Leucine

FDA 483 Insights Report

Aurobindo Pharma Ltd., Hyderabad, India (Sept 2025)

This report reflects Leucine's analysis and is shared for informational context only; it is not prescriptive.

483 Risk Summary

Facility Name	Aurobindo Pharma Ltd., Hyderabad, India
Inspection Date	25. Aug - 05 Sept, 2025
Subsystems Impacted	Media Fill, Environmental Monitoring, Investigations, Process Validation, Batch Records, Equipment Cleaning, Facility Design, Cleaning Validation
Site History	Earlier Received 483 in Feb 2020

	Observation	Scope	Patient Severity	Risk of Escalation	Cost of Remediation
1	Inadequate aseptic process controls (RABS, interventions, smoke studies, vial sealing not validated)	Sterile Manufacturing, Aseptic Processing, Barrier Systems	🔴	🔴	🔴
2	Deficient environmental monitoring (viable/non-viable counts, poor swab validation, gaps in personnel monitoring)	Cleanroom Monitoring, Microbiology QA/QC	🔴	🔴	🟡
3	Failure to review batch discrepancies and deviations thoroughly	Batch Records, QA Investigations, Product Quality System	🟡	🔴	🟡
4	Inadequate written procedures & process validation (critical parameters not challenged, dissolution/assay	Process Validation, Manufacturing Operations, Batch Release	🔴	🔴	🔴

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	risk)				
5	Production parameters changed, but were not recorded in the batch records	Manufacturing Execution, Process Control, Documentation	🟠	🟢	🟠
6	Inadequate cleaning validation & residues found post-cleaning	Equipment Cleaning, Cross-Contamination Control	🔴	🟠	🟠
7	Facility maintenance issues (leaking ceilings, corrosion, water ingress in storage)	Facilities & Utilities, Warehousing, Storage Areas	🟠	🔴	🟢
8	Quality Unit failures (inadequate cleaning verification, poor calibration, passivation ignored)	QC Unit, Calibration Management, Quality Systems	🔴	🔴	🟠

Eileen A Liu's Profile 🔴

Inspections	483s	Recent 483s
75+	**62**	Aurobindo Pharma Limited (Sep 2025), Somerset Therapeutics Private Limited (Feb 2025), Boiron (Nov 2024), Excelvision (Nov 2024), Amicogen (China) Biopharm Co., Ltd. (Aug 2024), and others.

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This section provides actionable insights into root cause and CAPA strategy, ensuring transparency, regulatory compliance, and continuous improvement.

Observation 1

Inadequate Aseptic Practices and Validation of the Aseptic Process

Issue Description		Root Cause	- CAPA Actions
1.1	Weak implementation of aseptic design principles and inadequate QA oversight of interventions.	Weak implementation of aseptic design principles and inadequate QA oversight of interventions.	- Revise aseptic filling SOPs to clearly define and limit intervention types. - Implement QA authorisation and periodic audits for all aseptic interventions.
1.2	Stopper bags were not sanitised before transfer into the Grade A area, and interventions during vial sealing were not recorded or validated.	Inadequate aseptic handling controls and incomplete validation of vial sealing operations.	- Update transfer procedures to require sanitisation and documentation of all interventions. - Expand aseptic process validation to include vial sealing operations.
1.3	Operators blocked the first air during interventions and mishandled stopper bags, resulting in unrejected exposed vials.	Insufficient operator training and inadequate supervision in aseptic practices.	- Conduct targeted retraining on aseptic technique and first-air maintenance. - Enforce QA verification and rejection of any vials potentially exposed during interventions.
1.4	Smoke studies and media fill simulations were incomplete; dynamic vial sealing was not included, and turbulent airflow was observed.	Deficient airflow visualisation strategy and inadequate media fill protocol design.	- Redesign smoke studies to include vial sealing and intervention simulations. -

