EFFECTIVENESS OF A STERILE BOTTLE FOR INTRAVENOUS FLUIDS USED IN MAHARAJ NAKORN CHIANG MAI HOSPITAL

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Abstract  A 500 mL sterile bottle for intravenous fluids has been developed for use in Maharaj Nakorn Chiang Mai Hospital. The sterilities of 200 bottles each filled with 50 mL water were tested by sampling the water after 0, 1, 2, 3, 4, 5, 6 and 7 days and 3 and 12 months following sterilization. 3 mL of sterile water from each bottle was inoculated into a tryptic soy broth by an aseptic technique. No bacterial growth was observed after storage for 12 months. All of the sterile bottles remained clear throughout the storage period. The results showed that the 500 mL bottle was suitable for intravenous fluids and remained sterile for 12 months. Chiang Mai Med Bull 2006;45(3):101-104.

Keywords: sterile bottle, intravenous fluids, sterility

A container for intravenous (IV) fluids must be designed to maintain solution sterility and clarify the time of preparation, through storage, and during clinical administration.¹ Container closures must be designed to facilitate the insertion of administration sets through which injections are administered at a regulated flow-rate into suitable veins. Containers for IV use are not commercially available in Thailand. This research is aimed at designing suitable containers for intravenous fluids. The container chosen for this study was a 500 mL sterile bottle containing 50 mL of water. The bottle was terminally sterilized by saturated steam autoclaving. Since it was not possible to steam sterilize the inside of an empty closed container,² an aqueous solution was placed in the container to create a vapour pressure during autoclaving (approximately 2.05 abs bar) and thus sterilizing the inside. The internal vapour pressure was increased by the partial pressure of the air in the head space. Assuming that the initial pressure value was 1.0 bar, it could be increased to approximately 1.3 bar due to heating. Pressure increases could also occur due to thermal expansion of the solution and
evaluation of any gases dissolved in the solution. In the conditions described above, the total pressure inside the container exceeded the pressure in the chamber by approximately 1.4 bar, if the initial head space was 10 to 20% of the total volume of the container, as is usually the case.\(^{(2)}\)

The objective of this study was to assess the ability to sterilize a bottle containing 50 mL of water for 12 months.

**Materials and Methods**

**Glass Containers**

The 500 mL, Type I glass containers were made of borosilicate glass. Type I glass is composed principally of silicon dioxide and boric oxide with low levels of non-network-forming oxides. It is a chemically resistant glass (low leachability) with a low thermal coefficient of expansion.

**Equipment**

The autoclave used was manufactured by Getinge AB, SE-31044 Getinge, Sweden.

**Preparation of sterile bottles**

Each bottle was rinsed with distilled water before 50 mL of distilled water, previously passed through a 0.45 mm sterile filter, were poured into them. The bottles and their contents were terminally sterilized by saturated steam autoclaving. All samples were kept at room temperature throughout the study period of 12 months.

**Sampling and microbiological analysis**

The sampling periods were 0, 1, 2, 3, 4, 5, 6 and 7 days and 3 and 12 months after sterilization. Twenty samples in each period were handled under a laminar air flow and 3 mL of each one were injected by an aseptic technique into tryptic soy broth after disinfection of the surface with 70% alcohol. The tryptic soy broth was then incubated at 30-35 °C for 14 days.\(^{(3)}\)

**Preparation of negative test controls\(^{(4)}\)**

- Media sterility test
  10 samples of tryptic soy broth were incubated for 14 days after preparation.
- Negative product controls
  10 samples of physiological saline were taken under a laminar air flow and the 3 mL of distilled water were injected by an aseptic technique into the tryptic soy broth after disinfection of the surface with 70% alcohol. The tryptic soy broth was incubated at 30-35 °C for 14 days.

**Preparation of positive test controls\(^{(4)}\)**

- Growth promotion test
  30 samples of tryptic soy broth were inoculated with 100 CFU of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Bacillus subtilis* and incubated at 30-35 °C for 5 days.

