

INVESTIGATION REPORT [CRITICAL SEVERITY]

Ref ID: DEV-2024-0312 | Rev 01 | CONFIDENTIAL
Status: Audit Ready | Generated: 2024-10-12

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

AI Generated Summary

Batch BTC0048 of Paracetamol Tablets 500mg produced at Unit-III Hyderabad on 2024-10-12 experienced deviations in temperature parameters during the granulation process. The Inlet Air Temperature peaked at 74.8°C, exceeding the upper limit of 70°C, and the Product Bed Temperature reached 78.2°C, also above the limit. LIMS results indicated a Fail for the assay with a result of 2.3%, which is below the specification of 1.5%-3%. The batch is currently on HOLD.

01. Incident Overview

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

02. Detected Deviations

SIGNAL/EXCEPTION	DURATION	PEAK VALUE	LIMIT
Inlet Air Temperature	N/A	74.8°C	74.8°C
Product Bed Temperature	N/A	78.2°C	78.2°C
Inlet_Air_Temperature	N/A	22.4°C	65°C
Product_Bed_Temperature	N/A	70.4°C	65°C

3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg produced at Unit-III Hyderabad on 2024-10-12 experienced deviations in temperature parameters during the granulation process. The Inlet Air Temperature peaked at 74.8°C, exceeding the upper limit of 70°C, and the Product Bed Temperature reached 78.2°C, also above the limit. LIMS results indicated a Fail for the assay with a result of 2.3%, which is below the specification of 1.5%-3%. The batch is currently on HOLD.

4. Deviation Description

The first deviation was recorded on 2024-10-12 at 08:00 with operator ID OP123. The Inlet Air Temperature progressively rose from 68.4°C at 07:45 to 74.8°C at 08:00, and the Product Bed Temperature increased from 63.1°C at 07:30 to 78.2°C at 08:15. Immediate action was taken to stop the process at 08:15.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 was overdue for calibration by 5 days, with a thermocouple drift maintenance log.	Analysis of equipment logs and maintenance records.
CONCLUSION	
The root cause of the temperature deviations was identified as a calibration issue with the thermocouple in EQP_GRAN_01, which was o	

6. Scope of Review

Review of temperature parameters during granulation for batch BTC0048.

7. Exceptions

No exceptions noted outside of the identified deviations.

8. CAPA

CAPA actions include recalibration of EQP_GRAN_01 under work order ID WO-2024-0456, replacement of the thermocouple, and a requalification report is pending.

9. Impact Assessment

Product was impacted. Assay result of 2.3% is below specification of 1.5%-3%. The batch is currently on HOLD.

10. Conclusion

The current status of batch BTC0048 is HOLD due to the OOS investigation following the LIMS failure. Equipment EQP_GRAN_01 has been taken out of service for recalibration.

11. Regulatory Compliance

Standard	Status
GMP	Non-Compliant

Compliance Checklist

Standard	Description	Status
GMP	Good Manufacturing Practices compliance check	✗ Fail

Evidence Coverage Score: 85% - High Confidence

AI Insight: Temperature deviations were critical in impacting product quality, necessitating immediate corrective actions.