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 highlights a deviation in the granulation process. The Inlet Air Temperature exceeded the upper limit of 70°C, reaching 74.8°C at 08:00, and the Product Bed Temperature reached 78.2°C at 08:15. Equipment ID EQP_GRAN_01 was involved. LIMS results indicate a failure in the 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 a deviation on 2024-10-12 during the granulation process. The Inlet Air Temperature exceeded the upper limit of 70°C, reaching 74.8°C at 08:00, and the Product Bed Temperature reached 78.2°C at 08:15. Equipment ID EQP_GRAN_01 was involved. LIMS results indicate a failure in the 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.

4. Deviation Description

The first deviation was recorded at 08:00 on 2024-10-12 with the Inlet Air Temperature reaching 74.8°C. The operator ID was not recorded in the Equipment Log. The temperature progressively rose, with the Product Bed Temperature reaching 78.2°C at 08:15. Immediate actions included stopping the granulation

process at 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 2024-10-11.	Review of calibration records and maintenance logs.
CONCLUSION	
The root cause was identified as overdue calibration and thermocouple drift in EQP_GRAN_01. Maintenance Log dated 2024-10-11 conf	

6. Scope of Review

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

7. Exceptions

The Inlet Air Temperature and Product Bed Temperature exceeded their respective upper limits during the granulation process.

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. A requalification report was generated post-maintenance.

9. Impact Assessment

LIMS results show a failure in the 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 returned to service post-recalibration and requalification.

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: Ensure timely calibration of equipment to prevent deviations and maintain compliance.