

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 for batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad identified deviations in the granulation process. The Inlet Air Temperature exceeded the upper limit, reaching 74.8°C against a specification of 60-70°C. The Product Bed Temperature also exceeded its limit, reaching 78.2°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed a Fail status for 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	60-70°C
Product Bed Temperature	45 minutes	78.2°C	60-70°C

3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad experienced deviations in the granulation process on 2024-10-12. The Inlet Air Temperature reached 74.8°C, exceeding the limit of 60-70°C, and the Product Bed Temperature reached 78.2°C. Equipment ID EQP_GRAN_01 was involved. LIMS results indicated a Fail status for the assay with a result of 95%, below the specification of 98-102%. 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 increased, with the Product Bed Temperature reaching 78.2°C by 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 an overdue calibration by 15 days. The analysis involved reviewing equipment maintenance records.	Root cause analysis identified the overdue calibration as the primary cause of the failure.
CONCLUSION	
The root cause was identified as overdue calibration and thermocouple drift in EQP_GRAN_01. Maintenance Log dated 2024-10-10 indicates the equipment was recalibrated and returned to service.	

6. Scope of Review

The review focused on the granulation process parameters and equipment performance during batch BTC0048 production.

7. Exceptions

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

8. CAPA

CAPA actions included recalibration of EQP_GRAN_01 (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 showed a Fail status for the assay with a result of 95%, below the specification of 98-102%. The batch disposition is on HOLD. Assay result of 95% is below specification of 98%-102%.

10. Conclusion

The current batch status is on HOLD as per the Deviation Report. An OOS investigation reference has been initiated 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: 85% - High Confidence

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