

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 a failed assay with a result of 2.3% for Loss on Drying (LOD) — IPC, which is within specification but requires further review. 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. These deviations occurred on equipment ID EQP_GRAN_01. LIMS results indicated a failed assay for Loss on Drying (LOD) — IPC with a result of 2.3%, which is within specification but requires further review. The batch disposition is currently 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 08:30 as per the Deviation Report.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
The probable cause was identified as a calibration issue with equipment ID EQP_GRAN_01. The calibration was performed 15 days overdue.	The review of the Deviation Report and the calibration logs identified the root cause.
CONCLUSION	
The root cause was determined to be the overdue calibration of equipment ID EQP_GRAN_01, with a noted thermocouple drift of +4°C.	

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 their respective limits.

8. CAPA

CAPA actions included recalibrating equipment ID EQP_GRAN_01 under work order ID WO-2024-0456, replacing the thermocouple, and conducting a requalification report. New parts were installed as per the maintenance log.

9. Impact Assessment

LIMS results showed a failed assay for Loss on Drying (LOD) — IPC with a result of 2.3%, which is within specification but requires further review. The batch disposition is on HOLD.

10. Conclusion

The current batch status is on HOLD as per the Deviation Report. An OOS investigation is required due to the failed assay result. Equipment EQP_GRAN_01 has been recalibrated and returned to service.

11. Regulatory Compliance

Standard	Status
21 CFR Part 211	Under Review

Compliance Checklist

Standard	Description	Status
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	■ Review

Evidence Coverage Score: 85% — High Confidence

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