Leucine

FDA 483 Insights Report

Lupin Limited, Pithampur, India (July 2025)

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

483 Risk Summary

Facility Name	Lupin Limited, Pithampur, India
Inspection Date	8-9 July, 2025
Subsystems Impacted	Contamination Control, MediaFill, Environmental Monitoring, Sample Management
Site History	Earlier Received 483 in March 2023

	Observation	Scope	Patient Severity	Risk of Escalation	Cost of Remediation
1	Inadequate Aseptic Practices and EM	Sterile filling ops, Grade A/B areas	🔴	🔴	🔴
2	Deficiencies in Airflow and Smoke Studies	Facility airflow/ cleanroom	🔴	🔴	🟡
3	Inadequate Visual Inspection Procedures	Batch QC & release	🟡	🟢	🟢
4	Inadequate CAPA for Microbiological OOS Results	QA system, EM	🔴	🔴	🔴

Rafeeq Habeeb's Profile 🟡

Inspections	483s	Recent 483s
63	32	Eli Lily (May 2025) Q Labs (Apr 2025) Kuton (Mar 2025) Resilience (Jan 2025) Upsher-Smith (2024) Thorn Bioscience (2024) KP Pharmaceutical (2024) Gorilla Glue (2024) and more

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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 Environmental Monitoring

Observation Description		Root Cause	CAPA Actions
1.1	The operator reached over open vials during aseptic filling; exposed vials were not removed	Inadequate aseptic technique training and lack of procedural enforcement	- Update aseptic technique SOP, retrain operators - Implement stricter procedural adherence checks
1.2	No environmental monitoring for the Grade A area, where operators conduct weight checks	Lack of a comprehensive environmental monitoring plan	- Expand the environmental monitoring plan to include all critical areas - Install additional monitoring equipment
1.3	Operators travel between Grade A and B areas without appropriate gowning standards	Inadequate gowning procedures and enforcement	- Revise gowning SOPs, enforce stricter gowning protocols - Conduct regular compliance audits

Observation 2

Deficiencies in Airflow and Smoke Studies

Observation Description		Root Cause	CAPA Actions
2.1	Turbulent airflow patterns observed during smoke studies, compromising laminar flow	Inadequate smoke study execution and analysis	- Revise smoke study protocols, retrain personnel - Conduct a comprehensive airflow re-evaluation
2.2	Insufficient smoke generation to visualize airflow direction during studies	Inadequate smoke generation equipment and techniques	- Upgrade smoke generation equipment - Retrain staff on proper smoke study techniques

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2.3	Unclear smoke directionality, making it impossible to determine airflow patterns	Poorly designed smoke study protocols and execution	- Redesign smoke study protocols - Implement stricter execution standards - Conduct additional training

Observation 3

Inadequate Visual Inspection Procedures

Observation Description		Root Cause	CAPA Actions
3.1	Failure to conduct visual inspections of batches shipped to the US market	Lack of comprehensive visual inspection procedures	- Develop and implement detailed visual inspection SOPs - Train personnel - Conduct regular audits
3.2	Defect characterization is inadequate during destructive testing	Inadequate training and lack of standardized defect characterization protocols	- Establish standardized defect characterization protocols - Enhance training programs - Conduct regular assessments
3.3	Inspection parameters lack standardization across different products	Inconsistent inspection standards and lack of procedural guidance	- Standardize inspection parameters - Update SOPs - Ensure consistent application across all products

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Observation 4

Inadequate CAPA for Microbiological OOS Results

Observation Description		Root Cause	CAPA Actions
4.1	Failure to implement adequate CAPA for OOS microbiological results in Grade A environment	Inadequate CAPA procedures and lack of follow-up actions	Revise CAPA procedures, ensure thorough investigation, and follow-up Implement enhanced monitoring
4.2	Affected batches not placed on stability testing program post-microbiological excursion	Lack of comprehensive stability testing protocols post-deviation	Implement stability testing for affected batches Revise protocols to include post-deviation testing
4.3	No increased monitoring of Grade A environment following microbiological deviation	Inadequate environmental monitoring response to deviations	Enhance environmental monitoring protocols Ensure increased monitoring post-deviation

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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 Rafeeq Habeeb

