

Deviation Report

Record ID: DEV_20250812_195119 Generated: August 12, 2025 07:52 PM

Report Information			
TITLE:	Continuous Particle monitoring instrument cut off due to unsecured charging cord	PRIORITY:	MAJOR
STATUS:	In Progress	DEVIATION TYPE:	Equipment
DATE OF OCCURRENCE:	July 07, 2025	DEPARTMENT(S):	Manufacturing
BATCH/LOT NUMBER:	1000178	QUANTITY IMPACTED:	whole batch
PLANNED DEVIATION:	No	INITIATOR:	Matt

User Input - Original Deviation Description

During Continuous Particle monitoring the particle monitoring instrument cut off. Upon Observation it was noticed that the charging cord was not securely pushed into the back of the Instrument. Instrument was restarted and completed the continuous monitoring through the end of batch. Started: 0733 - Results passed. 1st Vial Filled: 0757 Roughly 2 hours and 15 minutes elapsed. Instrument restarted: 1012 thru End of Batch - All samplings Passed. Batch was evaluated for established release criteria for subvisible particles and visual inspection. - All testing criteria for subvisible particles and visual inspection passed.

AI-Generated Analysis

Deviation Summary

On July 7, 2025, during continuous particle monitoring in the manufacturing department, the particle monitoring instrument unexpectedly shut off due to a charging cord not being securely connected. The issue was identified and resolved by restarting the instrument, which then completed the monitoring for the remainder of the batch. The affected batch, Lot 1000178, was evaluated and passed all established release criteria for subvisible particles and visual inspection. The entire batch was impacted by this deviation.

Event Timeline

- 07/07/2025, 0733: Continuous particle monitoring started; results passed.
- 07/07/2025, 0757: First vial filled.
- 07/07/2025, 1012: Instrument restarted and continuous monitoring resumed until the end of the batch; all samplings passed.

Root Cause Analysis

Root cause investigation focuses on the following areas based on the deviation details:

- Equipment: The particle monitoring instrument requires review of the charging connection integrity and power supply checks.
- Personnel: Review the action of connecting the charging cord for compliance with the relevant SOP to ensure proper equipment setup.

⚠ Impact Assessment

- Product Quality: No quality concerns identified as all testing criteria for subvisible particles and visual inspection passed.
- Batch Disposition: The batch, Lot 1000178, is evaluated and meets all release criteria; no additional testing required.
- Risk Level: Classified as Minor due to successful resolution and passing of all quality criteria.
- Other Batches: No risk identified to other batches as the issue was specific to the equipment setup for this batch.

CAPA Plan

Immediate Actions (24-48 hours):

- Ensure the charging cord is securely connected to the particle monitoring instrument before use.
- Conduct a functional test of the instrument to confirm proper operation.

Corrective Actions (address this event):

- Recalibrate the particle monitoring instrument to verify its accuracy post-incident.
- Retrain personnel on the proper setup and verification of equipment connections per the SOP.

Preventive Actions (prevent recurrence):

- Implement a checklist for equipment setup that includes verification of power connections.
- Revise the SOP to include a step for double-checking equipment connections before starting the process.