Pharmaceutical Investigation Report

Deviation Investigation Report

1. Deviation Details

Deviation PRID: 1345 Site: B1 Location: Park Identified Date: 2025-01-03 Opened Date: 2025-01-03 Nature: Equipment Failure

2. Description

On January 3, 2025, a deviation was identified involving equipment temperature exceeding the established range of 25-30°C. The equipment temperature reached 32°C. Normal operating conditions dictate that the equipment temperature be maintained within the specified range.

3. Immediate Actions Taken

Upon identification of the temperature excursion, the chilled water flow to the equipment was immediately increased to reduce the temperature.

4. Investigation

The scope of the investigation included an inspection of the chilled water flow system supplying the affected equipment. The investigation revealed a reduced chilled water flow due to a clogged chilled water line.

5. Root Cause

The root cause of the reduced chilled water flow, and subsequent temperature deviation, was determined to be inadequate preventive maintenance procedures. The existing chilled water preventive maintenance procedure lacked a checkpoint for frequent inspection of the strainer, leading to clogging by particulates.

6. Corrective and Preventive Actions (CAPA)

Corrective Action: The chilled water preventive maintenance procedure for the affected equipment was updated to include a specific checkpoint for frequent strainer inspection and cleaning. This will ensure timely removal of any particulate buildup and maintain adequate chilled water flow.

Preventive Action: To prevent similar occurrences in other systems, the corrective action was extended to all chilled water systems across all sites. All relevant procedures were updated to include the enhanced strainer inspection and cleaning requirements.

7. Impact

The immediate impact of the deviation was minimal, as the temperature excursion to 32°C lasted only for three minutes. The investigation confirmed no impact to the process or product quality.

8. Conclusion

The deviation involving the equipment temperature excursion was successfully investigated and addressed. The root cause was identified as an inadequate preventive maintenance procedure for the chilled water system. Corrective actions have been implemented to address the specific issue and preventive actions have been implemented to mitigate the risk of similar deviations occurring in other chilled water systems across all sites. Based on the investigation and implemented CAPA, the deviation is considered closed.

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