DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	2/4/2026-2/6/2026
	FEI NUMBER 3019975128

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Vidya Sagar P.V, Zonal Head

FIRM NAME	STREET ADDRESS
Auriga Research Private Limited	Plot No 136, 6th Cross
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, Karnataka, 560022 India	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory

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 OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components and raw materials conform to appropriate standards of identity. Specifically,

Your firm's microbiological testing records demonstrated significant data integrity concerns, including failure to document testing operations, sample preparation activities, equipment identification, and microbiological test results for samples that had completed incubation, with at least two microbiologists stating that observed negative/absent results were not entered into the testing records.

Your contract testing laboratory maintains (b) (4) microbiology laboratory, with the same personnel responsible for testing pharmaceutical and (b) (4) products. My review of microbiology testing worksheets covered at least (b) (4) different analysts and approximately (b) (4) different ongoing test samples for TAMC, TYMC, *Escherichi coli*, *Salmonella*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Candida albicans*, and sterility testing. The itemized discrepancies observed within each sample are too numerous to list, however the deficiencies observed include the following:

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-For multiple samples too numerous to list, testing for *S. aureus*, *P. aeruginosa*, and other pathogens appeared to have finished, with incubation time completed and samples read by microbiologists, however no results were recorded on worksheets.

-No sample preparation activities such as sample pre-enrichment or any other activity prior to or during incubation has been documented for numerous samples.

-Sterility testing sample ongoing test result monitoring were observed to be blank for days that have already passed, with the analyst admitting that they observed the result but did not enter it yet.

My review found that there is no assurance that the microbiology personnel are reporting actual test data from microbiology testing operations.

OBSERVATION 2

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

Investigations initiated and performed by your Quality Unit in response to out-of-specification (OOS) reports for raw material, pharmaceutical, and other tested products were not comprehensive to determine all potential root causes. Corrective and Preventive Actions (CAPAs) resulting from investigations were not comprehensive to address root causes and were not adequately documented or implemented. Investigations performed in response to these quality events lacked clarity and details to support root cause determination, lacked scientific rationale for suspected root causes, lacked justification for repeat analysis using new sample solution preparations, and were incomplete with inadequate measures to

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address the stated root cause. For Example:

A. OOS/CHE/2025/087 was initiated on 12/09/2025 for raw material (b) (4) customer batch number (b)(4), laboratory sample # (b)(4), for assay by potentiometry test, which yielded an OOS result of (b) (4) % versus a specification of (b)(4) (b) (4) %.

On 09/12/2025, your firm performed hypothesis testing by retesting a fresh sample preparation using the same analyst and same Autotitrator equipment (ARL/BLEQ/APT-002). This yielded a passing result of (b) (4) %. Based solely on this single passing result, your firm suspected sample weighing error as the root cause without providing scientific rationale. Your firm then performed a repeat analysis in triplicate using the same analyst and equipment. The results were (b) (4) %, (b) (4) %, and (b) (4) %, with an average of (b) (4) %, which failed. Your firm then suspected insufficient electrode saturation as the root cause, again without scientific support.

A second repeat analysis was performed on 09/12/2025 with the same analyst and equipment but was aborted after two preparations due to high results. The two preparations yielded (b) (4) % and (b) (4) %, with an average of (b) (4) %. Your firm then suspected electrode sensing issues as the root cause without adequate rationale. On 12/16/2025, a third repeat analysis was performed on a different autotitrator (ARL/BLEQ/APT-001) in triplicate. The results were (b) (4) %, (b) (4) %, and (b) (4) %, with an average of (b) (4) %. This became the final reported value. Your firm failed to document that this equipment was from the (b) (4) laboratory, not the pharma laboratory.

Additionally, your firm did not follow SOP No. ARLBL/QA/SOP-009, "Handling Of Out of Specification Results" (effective 03/18/2025). The SOP requires that after hypothesis testing fails, the investigation moves to Phase II where the customer submits a second sample for analysis in (b) (4) by (b) (4) analysts. Instead, your firm performed multiple repeat analyses with the same analyst and same sample until passing results were reported.

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Despite concluding that electrode sensing issues caused the OOS, no CAPA addressed electrode maintenance or replacement. Your firm's SOP No. ARLB/CHE/SOP-278, "Operation & Calibration of Auto Titrator (Metrohm)," requires preventive maintenance of the electrode and solvotrode (b) (4) (b) (4), but this was not mentioned in the investigation or CAPA.

B. OOS/CHE/2025/003 was initiated on 01/06/2025 for raw material (b) (4) batch number (b)(4), laboratory sample # (b)(4), for assay by potentiometry test, which yielded an OOS result of (b) (4) % versus a specification of (b) (4) % to (b) (4) %. Similar to the observation above, your firm did not follow SOP No. ARLBL/QA/SOP-009, "Handling Of Out of Specification Results."

