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Clinical Response

Use of Sterile Water Irrigation to replace Sterile Water for Inhalation

The Clinical Services Team has created this document to answer the clinical question; can sterile water intended to be used for irrigation, be used for inhalation in ventilators and high velocity nasal insufflation (HVNI) devices in the event of a sterile water for inhalation shortage?

Device

Ventilators and HVNI devices utilize sterile water for inhalation to provide humidity to the air that is taken in by the patient.

Clinical Practice Guidelines/Best Practice

Included in the Institute for Safe Medication Practices (ISMP) Targeted Medication Safety Best Practices for Hospitals Document, sterile water for injection, irrigation and inhalation have resulted in patient harm including death when large doses of hypotonic sterile water were inadvertently infused intravenously (IV). These sterile water products look very similar in size, shape and type of container utilized for IV infusion of dextrose 5% and 0.9% sodium chloride. It is recommended by ISMP best practice #10 that alternatives be utilized to avoid storage and use of the 1,000 ml sterile water bags in patient care areas, i.e. replacing all 1,000 ml bags with 2,000 ml bags. In addition a policy should be established that only pharmacy can order 1,000 ml bags of sterile water.[1]

ISMP further discussed the use of two liter bags when addressing a concern regarding the weight of the bags breaking articulated ventilator arms in a frequently asked questions document. Per the ISMP, sterile water bags intended for inhalation should not be supported by the articulated arm of a ventilator, which is designed to support the circuit. The bag can be hung on a pole attached to the ventilator intended for this purpose or on an IV pole. If an IV pole is used the bag and tubing should be labeled, “For Respiratory Equipment-Not for IV Use”. Hard sided one liter sterile water bottles may also be utilized to avoid confusion. Additional consideration could be a change to passive humidification systems to avoid use of sterile water bags.[2]

Clinical Information

Sterile waters have specific intended uses, which are indicated by their names and may have restrictions based on those uses. There are differences between the acceptance criteria for chemical purities in the different types of waters. See Table One.

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Table One: USP requirements for Sterile Water for Irrigation and Sterile Water for Inhalation.[3, 4]

USP Criteria	Sterile Water for Irrigation	Sterile Water for Inhalation
Definition	Sterile water for irrigation is prepared from water for injection that is sterilized and suitably packaged. It contains no antimicrobial agent or other added substance.	Sterile water for inhalation is prepared from water for injection that is sterilized and suitably packaged. It contains no added antimicrobial agents, except where used in humidifiers or other similar devices and where liable to contamination over a period of time, or other added substances.
Packaging and Storage	Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass. The container may contain a volume of more than 1 L, and may be designed to empty rapidly.	Preserve in glass or plastic containers. Glass containers are preferably of Type I or Type II glass.
Labeling	Label it to indicate that no antimicrobial or other substance has been added. The designations "For irrigation only" and "Not for injection" appear prominently on the label.	Label it to indicate that it is for inhalation therapy only and that it is not for parenteral administration.
Particulate Matter Requirements	Not required to meet.	Not required to meet.
Bacterial endotoxins	It contains less than 0.25 Endotoxin Unit/mL.	It contains less than 0.5 USP Endotoxin Unit/mL.
Sterility	It meets the requirements.	It meets the requirements.
pH	It is between 5.0 and 7.0 in a solution containing 0.3 mL of saturated potassium chloride solution per 100 mL of test specimen.	It is between 4.5 and 7.5, in a solution containing 0.3 mL of saturated potassium chloride solution per 100 mL of test specimen.
Ammonia	Any yellow color produced immediately is not darker than that of a control containing 30 µg of added ammonia.	Any yellow color produced immediately is not darker than that of a control containing 30 µg of added ammonia.
Calcium	No turbidity is produced.	No turbidity is produced.
Carbon dioxide	The mixture remains clear.	The mixture remains clear.
Chloride	Any turbidity formed within 10 minutes is not greater than that produced in a similarly treated control consisting of 20 mL of *High-Purity Water* containing 10 µg of chloride (0.5 mg per L), viewed downward over a dark surface with light entering the tubes from the sides.	Any turbidity formed within 10 minutes is not greater than that produced in a similarly treated control consisting of 20 mL of *High-Purity Water* containing 10 µg of chloride (0.5 mg per L), viewed downward over a dark surface with light entering the tubes from the sides.
Sulfate	No turbidity is produced.	No turbidity is produced.
Oxidizable Substances	If a precipitate forms, cool in an ice bath to room temperature, and pass through a sintered-glass filter: the pink color does not completely disappear.	If a precipitate forms, cool in an ice bath to room temperature, and pass through a sintered-glass filter: the pink color does not completely disappear.

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Summary/Considerations:

It is noted that there are fewer endotoxins in sterile water for irrigation and the standard pH range is slightly lower at 5.0-7.0.[3, 4] The recommendation for use of 2 liter bags is universal for both situations if ISMP guidelines are followed. Otherwise sterile water for irrigation meets the same standards as the sterile water intended for inhalation. There is no clinical evidence to support the interchangeability of these products. If this off label practice is being considered in your institution, the practice should be reviewed and approved by a multi-disciplinary team including, but not limited to staff from infection prevention, pulmonology, respiratory therapy and pharmacy.

References

1. 2020-2021 ISMP targeted medication safety best practices for hospitals. 2020. *Institute for Safe Medication Practices* Available at: https://www.ismp.org/sites/default/files/attachments/2020-02/2020-2021%20TMSBP-%20FINAL_1.pdf Accessed 1.22.2020
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3. USP Monographs: sterile water for inhalation-USP29-NF24. 2020. *U.S. Pharmacopedia*, Available at: http://www.pharmacopeia.cn/v29240/usp29nf24s0_m88860.htmls. Accessed 11.20.2020
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Initial or Update	Date	Completed by:	Changes Made
Initial	11.2020	KSB	Created

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