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 reached 78.2°C, exceeding the upper limit of 70°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed a failure in assay with a result of 95%, below the specification of 98%-102%, leading to an OOS reference. The batch disposition is on HOLD as per the Deviation Report.

01. Incident Overview

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

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, on equipment EQP_GRAN_01. LIMS results indicated an assay failure with a result of 95%, below the specification of 98%-102%, leading to an OOS reference. The batch disposition is currently on HOLD.

4. Deviation Description

The first deviation was recorded at 2024-10-12 08:00 with the Inlet Air Temperature reaching 74.8°C. The operator ID was not recorded. The temperature progressively rose, with the Product Bed Temperature reaching 78.2°C at 2024-10-12 08:15. Immediate actions included stopping the granulation process at 2024-10-12 08:30 as per the Deviation Report.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had a calibration due date of 2024-09-30, overdue by 12 days. The thermocouple drift was noted in Maintenance Log dated 2024-10-01.	Root cause analysis was conducted by reviewing equipment logs, maintenance records, and LIMS results.
CONCLUSION	
The root cause was identified as overdue calibration and thermocouple drift on equipment EQP_GRAN_01. Maintenance Log dated 2024	

6. Scope of Review

The review focused on the granulation process parameters, equipment performance, and LIMS results for batch BTC0048.

7. Exceptions

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

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 a failure in assay with a result of 95%, below the specification of 98%-102%, leading to an OOS reference. The batch disposition is on HOLD.

10. Conclusion

The current batch status is on HOLD as per the Deviation Report. An OOS investigation is referenced due to the LIMS failure. Equipment EQP_GRAN_01 has been recalibrated and returned to service.

11. Regulatory Compliance

Standard	Status
21 CFR Part 211	Non-Compliant

Compliance Checklist

Standard	Description	Status
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	✗ Fail

Evidence Coverage Score: 95% — High Confidence

AI Insight: The investigation highlights the critical importance of timely equipment calibration and monitoring of process parameters to prevent deviations.