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Observation 2

Deficient Environmental Monitoring in Aseptic Processing Areas

Observation Description		Root Cause	CAPA Actions
2.1	Viable and non-viable particle count monitoring was not adequately implemented in Grade A RABS areas.	An incomplete environmental monitoring strategy and the absence of continuous viable monitoring provisions.	- Revise the environmental monitoring (EM) program to include continuous viable and non-viable particle monitoring in all critical areas. - Validate sampling locations and frequencies based on risk assessment.
2.2	Personnel finger dab monitoring was not performed after critical aseptic interventions.	Non-adherence to SOP FU12-QC-MIC-GEN-023 and lack of QA supervision during aseptic operations.	- Reinforce personnel monitoring requirements through operator retraining. - Establish QA verification of post-intervention monitoring during each aseptic operation.
2.3	Swab recovery validation for viable surface monitoring was incomplete and did not evaluate recovery in the presence of product residue.	Outdated 2016 validation, lacking simulation of actual manufacturing conditions.	- Revalidate swab recovery study, including product residue challenge tests. - Establish periodic revalidation frequency aligned with product risk and facility changes.
2.4	Limited Grade A and B surface coverage was observed during routine EM sampling.	Inadequate sampling plan and lack of data-driven risk mapping.	- Update EM site mapping to ensure comprehensive coverage of all critical contact surfaces. - Trend EM results to identify recurring contamination points and implement corrective measures.

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Observation 3

Inadequate Review of Batch Discrepancies and Failures

Observation Description		Root Cause	CAPA Actions
3.1	Batch discrepancies and deviations were not thoroughly investigated before final disposition.	Weak QA oversight and an inadequate deviation management process.	- Revise deviation management SOPs to require root cause analysis prior to batch disposition. - Train QA personnel on investigation completeness and documentation standards.
3.2	Complaint investigations did not include evaluation of potential material or process-related causes.	Limited scope of investigations and absence of trending analysis.	- Expand complaint investigation templates to include process and material traceability checks. - Implement periodic complaint trending and CAPA effectiveness review.
3.3	Retain sample testing was not consistently performed to confirm product quality in complaint cases.	Incomplete complaint investigation procedure.	- Update complaint handling SOPs to require retention testing for all quality-related complaints. - Ensure investigation closure includes product impact assessment and QA approval.

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Observation 4

Inadequate Written Procedures and Process Validation

Observation Description		Root Cause	CAPA Actions
4.1	Process validation studies did not challenge critical parameters or incorporate worst-case conditions.	Insufficient validation design and lack of cross-functional review.	- Redesign validation protocols to include range and stress testing of all critical parameters. - Ensure QA review and approval of all process validation protocols and reports.
4.2	Batch records did not reflect validated process ranges.	Incomplete incorporation of validation data into routine documentation.	- Revise master batch records to align with validated parameters. - Implement QA verification during batch record review to ensure compliance with validation limits.
4.3	Handling of light-sensitive or critical drug substances was not validated for environmental impact.	Lack of risk-based evaluation of material stability during processing.	- Conduct light and temperature challenge studies for all sensitive materials. - Update material handling SOPs to incorporate validated storage and handling conditions.

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Observation 5

Non-Adherence to Production and Process Control Procedures

Observation Description		Root Cause	CAPA Actions
5.1	Equipment parameters were changed after setup and not recorded in the batch record.	Lack of procedural control for post-setup parameter changes.	- Revise equipment operation SOPs to mandate documentation and QA approval of any parameter change. - Introduce automated data logging for critical process parameters.
5.2	The batch review did not identify deviations between the setup and actual operating parameters.	Inadequate QA review process for equipment reports.	- Enhance QA review checklist to include cross-verification of equipment reports with batch data. - Provide QA training on identifying unapproved parameter changes during review.

Observation 6

Inadequate Equipment Cleaning and Campaign Management

Observation Description		Root Cause	CAPA Actions
6.1	Campaign cleaning studies lacked justification for the number of batches between Type C cleanings.	Absence of scientific rationale in cleaning validation design.	- Reassess campaign cleaning studies to include residue accumulation and microbial risk evaluation.
6.2	Residues were observed on equipment surfaces after cleaning.	Ineffective cleaning verification and poor visual inspection practices.	- Retrain operators on visual inspection and cleaning verification procedures.

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Observation 7

Facility Maintenance and Infrastructure Deficiencies

Observation Description		Root Cause	CAPA Actions
7.1	Leaking ceilings and water ingress were observed in the packing material storage area.	Poor preventive maintenance and inadequate facility inspection frequency.	- Conduct facility integrity assessment and repair all affected areas. - Implement preventive maintenance schedules with QA verification of completion.
7.2	Corroded ceiling tiles and piping were observed above finished goods and material storage areas.	Lack of environmental control and delayed facility repairs.	- Replace corroded materials with GMP-compliant finishes. - Perform environmental monitoring after repair to verify the absence of contamination.