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

Focus Area		CAPA Priority	Evidence Required	Preventive Actions
1	**Preventive Maintenance**	Revise and enforce preventive maintenance SOPs; ensure timely calibration and maintenance of equipment; conduct periodic reviews of maintenance logs.	Updated SOPs, maintenance logs, calibration records, and periodic review documentation.	Implement automated maintenance scheduling system; conduct quarterly maintenance audits.
2	**Laboratory Controls**	Enhance laboratory control procedures; validate all test methods; ensure prompt action on deviations.	Validation reports, deviation investigation reports, and laboratory audit records.	Deploy real-time laboratory monitoring tools; perform monthly trend analysis reviews.
3	**Process Validation**	Ensure comprehensive process validation; enforce strict adherence to validation protocols; document all validation activities.	Process validation protocols, validation reports, and deviation logs.	Implement validation tracker with escalation triggers for overdue validations.
4	**Training Management**	Ensure all training is competency-based with formal assessments; retrain promptly after SOP updates.	Training matrix, pass/fail assessment reports, overdue training alerts.	Use LMS reminders; conduct quarterly training effectiveness checks.
5	**Complaint Management**	Revise complaint handling procedures; ensure timely investigation and resolution of complaints; track effectiveness of CAPA related to complaints.	Complaint logs, investigation reports, CAPA records, and effectiveness check documentation.	Implement a complaint tracking system with automated alerts for overdue actions.

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 Environmental Monitoring

Questions		YES	NO	N/A	Recommended Evidence
1.1	Show me how operators perform interventions during aseptic filling (media fills & production).	☐	☐	☐	Media fill videos; aseptic intervention SOP; batch records documenting interventions; training records of operators.
1.2	What procedures exist to prevent reaching over exposed sterile units?	☐	☐	☐	Written SOPs on aseptic techniques; deviation reports showing corrective action when breached; internal audit checklists.
1.3	How do you ensure Grade B equipment/materials are not introduced into Grade A?	☐	☐	☐	Material transfer SOPs; logs of equipment disinfection before Grade A entry; records of Grade A/B segregation validation.
1.4	What environmental monitoring is performed in Grade A during interventions?	☐	☐	☐	EM protocols; EM data logs (settle plates, air sampling, non-viable particle counts); trend reports showing compliance.
1.5	How do you ensure gowning is appropriate for Grade A entry?	☐	☐	☐	Gowning SOP; gowning qualification training records; gowning audit reports/photos; deviation logs.

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Observation 2

Deficiencies in Airflow and Smoke Studies

Questions		YES	NO	N/A	Recommended Evidence
2.1	Show me your airflow visualization (smoke study) reports for all Grade A/B areas.	☐	☐	☐	Smoke study protocols; final qualification reports; videos from studies.
2.2	How do you demonstrate unidirectional airflow and absence of turbulence at critical points?	☐	☐	☐	Annotated smoke study footage; qualification acceptance criteria; engineering reports confirming compliance.
2.3	How do you ensure smoke study conditions are representative of dynamic (production) operations?	☐	☐	☐	Smoke study reports conducted during equipment operation and simulated interventions; signed protocols showing scope.
2.4	What changes were made if smoke studies revealed swirling or turbulence?	☐	☐	☐	Change control records for HVAC adjustments; HEPA filter replacement logs; requalification reports post-change.

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Observation 3

Deficiencies in Airflow and Smoke Studies

Questions		YES	NO	N/A	Recommended Evidence
3.1	How do you ensure all in-process materials are visually inspected before release?	☐	☐	☐	Batch records with signed visual inspection checklists; SOP on in-process visual inspection; QA release documentation.
3.2	Show me how inspectors are trained and qualified for defect detection.	☐	☐	☐	Training records; inspector qualification test results; challenge kit outcomes with acceptance/rejection data.
3.3	Do you use defect libraries or challenge kits to assess inspector proficiency?	☐	☐	☐	Physical or digital defect library; documented use of challenge kits in qualification; periodic requalification results.
3.4	Are visual inspection parameters (lighting, time per container, unit size) standardized and reflective of production?	☐	☐	☐	SOP specifying lighting, magnification, inspection time per unit; calibration logs of inspection stations; qualification vs. production condition alignment reports.

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Observation 4

Inadequate CAPA for Microbiological OOS Results

Questions		YES	NO	N/A	Recommended Evidence
4.1	Show me records of Grade A environmental monitoring where OOS results were obtained.	☐	☐	☐	Raw EM logs; microbiological monitoring reports; batch-linked OOS reports.
4.2	How do you investigate OOS microbiological results?	☐	☐	☐	Investigation reports (root cause analysis); deviation records; QA review approvals.
4.3	Were affected batches placed on stability to evaluate impact?	☐	☐	☐	Stability program protocols; logs showing addition of affected lots; stability data results.
4.4	How do you escalate and document CAPA for repeated OOS events?	☐	☐	☐	CAPA forms; trend reports of OOS; CAPA effectiveness checks; QA management review minutes.
4.5	What increased monitoring is triggered after microbiological excursions?	☐	☐	☐	SOP for EM escalation; monitoring frequency change records; post-deviation EM data showing enhanced sampling.

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