Pharmaceutical Investigation Report

Deviation Investigation Report

1. Deviation Details

Deviation PRID: PRID-20240409-001 Site: ABC Pharma Pvt. Ltd. Location: Manufacturing Unit 3, Clean Room B Identified Date: 2025-04-05 Opened Date: 2025-04-06 Nature of Deviation: Temperature excursion in raw material storage

2. Description

On April 5, 2025, a temperature excursion occurred in Clean Room B of Manufacturing Unit 3. The temperature reached 28°C and remained at this level for six hours, exceeding the defined storage temperature range of 15°C to 25°C. This deviation was identified during routine temperature monitoring.

3. Immediate Actions Taken

Upon discovery of the temperature excursion, the HVAC system was restarted, and the temperature was restored to the acceptable range. The potentially impacted raw materials were quarantined to prevent further processing until a quality assessment could be conducted.

4. Investigation

The investigation scope included a comprehensive review of temperature logs, HVAC system functionality, and the stability of the potentially affected raw materials. This involved analysis of historical temperature data, inspection of the HVAC system components, and assessment of the materials' compliance with stability specifications under the excursion conditions.

5. Root Cause

The investigation determined that the HVAC system malfunctioned due to clogged filters. This malfunction contributed to the temperature excursion. Additionally, a delay in the response to the temperature alert exacerbated the duration of the excursion. The root cause of these issues was determined to be inadequate adherence to the preventive maintenance schedule for the HVAC system.

6. Corrective and Preventive Actions (CAPA)

Corrective actions included replacing the HVAC filters, restarting the system, and revalidating temperature control within Clean Room B. Preventive actions included implementing automated temperature alerts to provide immediate notification of excursions and revising the HVAC preventive maintenance schedule to ensure strict adherence and prevent recurrence of this issue. This revised schedule includes more frequent filter changes and regular system inspections.

7. Impact

The initial assessment suggests no immediate risk to product quality. However, as a precautionary measure, additional testing of the quarantined raw materials will be required before batch release can be authorized. This additional testing will confirm the materials' continued suitability for use.

8. Conclusion

The temperature excursion in Clean Room B was successfully addressed through immediate actions and a thorough investigation. The root cause, inadequate adherence to the preventive maintenance schedule, has been identified and addressed through corrective and preventive actions. While no immediate risk to product quality is anticipated, additional testing of the impacted raw materials will be conducted to ensure patient safety and product quality. The implemented CAPA are designed to prevent similar deviations from occurring in the future.

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