame.
- B. Yields reaction A characteristic of sodium salts and the reactions characteristic of bicarbonates, Appendix VI.

TESTS

Bacterial endotoxins

Carry out the <u>test for bacterial endotoxins</u>, <u>Appendix XIV C</u>. The endotoxin limit concentration is less than 1.7 IU per mL of Sodium Bicarbonate Infusion.

ASSAY

Titrate a volume containing 1 g of Sodium Bicarbonate with 0.5M hydrochloric acid VS using methyl orange solution as indicator. Each mL of 0.5M hydrochloric acid VS is equivalent to 42.00 mg of NaHCO₃.

STORAGE

Containers that have previously been subjected to heating in an autoclave should not be re-used to keep Sodium Bicarbonate Infusion.

LABELLING

https://nhathuocngocanh.com/bp/ The strength is stated as the percentage w/v of Sodium Bicarbonate.

The label states (1) that containers containing visible particles must not be used; (2) the approximate concentrations, in millimoles per litre, of the sodium ions and the bicarbonate ions.

For a preparation containing 1.4% w/v of Sodium Bicarbonate the concentration of each ion is stated as 167 millimoles per