**Results and discussion**

This study was concerned with the effectiveness of sterilizing a bottle containing 50 mL of distilled water by autoclaving. On examination of the water in the bottle, it was found that saturated steam autoclaving sterilized the bottle in all time periods tested. All of the sterile bottles remained that way throughout the duration of the storage time; after 1, 2, 3, 4, 5, 6, 7 days and 3 and 12 months. All the positive controls were inoculated with 100 CFU of *Staphylococcus aureus*, *Pseudomonas aerugi-nosa* and *Bacillus subtilis*, and they showed positive results during the first 3 days. Negative controls of physiological saline were...
examined for 14 days and they demonstrated the efficiency of the previous sterilization. No microbial growth was observed in any of the groups tested.

For a sterile bottle containing 50 mL of water to be considered for intravenous fluids, water needs to be able to sterilized the bottle based on 5 events as the container is heated. These are as follows:\(^{(4)}\)

1. The water in the container evaporates into the headspace.
2. The liquid phase expands.
3. Dissolved gases leave the solution and enter the headspace.
4. The vapor phase in the headspace attempts to expand as the temperature increases.
5. The walls of the container expand reversibly to increase the total volume of the container.

For comparison between using and not using water, as in the case of mixing a drug, the water can be removed by means of a disposable syringe before the drug is introduced.

Conclusions

In summary, the experimental results provide strong evidence in support of developing a container for intravenous fluids by using a sterile bottle containing 50 mL of water, and terminal sterilization by saturated steam autoclaving. This is an appropriate method for filling a container with intravenous fluids. The sterile bottle can be stored for 12 months after sterilization.

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References

ประสิทธิภาพของขวดปราศจากเชื้อสำหรับเติมสารละลายที่ให้ทางหลอดเลือดดำที่ใช้ในโรงพยาบาลมหาราชนครเชียงใหม่

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ที่วิทยาศาสตรการทำขวด งานผลิตยา ฝ่ายเภสัชกรรม งานปฏิบัติการกลางและชันสูตรโรค
โรงพยาบาลมหาราชนครเชียงใหม่ คณะแพทยศาสตร์ มหาวิทยาลัยเชียงใหม่

บทคัดย่อ หน่วยผลิตยาปราศจากเชื้อ งานผลิตยา โรงพยาบาลมหาราชนครเชียงใหม่ พัฒนาขวดปราศจากเชื้อสำหรับเติมสารละลายที่ให้ทางหลอดเลือดดำ เพื่อใช้ในโรงพยาบาลมหาราชนครเชียงใหม่ ขวดปราศจากเชื้อจำนวน 200 ขวดขนาด 500 ซีซี ซึ่งบรรจุน้ำปราศจากเชื้ออยู่ในขวด 50 ซีซี ในการทดสอบความสามารถปราศจากเชื้อ โดยการเก็บตัวอย่างน้ำปราศจากเชื้อในขวดปราศจากเชื้อที่ผ่านการฆ่าเชื้อด้วยการนึ่งด้วยไอน้ำ นำมาทดสอบในอาหารเลี้ยงเชื้อด้วยเทคนิคการใช้เทคนิคการใช้เทคนิค ประสิทธิภาพในวันแรกวันที่ 1, 2, 3, 4, 5, 6, 7, แล้ววันที่ 3 และวันที่ 12 พบว่าขวดปราศจากเชื้อ 500 ซีซีที่บรรจุน้ำ 50 ซีซี นั้นมีความสามารถปราศจากเชื้อสำหรับเติมสารละลายที่ใช้ทางหลอดเลือดดำ โดยมีความสามารถเป็นเวลา 12 เดือนที่สึกษา ซึ่งนั่นหมายถึงเวชสาร 2549;45(3):101-104.

คำสำคัญ: ขวดปราศจากเชื้อ สารละลายที่ใช้ทางหลอดเลือดดำ ความปราศจากเชื้อ