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IMPLEMENTATION OF AN ASEPTIC TECHNIQUE VALIDATION PROTOCOL IN A PHARMACY DEPARTMENT

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BACKGROUND AND IMPORTANCE:

Aseptic technique validation is crucial in ensuring the safety and quality of sterile products, reducing contamination risks in hospital pharmacy preparations.

OBJETIVES

To establish a protocol for the validation of aseptic technique (VTA) in the Pharmacy Department (PD) through simulation, assessing the performance of personnel working in aseptic conditions in compliance with good practice standards.

MATERIAL AND METHODS

- Following a literature review, the recommendations outlined in Chapter 797 of the United States Pharmacopeia (USP) and the guide on good preparation practices in hospital pharmacy services were adopted.
- According to USP guidelines, the process simulation test should closely mimic standard aseptic manufacturing, using a liquid culture medium instead of the usual products. The USP categorizes sterile preparations into three risk levels: low, medium, and high, detailing quality control standards for each.
- We implemented a high-risk protocol, involving the preparation of sterile products where either a non-sterile product or device is used, utilizing thioglycolate as the liquid culture medium. This scenario represents the highest-risk conditions that could occur in a laminar flow hood.

RESULTS

The following protocol was developed:

1. Approximately 50 mL of non-bacteriostatic water is measured into a beaker.
2. A 0.2-micron filter is attached to a 5 mL syringe, and 3 mL of water is drawn.
3. A new 0.2-micron filter is applied, and 2.4 mL of water is injected into a vial containing thioglycolate. This procedure is repeated with another vial.
4. Three different 1 mL syringes are used to draw 0.5 mL of water each and injected into the thioglycolate vials.
5. Finally, the content of both vials is transferred to a 100 mL vacuum flask using a 50 mL syringe, labeled, and sealed.
6. A positive control (CP) is prepared by swabbing the forearm skin and placing the swab in a new thioglycolate vial.

The preparations, along with the CP and a negative control (NC), are stored at room temperature for 14 days.

After the incubation period, a visual inspection is performed.

If the vials remain clear → They are considered free from contamination.

If the vials doesn´t remain clear → Any turbidity indicates non-compliance, necessitating corrective measures, including revalidation

CONCLUSION AND RELEVANCE

- VTA is a simple, cost-effective, and easy-to-implement process.
- Implementing VTA alongside environmental and surface controls in cleanrooms ensures the safety and quality of sterile products, reducing the need for routine microbiological cultures in most cases.

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