

Deviation Report

Record ID: DEV_20250812_210640 Generated: August 12, 2025 09:08 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:	10000456	QUANTITY IMPACTED:	full batch
PLANNED DEVIATION:	No	INITIATOR:	Clara

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

During continuous particle monitoring on 07/07/2025, the particle monitoring instrument unexpectedly shut off due to an unsecured charging cord. The issue was identified when the instrument was observed to be offline. The instrument was restarted at 1012 and completed the monitoring for the remainder of the batch, which passed all testing criteria. The impacted batch is Lot 10000456, affecting the entire batch quantity. The current status is that all established release criteria for subvisible particles and visual inspection have been met.

Event Timeline

- 07/07/2025, 0733: Continuous particle monitoring began.
- 07/07/2025, 0757: First vial filled.
- 07/07/2025, 1012: Instrument was restarted and completed monitoring through the end of the batch.

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 functionality to prevent future disconnections.
- Personnel: Review the procedure for securing equipment connections to ensure compliance with relevant SOPs and prevent recurrence of similar issues.

⚠ Impact Assessment

- Product Quality: There is no impact on product quality as all subvisible particle and visual inspection criteria are met.
- Batch Disposition: The batch Lot 10000456 is cleared for release as it meets all testing criteria.
- Risk Level: Classified as Minor due to successful completion of monitoring and passing results post-restart.
- Other Batches: No risk to other batches as the issue was isolated to equipment setup for this specific batch.

CAPA Plan

Immediate Actions (24-48 hours):

- Verify the integrity of the charging cord and connection for the particle monitoring instrument.
- Conduct a review of the batch Lot 10000456 to ensure all other parameters are within specifications.

Corrective Actions:

- Recalibrate the particle monitoring instrument to ensure accurate functionality.
- Retrain personnel on the proper setup and verification of equipment connections before operation.

Preventive Actions:

- Implement a checklist for equipment setup that includes verification of secure connections.
- Revise SOP to include mandatory double verification of equipment setup by a second operator before starting the process.
- Install an automated alert system to notify operators of equipment disconnection or power loss during operation.