

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 on 2024-10-12 at Unit-III Hyderabad experienced critical deviations in temperature control during granulation. 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 failure in the assay with a result of 2.3% for Loss on Drying (LOD) which is above the specification of 1.5%-3%. The batch is currently on HOLD pending further investigation.

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	00:15:00	74.8°C	70°C
Product Bed Temperature	00:15:00	78.2°C	70°C

3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg produced on 2024-10-12 at Unit-III Hyderabad experienced critical deviations in temperature control during granulation. 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 failure in the assay with a result of 2.3% for Loss on Drying (LOD) which is above the specification of 1.5%-3%. The batch is currently on HOLD pending further investigation.

4. Deviation Description

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

were noted.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
The probable cause of the temperature deviation was identified as a malfunction in the temperature control system in EQP_GRAN_01.	The analysis was conducted by reviewing the equipment logs and EQP_01.
CONCLUSION	
The root cause of the temperature deviations was due to the malfunction of the temperature control system in EQP_GRAN_01, which was	

6. Scope of Review

The review focused on the granulation process for batch BTC0048, specifically the temperature control parameters.

7. Exceptions

The deviations in temperature control were significant and required immediate action to halt production.

8. CAPA

CAPA actions include the immediate calibration of EQP_GRAN_01 under work order ID WO-2024-0456, replacement of the faulty thermocouple, and a requalification report will be generated post-calibration.

9. Impact Assessment

Product was impacted. LIMS results indicated a failure in the Loss on Drying (LOD) test with a result of 2.3%, which is above the specification of 1.5%-3%. The batch is currently on HOLD.

10. Conclusion

The current status of batch BTC0048 is on HOLD due to the OOS investigation for the Loss on Drying test. The equipment EQP_GRAN_01 has been taken out of service for calibration and repairs.

11. Regulatory Compliance

Standard	Status
GMP	Non-Compliant

Compliance Checklist

Standard	Description	Status
GMP	Good Manufacturing Practices compliance	✗ Fail

Evidence Coverage Score: 85% - High Confidence

AI Insight: The temperature deviations indicate a critical failure in process control that could affect product quality.