On 01/06/2025, your firm performed hypothesis testing by analyzing a fresh preparation of sample with remaining sample using the same autotitrator equipment. This yielded a passing result of (b) (4) %. Based solely on this single passing result, your firm suspected that the probable root cause for the OOS was due to sample weighing error without providing scientific rationale. Your firm then performed multiple repeat analyses in triplicate, continuing to test until passing results were obtained:

Repeat Analysis 1:Performed on 01/06/2025 in triplicate, with 2 out of 3 preparations yielding OOS results. Without any explanation of what happened, your firm performed another repeat analysis.

Repeat Analysis 2: Performed on 01/06/2025 in triplicate, again with 2 out of 3 preparations yielding OOS results. Your firm stated the variation in results might be due to air bubble entrapment in the flow channel, without scientific rationale.

Repeat Analysis 3: Your firm cleaned the flow channel with solvent and rinsed with (b) (4) (b) (4) volumetric solution. On 01/06/2025, the test was repeated once more with new preparations, where all three preparations were OOS.

Repeat Analysis 4: The electrode was kept saturated overnight in (b) (4) solution. On 01/08/2025, another repeat analysis was performed in triplicate, where 1 out of 3 preparations were OOS. Your firm stated they suspected there may be a sample weighing error during sample preparation-3, without scientific rationale.

Repeat Analysis 5: On 01/09/2025, this analysis was performed "taking more precautions during sample weighing and sample transferring to beaker," where once again all three preparations resulted in OOS results.

Repeat Analysis 6: Finally, on 01/09/2025, this repeat analysis was performed in triplicate with all three preparations within specification, yielding an average result of (b) (4) %.

After multiple sample preparations where precautionary measures were taken for weighing and electrode saturation, your firm concluded the root cause was sample weighing error and insufficient electrode saturation. The CAPA stated "awareness given to the concerned analysts i.e. sample technique and electrode regeneration to avoid such type of errors in the future." This CAPA does not address why the same analyst continued to make weighing errors across multiple attempts or why electrode saturation issues persisted despite overnight saturation between analyses.

C. OOS/CHE/2025/081 was initiated on 11/14/2025 for raw material (b) (4) batch number (b)(4), laboratory sample # (b)(4), for assay by potentiometry test, which yielded an OOS result of (b) (4) % versus a specification of (b) (4) % to (b) (4) %. Your firm's hypothesis study concluded the probable root cause was due to blockage in the anti-diffusion tube of the equipment, without identifying an assignable root cause or providing scientific rationale for this

conclusion. The hypothesis study included (b) (4) the anti-diffusion tube with (b) (4) (b)(4), then testing a new fresh preparation, which yielded results within specification. Your firm's CAPA did not address the lack of adherence to SOP No. ARLB/CHE/SOP-278, "Operation & Calibration of Auto Titrator (Metrohm)." Section 5.2.5 of this SOP, "Cleaning of Anti-Diffusion Tube," requires (b) (4) cleaning (b) (4) and replacement (b) (4)

D. OOS/CHE/2025/050 was initiated on 07/17/2025 for raw material (b) (4) batch number (b)(4), for assay by potentiometry test, which yielded an OOS result of (b) (4) % versus a specification of (b) (4) % to (b) (4) %. Your firm's hypothesis testing included retesting with a fresh preparation, which yielded passing results. Based on this single passing result, your firm concluded the root cause was blockage of the anti-diffusion tube without providing scientific rationale. Repeat analysis by the same analyst in triplicate was within specification. Your firm provided no documentation of corrective actions taken to address the blockage. At the time of this investigation, SOP No. ARLB/CHE/SOP-278, "Operation & Calibration of Auto Titrator (Metrohm)," did not include procedures for cleaning the anti-diffusion tube. The SOP was later revised on 10/09/2025 to include this procedure, but this OOS investigation did not identify the missing procedure as a CAPA.

E. OOS/CHE/2025/046 was initiated on 07/08/2025 for (b) (4) Tablets stability samples, batch numbers (b) (4) analyzed via LCMSMS. The OOS results were (b) (4) ppm versus a specification of NMT (b) ppm. Phase 1a investigation included testing the same vial and re-vial of the same preparation, which confirmed the OOS results. Phase 1B checklist identified the root cause as contamination of the MS source. Corrective action included cleaning the source and repeat analysis with fresh preparation, which yielded results within specification. As preventive action, your firm instructed the analyst to clean the source (b) (4) However, this preventive action is not documented in any procedure. SOP No. ARLBL/CHE/SOP-203, "Operation and Calibration of LCMSMS System" (effective 04/09/2025), includes source

cleaning instructions in Section 7.2 but does not specify frequency. Based on the format in the SOP, cleaning appears to be performed (b) (4) Your firm's CAPA to clean (b) (4) was not incorporated into the SOP or any other documented procedure.