Observation 8

Quality Unit Oversight and Calibration Deficiencies

Observation Description		Root Cause	CAPA Actions
8.1	Passivation reports showed out-of-specification results for water systems, yet the system was released for use.	Inadequate QA oversight and deviation management in utility qualification.	- Revise utility system SOPs to prohibit use until results meet specifications. - Implement QA release approval for all critical utilities post-maintenance or passivation.
8.2	Calibration of micropipettes was performed using equipment with insufficient sensitivity.	Poor calibration method selection and inadequate QC review.	- Update calibration SOPs to specify equipment sensitivity requirements.

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Manufacturing	Quality	Contamination Control
Batch Execution AI-powered Batch Execution	**AI Investigator** Close Investigations Faster	**Environmental Monitoring** Plan/Track & analyze EM Samples
Batch Intelligence Deliver On-time In-Full	**QMS/DMS** Simplify Quality & Doc Managentent	**Cleaning Validation** FDA-ready Cleaning Validation
Production Logbook Integrate Production Logbooks	**FDA Tracker** Track 483/WL data	**Media Fill Simulation** Validate aseptic processing

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Audit Checklist to prepare for Eileen A Liu

This section provides insights into the investigator's focus area, along with the audit checklist to follow in case the investigator visits the site.

Focus Area		CAPA Priority	Evidence Required	Preventive Actions
1	**Contamination Control**	Strengthen aseptic operations and contamination barriers to ensure sterility assurance.	Media fill reports, smoke study videos, intervention logs, EM data, and aseptic operator qualification records.	• Conduct periodic dynamic smoke studies covering critical interventions. • Implement QA-led aseptic behaviour audits and update the Contamination Control Strategy (CCS).
2	**Process Validation**	Ensure all processes are validated under worst-case conditions and aligned with actual manufacturing parameters.	Process validation protocols, qualification reports, sampling data, and re-validation schedules.	• Redesign validation protocols to include stress and challenge parameters. • Conduct periodic re-validation and establish QA oversight on all validation activities.
3	**Batch Records**	Reinforce accuracy and completeness of documentation across production and QA review stages.	Executed batch records, deviation logs, in-process monitoring data, and QA audit reports.	• Implement electronic batch record (EBR) systems to ensure data integrity. • Conduct regular QA audits and retrain staff on real-time documentation practices.
4	**Laboratory Controls**	Enhance reliability, integrity, and traceability of laboratory data and analytical results.	Certificate of Analysis (COA), sterility and bioburden test results, calibration logs, and audit trail reviews.	• Revalidate analytical methods and ensure alignment with USP standards. • Conduct data integrity audits and retrain QC personnel on contamination prevention.
5	**Cleaning Validation**	Verify and document cleaning effectiveness through validated analytical and visual methods.	Cleaning validation reports, residue recovery studies, analytical method validation data, and cleaning logs.	• Reassess cleaning validation protocols based on product risk and residue profiles. • Perform periodic revalidation and implement enhanced visual inspection checks.

Get Inspection Ready against this 483

This section helps in staying audit-ready for this particular 483's observations, along with recommended evidence.

Observation 1

Inadequate Aseptic Practices and Validation of the Aseptic Process

Questions		YES	NO	N/A	Recommended Evidence
1.1	Inadequate Aseptic Practices and Validation of the Aseptic Process	☐	☐	☐	Were aseptic interventions (Grade A/B) justified, documented, and approved as per intervention logs?
1.2	Have operators been trained and qualified to perform aseptic manipulations, including maintaining a sterile field?	☐	☐	☐	Operator qualification records, training assessments, and aseptic behaviour audit reports.
1.3	Are stopper bag sanitisation procedures validated and performed consistently before transfer into Grade A?	☐	☐	☐	Sanitisation SOPs, validation reports, and transfer operation logs.
1.4	Were vial sealing and aseptic interventions simulated and validated in dynamic smoke studies or media fills?	☐	☐	☐	Dynamic smoke study videos, media fill protocols, and airflow visualisation reports.
1.5	Are interventions during vial sealing recorded, trended, and reviewed by QA	☐	☐	☐	Intervention trend data, QA review summaries, and deviation records.

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	for impact on product sterility?				
1.6	Do smoke studies demonstrate unidirectional airflow without turbulence across critical aseptic zones?	☐	☐	☐	Airflow visualisation study reports, HVAC qualification records, and video evidence.
1.7	Has the aseptic process validation been updated to include all critical activities (e.g., vial sealing, stopper handling)?	☐	☐	☐	Updated process validation protocols, APS qualification data, QA change control records.

