DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, Room #2032, 12420 Parklawn Drive, Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/22/2026-06/26/2026* FEI NUMBER 3030708811

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

To: Mr. Sathyanarayana Ponnam, Senior Vice President Operations

FIRM NAME	STREET ADDRESS
Auroactive Pharma Private Limited	Sy.Nos. 231, 285 to 291, Sancham Village, Ranasthalam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sancham Village, Srikakulam District-532 409, Andhra Pradesh, India	Intermediate, Active Pharmaceutical Ingredient and Pharmaceutical Formulation Intermediate Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Laboratory Incident Investigations for High-Performance Liquid Chromatography (HPLC) Injection-to-Injection Area Variability Failures Were Inadequate. Specifically,

The firm's Quality Control (QC) laboratory failed to conduct thorough investigations in accordance with SOP QC042 – "Handling of Laboratory Incidents" for the following Laboratory Incident Reports (LIRs): LIR-25-00008, LIR-25-00013, LIR-25-00014, LIR-25-00015, LIR-25-00038, LIR-25-00042, and LIR-25-00045 involving injection-to-injection area variability attributed to possible vial septa damage. Specifically:

- The firm's corrective actions states as 'not applicable', root cause analyses were not supported with adequate scientific evidence, and incorrect sample weight was used in calculation at one instance
- Several of the cited LIRs — specificallyLIR-25-00038, LIR-25-00042, and LIR-25-00045— lack documented rationale for why new sample preparation was selected over reinjection of the existing prepared solution as the corrective path.
- For all cited LIRs, initial results were invalidated without scientific justification, and the reinjected or reanalyzed results were accepted and used for batch release.

The specific findings for each LIR are detailed in the table below:

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE	Lata Mathew	Lata C. Mathew, Ph.D. (b) (4) Manager	06/26/2026

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LIR Number	Batch	Key Issue
LIR-25-00008	(b) (4) (1M-ACC)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); The original samples were reinjected stating that the failure was due to 'vial septa damaged' error without enough scientific evidence; The batch was released based on the one reinjected passing result. The API batch was utilized in manufacturing (b) (4) batch that was dispatched to the domestic market
LIR-25-00013	(b) (4) (3M-LT)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); The original samples were reinjected stating that the failure was due to 'vial septa damaged' error without enough scientific evidence; The batch was released based on the one reinjected passing result. The Indian Pharmacopoeia (IP) grade API batch was dispatched to the domestic market.
LIR-25-00014	(b) (4)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); The original samples were reinjected stating that the failure was due to 'vial septa damaged' error without enough scientific evidence; The batch was released based on the one reinjected passing result. The API batch was dispatched to the domestic market.
LIR-25-00015	(b) (4) (3M-ACC)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); The original samples were reinjected stating that the failure was due to 'vial septa damaged' error without enough scientific evidence. Also

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		sample weight discrepancy was observed — the balance printout recorded (b) (4) mg, whereas (b) (4) mg was used in the result calculation; results were calculated and printed on an external Excel spreadsheet and not in the official analytical data worksheet; The batch was released based on the one reinjected passing result. The API was utilized in manufacturing (b) (4) (b) (4) process validation batch # (b) (4) (b) (4) About (b) (4) of (b) (4) was shipped to the US market.
LIR-25-00038	(b) (4) (9M-LT)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); original samples were not reinjected — instead, new samples were prepared and injected with no documented scientific rationale to support new sample preparation; a 4-day gap existed between initial sample preparation (October 15, 2025) and retesting (October 19, 2025), which was not documented or justified in the investigation report; The batch was released based on the one passing result from the new sample preparation. The API was utilized in manufacturing (b) (4) process validation batch # (b) (4) About (b) (4) of (b) (4) was shipped to the US market.
LIR-25-00042	(b) (4) (3M-LT)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); the original preparation was discarded and a new sample was prepared and injected on the same day without any scientific rationale; The batch was released based on the one passing result from the new sample preparation. The API batch is not dispatched.

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LIR-25-00045	(b) (4)	The average results from both injections met the product specification ((b) (4) to (b) (4) %w/w); however, failed (b) (4) to meet variability ratio specification ((b) (4) to (b) (4)); original samples were not reinjected — instead, new samples were prepared and injected with no documented scientific rationale to support new sample preparation; The batch was released based on the one passing result from the new sample preparation. The API was utilized in manufacturing (b) (4) (b) (4) and released for distribution in domestic market.

OBSERVATION 2

The firm failed to thoroughly investigate unexplained discrepancies, Specifically,

SOP QC044 – Handling of Laboratory Occurrences, Version 01, effective January 1, 2025, does not explicitly define what constitutes "reanalysis." The SOP fails to distinguish between:

- Reinjection of an existing prepared solution,
- Fresh sample preparation from the original material, or
- Repeat of the entire analytical sequence.

Sections 5.1 and 5.2 of SOP QC044 define laboratory occurrences only in broad terms, and Section 5.8.13 references "re-analysis" without defining its scope.

A review of Laboratory Occurrence Reports (LORs) conducted by the firm from February 2024 through June 20, 2026, reveals the following root cause trends, which further illustrate the systemic nature of these deficiencies:

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Root Cause Category	2024 Count (~180)	2024 %	2025 Count (~298)	2025 %	2026 Count (~83, partial)	2026 %
Analyst oversight / lack of attention	~47	~26%	~75	~25%	~40	~48%
Improper column washing / system preparation	~22	~12%	~85	~29%	~12	~14%
Instrument failure / technical issues	~22	~12%	~38	~13%	~30	~36%
Air bubbles / (b) (4) issues	~14	~8%	~40	~13%	~10	~12%
IR (b) (4) spectrum issues	~9	~5%	~22	~7%	~8	~10%
Improper integration / processing method	~17	~9%	~18	~6%	~3	~4%
Unidentified / "might be" root causes	~8	~4%	~5	~2%	~0	~0%
Other	~41	~23%	~15	~5%	~0	~0%

The Consolidated CAPA Count shows the following CAPAs initiated using the following terminologies

CAPA Category	Variants Included	Count
Re Performed	Re Performed, Reperfomed, Re Peformed, Re P[erformed, Re Perfomed, Re Peroformed, Re Perfomed	~180
Re Analysis	Re Analysis, Re analysis, Re analysis performed, Re Analysis performed, Reanalysis	~85
Re Processed	Re Processed, Re processed, Reprocessed, Re proceessed, Re propcessed, Reprcessed	~46
NA (No CAPA)	NA, blank	~148
Training	Training provided, Trainng provided, Training shall be provided to analyst, Training shall be provided to the analyst	~45

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Other	Sensor leakage, Change another system, Re calculated, Re Print, re printing, etc.	~21
Grand Total		~549

~148 entries (approximately 27%) have CAPA recorded as "NA", meaning no corrective action was taken or documented whereas Section 5.8.20 of the SOP requires corrective and/or preventive actions to be proposed and implemented based on investigation findings.

***DATES OF INSPECTION**

6/22/26 (Mon), 6/23/26 (Tue), 6/24/26 (Wed), 6/25/26 (Thu) and 6/26/26 (Fri)

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