



SODIUM BICARBONATE INTRAVENOUS INFUSION

Draft proposal for *The International Pharmacopoeia*

(August 2010)

REVISED DRAFT FOR COMMENT

This document was provided by a quality control expert and was discussed at the recent WHO consultation on specifications for medicines and quality control laboratory issues. Previous comments received have been incorporated into this revised draft. Should you have any comments, please send these to Dr S. Kopp, Manager, Medicines Quality Assurance Programme, Quality Assurance and Safety: Medicines, World Health Organization, 1211 Geneva 27, Switzerland; fax: (+41 22) 791 4730 or e-mails: kopps@who.int with a copy to Ms C. Mendy mendyc@who.int by 11 October 2010.

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SCHEDULE FOR THE ADOPTION PROCESS OF DOCUMENT QAS/10.366
International Pharmacopoeia monograph on Artesunate injection

	Date
Preparation of first draft by laboratory	September 2009–April 2010
Discussion at consultation on specifications for medicines and quality control laboratory issues	10-12 May 2010
Draft monograph mailed out for comments	July 2010
Collation of comments	August 2010
Comments discussed during video-/teleconference on specifications for medicines	25 August 2010
Revised draft mailed out for comments	September 2010
Presentation to WHO Expert Committee on Specifications for Pharmaceutical Preparations	18-22 October 2010
Further action as necessary	

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Category. Alkalinising agent.

Storage. Sodium bicarbonate intravenous infusion should be kept in a sealed container. Containers that have previously been subjected to heating in an autoclave should not be re-used to keep Sodium bicarbonate intravenous infusion.

Labelling. The designation on the container of Sodium bicarbonate intravenous infusion should state:

- the strength as the percentage m/v of Sodium bicarbonate, as well as the approximate concentrations, in millimoles per litre, of the sodium ions and the bicarbonate ions;
- that containers containing visible particles due to the possible formation of sodium carbonate precipitates must not be used.

Additional information. For a preparation containing 1% m/v of Sodium bicarbonate the concentration of each ion is about 119 millimoles per litre.

Requirements

Complies with the monograph for "Parenteral Preparations".

Definition. Sodium bicarbonate intravenous infusion is a sterile solution of Sodium bicarbonate in Water for injections. It contains not less than 94.0% and not more than 106.0% of the amount of sodium bicarbonate (NaHCO_3) stated on the label.

The infusion is sterilized by a suitable method (see 5.8 Methods of sterilization).

Identity tests

- A. The infusion yields reaction A described under 2.1 General identification tests, as characteristic of sodium.
- B. Introduce 2 ml of the infusion into a test tube and add 3 ml of acetic acid (~120 g/l) TS. Close the tube immediately using a stopper fitted with a glass tube bent at two right angles. The solution effervesces evolving a colourless and odourless gas. Heat gently and collect the gas in 5 ml of barium hydroxide (15 g/l) TS. A white precipitate is produced which dissolves on addition of an excess of hydrochloric acid (~330 g/l) TS.

Bacterial endotoxins. Carry out the test as described under 3.4 Test for bacterial endotoxins; contains not more than 1.0 IU of endotoxin per ml.

Assay. Titrate a suitable volume of the infusion, accurately measured, containing about 1 g of Sodium bicarbonate with hydrochloric acid (0.5 mol/l) VS using methyl orange ethanol TS as indicator. Each ml of hydrochloric acid (0.5 mol/l) VS is equivalent to 42.00 mg of NaHCO_3 .

Revised draft for comment