Observation 2

Deficient Environmental Monitoring in Aseptic Processing Areas

Questions		YES	NO	N/A	Recommended Evidence
2.1	Is viable and non-viable particle count monitoring performed in all Grade A/B areas?	☐	☐	☐	EM monitoring logs, particle count data, and calibration certificates.
2.2	Are personnel finger dab and glove monitoring performed after each aseptic intervention?	☐	☐	☐	Personnel monitoring records, SOP FU12-QC-MIC-GEN-023, and EM summary reports.
2.3	Is the swab recovery method validated for surfaces exposed to product contact?	☐	☐	☐	Swab validation reports, microbial recovery studies, and trending data.

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2.4	Are sampling sites and frequencies defined through risk-based EM mapping?	☐	☐	☐	EM site maps, validation protocols, and trending summary reports.

Observation 3

Inadequate Review of Batch Discrepancies and Failures

Questions		YES	NO	N/A	Recommended Evidence
3.1	Are batch discrepancies thoroughly investigated with documented root cause?	☐	☐	☐	Deviation logs, investigation reports, and QA closure records.
3.2	Are complaint investigations reviewed for potential material or process impact?	☐	☐	☐	Complaint files, CAPA reports, and trending analysis.
3.3	Are retained samples tested during complaint investigations for confirmation?	☐	☐	☐	Retain sample analysis data, complaint SOPs, and investigation summaries.

Observation 4

Inadequate Written Procedures and Process Validation

Questions		YES	NO	N/A	Recommended Evidence
4.1	Do process validation protocols include all critical and worst-case	☐	☐	☐	Validation protocols, PPQ reports, and risk assessment documents.

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	parameters?				
4.2	Are validated process parameters reflected accurately in batch records?	☐	☐	☐	Master batch records, validation summaries, and QA approval logs.
4.3	Are environmental conditions (e.g., humidity, temperature) validated for product stability?	☐	☐	☐	Stability studies, process validation reports, and qualification data.

Observation 5

Non-Adherence to Production and Process Control Procedures

Questions		YES	NO	N/A	Recommended Evidence
5.1	Are equipment parameter changes recorded in batch records and approved by QA?	☐	☐	☐	Batch records, change control forms, and QA approval logs.
5.2	Are post-setup parameter changes supported by in-process checks or requalification?	☐	☐	☐	Change control documentation, deviation reports, and data logs.
5.3	Are QA reviews verifying setup parameters and change reports before disposition?	☐	☐	☐	QA batch review checklist, deviation summary, and CAPA records.

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Observation 6

Inadequate Equipment Cleaning and Campaign Management

Questions		YES	NO	N/A	Recommended Evidence
6.1	Are campaign cleaning intervals scientifically justified and validated?	☐	☐	☐	Cleaning validation reports, campaign study data, and risk assessment reports.
6.2	Are visual and analytical verifications performed after each cleaning?	☐	☐	☐	Swab/rinse test reports, analytical results, and cleaning checklists.
6.3	Are residues or contamination identified post-cleaning investigated promptly?	☐	☐	☐	Deviation reports, cleaning logbooks, and CAPA documentation.

Observation 7

Facility Maintenance and Infrastructure Deficiencies

Questions		YES	NO	N/A	Recommended Evidence
7..1	Are storage and production areas free from leaks, corrosion, and water ingress?	☐	☐	☐	Facility maintenance logs, inspection photos, and repair records.
7.2	Are preventive maintenance and repair activities documented and verified by QA?	☐	☐	☐	PM schedules, facility inspection reports, and QA verification sheets.

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7.3	Are environmental controls in warehouses validated to prevent moisture ingress?	☐	☐	☐	HVAC qualification reports, BMS trend data, and calibration records.

Observation 8

Quality Unit Oversight and Calibration Deficiencies

Questions		YES	NO	N/A	Recommended Evidence
8.1	Were OOS passivation results for the water system reviewed before system release?	☐	☐	☐	Passivation reports, QC review records, and QA release documentation.
8.2	Was the calibration of laboratory instruments conducted using qualified standards?	☐	☐	☐	Calibration reports, balance qualification certificates, and method SOPs.
8.3	Are QC approvals linked to the review of calibration accuracy and sensitivity?	☐	☐	☐	QC approval forms, audit reports, and equipment verification logs.

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