Pharmaceutical Investigation Report

Deviation Investigation Report

1. Deviation Details

Deviation PRID: PRID-20240409-006 Site: BioPharma Inc. Location: Sterile Filling Area Deviation Identified Date: 2025-04-07 Deviation Opened Date: 2025-04-08

2. Description

On April 7, 2025, a deviation occurred during aseptic processing in the Sterile Filling Area at BioPharma Inc. A small tear was observed in the glove of an operator performing aseptic manipulations. This deviation compromises the required sterile barrier necessary for aseptic processing, potentially leading to microbial contamination of the product.

3. Immediate Actions Taken

Upon identification of the glove breach, the filling line was immediately stopped. The affected batch was quarantined to prevent further processing or release until a thorough investigation could be conducted and appropriate disposition determined.

4. Investigation

The investigation included a comprehensive review of video monitoring footage of the filling operation and review of glove integrity test records for the affected operator. The scope aimed to determine the precise sequence of events leading to the glove breach and identify any contributing factors.

5. Root Cause

The investigation revealed that the glove was punctured when the operator was handling materials required for the filling process. Further analysis indicated that the operator did not adhere to the established Standard Operating Procedure (SOP) for material handling, which outlines the correct procedures for handling these materials in a manner that minimizes the risk of glove damage. The root cause was determined to be inadequate adherence to established procedures due to insufficient operator training on the specific material handling steps.

6. Corrective and Preventive Actions (CAPA)

Corrective Action: The existing SOP for material handling has been revised to include a detailed step-by-step guide with visual aids, clearly illustrating the correct method for handling materials to prevent glove damage.

Preventive Action: The affected batch is currently undergoing sterility testing to determine its suitability for release. Production in the Sterile Filling Area resumed only after all

operators involved in aseptic processing received retraining on the revised material handling SOP, including a practical demonstration of the correct technique.

7. Impact

The potential impact of this deviation is considered minor. While a breach in the sterile barrier introduces a risk of microbial contamination, the immediate actions taken, including stopping the line and quarantining the affected batch, mitigated this risk. Preliminary results from the sterility testing have not indicated any compromise to product sterility. The full sterility test results are pending.

8. Conclusion

The glove breach incident highlights the critical importance of strict adherence to established SOPs during aseptic processing. The implemented corrective and preventive actions, including SOP revision and retraining, aim to strengthen procedural adherence and minimize the risk of similar deviations occurring in the future. The affected batch remains under quarantine pending final sterility testing results, after which a final disposition will be determined.
Continuous monitoring and reinforcement of aseptic techniques will be implemented to ensure ongoing compliance and maintain the integrity of sterile operations.

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