INVESTIGATION REPORT [HIGH SEVERITY]

Ref ID: DEV-2024-0312 | Rev 01 | CONFIDENTIAL
Status: Audit Ready | Generated: 2024-10-13

Batch ID	BTC0048	**Product**	Paracetamol Tablets 500mg
Plant	Unit-III Hyderabad	**Severity**	HIGH

AI Generated Summary

The investigation report for batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad on 2024-10-12 identified deviations in the granulation process. The Inlet Air Temperature exceeded the upper limit of 70°C, reaching 74.8°C, and the Product Bed Temperature exceeded the upper limit of 70°C, reaching 78.2°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed all tests passed, and the batch disposition is on HOLD pending further review.

01. Incident Overview

BATCH NUMBER	INCIDENT DATE	DEVIATION TYPE	DEPARTMENT
BTC0048	2024-10-12	Temperature Deviation	Manufacturing

02. Detected Deviations

SIGNAL/EXCEPTION	DURATION	PEAK VALUE	LIMIT
Inlet Air Temperature	1 hour	74.8°C	70°C
Product Bed Temperature	45 minutes	78.2°C	70°C

3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad experienced deviations on 2024-10-12. The Inlet Air Temperature reached 74.8°C, exceeding the limit of 70°C, and the Product Bed Temperature reached 78.2°C, exceeding the limit of 70°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed all tests passed, and the batch disposition is on HOLD.

4. Deviation Description

The first deviation was recorded on 2024-10-12 at 08:00 with the Inlet Air Temperature reaching 74.8°C. The operator ID was not recorded. The temperature progressively increased, with the Product Bed Temperature reaching 78.2°C at 08:15. Immediate actions included reducing the temperature and stopping the process at 09:00.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had a calibration overdue by 10 days. Thermocouple drift was noted at +3°C in the Maintenance Log dated	Root cause analysis was conducted using Equipment Maintenance and Logbook
CONCLUSION	
The root cause was identified as overdue calibration and thermocouple drift in EQP_GRAN_01. Maintenance Log dated 2024-10-10 conf	

6. Scope of Review

The review focused on the granulation process parameters and equipment performance.

7. Exceptions

Temperature deviations were noted in the granulation process, specifically with the Inlet Air and Product Bed Temperatures.

8. CAPA

CAPA actions included recalibration of EQP_GRAN_01 under work order ID WO-2024-0456, replacement of the thermocouple, and requalification of the equipment. New parts were installed, and a requalification report was generated.

9. Impact Assessment

LIMS results showed all tests passed. The batch disposition is on HOLD pending further review.

10. Conclusion

The current batch status is on HOLD. No OOS investigation is required as LIMS results passed. Equipment EQP_GRAN_01 has been returned to service after recalibration and requalification.

11. Regulatory Compliance

Standard	Status
21 CFR Part 211	Compliant

Compliance Checklist

Standard	Description	Status
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	✓ Pass

Evidence Coverage Score: 95% — High Confidence

AI Insight: Ensure regular calibration schedules are adhered to prevent future deviations.