F. OOS/CHE/2025/037 was initiated on 05/28/2025 for raw material (b) (4) (b) (4) batch number (b) (4) laboratory sample # (b) (4), for assay by potentiometry test, which yielded an OOS result of (b) (4) % versus a specification of (b) (4) % to (b) (4) %. Your firm's investigation identified the assignable root cause as usage of (b) (4) (b) (4) volumetric solution due to multiple usage of the bottle. This reagent is purchased from an outside vendor. Your firm's investigation provided no information regarding the shelf life of the reagent, whether it was tested upon receipt or during use, whether it was expired, or what constitutes excessive usage. Your firm provided no scientific rationale to support the conclusion that multiple usage of the bottle caused the OOS result. The OOS was determined to be invalid and the sample was reanalyzed with passing results reported.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

Your firm failed to adequately document laboratory operations and testing activities on worksheets, failed to initiate laboratory incidents when required, provided contradictory information regarding testing status, demonstrated potential data integrity concerns during the inspection, lacked adequate control over the issuance and management of controlled test records, and lacked standard test procedures for certain testing operations. For Example:

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A. On 02/04/2026, while walking past the microbiology laboratory, I observed through the glass windows into the microbiology office an analyst writing information on what appeared to be worksheets. When one analyst noticed my presence, they stopped writing and closed the notebook on the worksheets. Your firm informed me that personnel would be taking lunch for approximately (b) (4) I requested the analyst bring the records out of the office for my review. My review of the analyst's records revealed microbiology worksheets for products currently under incubation. The worksheets contained no sample preparation data, results, or equipment identification, despite the firm stating the samples had been prepared and were currently under incubation. I requested that the microbiology manager and firm representatives, including the most responsible person for the laboratory and the QA Manager to notify me when personnel returned from lunch and that no one enter the microbiology laboratory without me entering with them. I confirmed with a microbiologist that no individuals were present inside the microbiology laboratory after all personnel left for lunch. Upon waiting in the inspection office reviewing the first analyst's worksheets for approximately (b) (4), I headed toward the microbiology laboratory entrance to wait for personnel to return from lunch, however, I was informed that several individuals had already entered the laboratory. After entering the laboratory, I observed more than (b) (4) microbiologists in one room. My review of ongoing microbiology worksheets revealed similar deficiencies in testing records for multiple analysts, while several analysts with fewer worksheets had neatly written information on their worksheets. See Observation 1 for details.

B. On 02/04/2026, during a walkthrough of the QC laboratory area, I observed multiple QC personnel (at least (b) (4) individuals) rapidly exiting the room in different directions with documents in hand. I was able to stop two individuals before they exited the room.

-The first individual was carrying laboratory records for (b) (4) Sample # (b) (4) dated 01/31/2026, a (b) (4) product tested for (b) (4) by HPLC. According to the analyst, another analyst had weighed samples on 02/03/2026 and prepared sample solutions but was unable to start testing due to the instrument being used by another analyst. For this

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reason, the sample was discarded that morning and transferred for re-preparation and testing. Your firm failed to initiate a laboratory incident for this occurrence. Additionally, complete raw data of laboratory activities were not documented on the testing worksheets, including sample preparation activities, balance ID, equipment instrument name, and date of calibration.

-The second individual was carrying an approximate 3-inch stack of laboratory test records. Review of one worksheet, sample number (b)(4) for pharmaceutical excipient (b) (4) (b)(4), dated 01/20/2026, for viscosity test, revealed the following. Based on limited information on the worksheet, weighing appeared to have been performed on 01/21/2026. On 02/04/2026, the QC reviewer stated testing had been completed. However, the worksheet contained no information on the sample, laboratory activities performed, or results calculations. The test method referenced BP-2025 for the viscosity test. No documentation of any testing activity was recorded on the worksheet, and the data had not been reviewed by QC. On 02/05/2026, the QC reviewer stated that weight of sample and density activity with (b) (4) of weighed sample still needed to be performed, calculations for density needed to be completed, and then viscosity testing using a U-Tube viscometer needed to be conducted. This contradicted the previous day's statement that all testing was completed.

Additionally, the records from the second individual included multiple laboratory work orders along with purported controlled test sheets for at least (b) (4) different pharmaceutical products, including [redacted] These records covered various types of tests including assay, identification, solubility, IR, and pH, with some dating back several months. Your firm stated these were extra printouts of tests that had already been performed on other work orders. This demonstrates that your Quality Unit lacks adequate control over the issuance and management of controlled test records.

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C. Your firm's quality control unit did not follow established SOPs for handling out-of-specification results, equipment maintenance, and cleaning procedures. Additionally, some SOPs lacked adequate detail for required activities to be performed. See Observation 2 for details.

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