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 CDER-OC-OMQ-International483Response@fda.hhs.gov	02/19/2026-02/27/2026 FEI NUMBER 3009510975

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Santhosh Mathai, Business Head - Pharmaceuticals

FIRM NAME	STREET ADDRESS
Reliance Life Sciences Private Limited	Dhirubhai Ambani Life Sciences Centre, R-282 Ttc Area of MIDC, Thane Belapur Road, Rabale
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Navi Mumbai, Maharashtra 400701 IN	Drug 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 WE OBSERVED:

OBSERVATION 1

Laboratory records do not include complete data derived from all tests, examinations, and assay necessary to assure compliance with established specifications and standards. Specifically,

A. Environmental monitoring (EM) samples were documented in Logbooks as collected but were not actually taken. Specifically, on 02/19/2026 we inspected the Quality Control Pharma (QCP) Microbiology Laboratory. We inspected EM samples under incubation. We noted the following.

1. Plant (b) (4) injection line aseptically fills products for the U.S. market. (b) (4) Plant (b) (4) ISO 5 active air samples were documented as collected in Logbook LB/QCP6/26/005-01 from 08:06 to 10:44 on 02/16/2026 during (b) (4) Injection Batch (b) (4) (domestic market) sealing activity. According to the Logbook record, these samples were under 20-25°C incubation from 02/16/2026 to 02/19/2026. However, on 02/19/2026 no samples were found in the laboratory incubator. Your QCP personnel confirmed these samples were never collected.

In addition, we reviewed Plant (b) (4) filling line (non-U.S.) EM records. Plant (b) (4) aseptically fills (b) (4) products. On 02/19/2026, we reconciled Plant (b) (4) EM samples under incubation and found the following.

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		Eileen A. Liu, Investigator **Ashar P. Parikh, Investigator**	02/27/2026

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2. Prior to sterile (b) (4) Batch (b) (4) fill line assembly activity:
   i. (b) (4) Grade A active air samples were documented in Logbook LB/QCP9/26/001-01 as collected from 09:50 to 11:36 on 02/14/2026 from Plant (b) (4) LAF (b) (4) locations for Batch (b) (4). According to the Logbook record, these samples were under 30-35°C incubation from 02/17/2026 to 02/20/2026. However, on 02/19/2026 no sample plates were found in the laboratory incubator. Your QCP personnel confirmed these samples were never collected. Despite no samples being collected, on 02/17/2026 at the end of 20-25°C incubation, the result of "Nil" cfu was documented in the Logbook for each of the (b) (4) Grade A location.

   ii. (b) (4) Grade B and (b) (4) Grade C active air samples were documented in Logbook LB/QCP9/25/002-01 as collected from 09:50 to 11:36 on 02/14/2026 from Plant (b) (4) EM filling and sealing areas for Batch (b) (4). According to the Logbook record, these samples were placed under 30-35°C incubation from 02/17/2026 to 02/20/2026. However, on 02/19/2026, no sample plates were found in the incubator. Your QCP personnel confirmed these samples were never collected. Despite no samples being collected, on 02/17/2026 at the end of 20-25°C incubation, the results of (b) (4) cfu, and "Nil" cfu were documented in the Logbook for each of the (b) (4) Grade B and C location.

3. Prior to sterile (b) (4) Batch (b) (4) fill line assembly activity:
   i. (b) (4) Grade A active air samples were documented in Logbook LB/QCP9/26/001-01 as collected from 10:30 to 12:06 on 02/17/2026 from Plant (b) (4) LAF (b) (4) locations for Batch (b) (4). According to the Logbook record, these samples were placed under 20-25°C incubation from 02/17/2026 to 02/21/2026. However, on 02/19/2026 no sample plates were found in the incubator. Your QCP personnel confirmed these samples were never collected.

   iii. (b) (4) Grade B active air samples were documented in Logbook LB/QCP9/25/002-01 as collected from 10:30 to 12:06 on 02/17/2026 from Plant (b) (4) EM filling and sealing areas for Batch

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(b) (4) According to the Logbook record, these samples were placed under 20-25°C incubation from 02/17/2026 to 02/21/2026. However, on 02/19/2026 no sample plates were found in the incubator. Your QCP personnel confirmed these samples were never collected.

4. (b) (4) Plant (b) (4) Grade A active air samples were documented in Logbook LB/QCP9/26/001-01 as collected from 12:17 to 13:20 on 02/12/2026 from LAF (b) (4) locations under static condition. According to the Logbook record, these samples were placed under 30-35°C incubation from 02/16/2026 to 02/19/2026. On 02/19/2026 we found one sample plate (b) (4) showed (b) (4) desiccation. We observed only (b) (4) out of a total (b) (4) active air samples showed impaction patterns where the (b) (4) surface displayed small depressions when (b) (4) of air was forced through a perforated lid onto each (b) (4) surface during active air sampling. The remaining (b) (4) sample (b) (4) surfaces appeared smooth and lacked evidence of air impaction made during active air sampling. The lack of impaction patterns on (b) (4) samples indicates active air sampling may not have been performed as documented.

B. You stated there have been no Plant (b) (4) (Grade A, C, D) and Plant (b) (4) (Grade A, B, C, D) EM excursions since January 2023. During day 1 of the inspection, we inspected Plant (b) (4) and Plant (b) (4) EM plates under incubation in the QCP Microbiology Laboratory. We observed action limit level cfu on EM plates. Specifically,

1. (b) (4) ISO 5 / Grade A action limit excursions for bacteria growth from (b) (4) cfu (Limit: < (b) (4) cfu) were observed in Plant (b) (4) LAF (b) (4) EM locations.
2. (b) (4) Grade A action limit excursions for bacteria growth from (b) (4) cfu (Limit: < (b) (4) cfu) were observed in Plant (b) (4) LAF (b) (4) EM locations.
3. (b) (4) Grade B settle plate action limit excursions for bacteria growth from (b) (4) cfu (Limit: (b) (4) cfu) were observed in Plant (b) (4) filling and sealing areas.

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Your firm management and QCP employees stated multiple times that no Plant-(b)(4) (Grade A, C, D) and Plant-(b)(4) (Grade A, B, C, D) EM deviations have been initiated since 01/2023. During this inspection, based on our findings, five deviations were initiated for missing EM samples and out of limit (OOL) EM results.

C. While reviewing (b)(4) sampling records for Plant-(b)(4) for (b)(4) a discrepancy was identified between documented sampling activities and facility access records. The QCP Deputy Manager was documented as having collected (b)(4) samples from Plant-(b)(4) on (b)(4) however, facility cardholder access records confirmed this employee did not enter Plant-(b)(4) on this date.

When questioned about this discrepancy, the QCP Deputy Manager confirmed she did not collect the scheduled samples from Plant-(b)(4) on (b)(4) She admitted to the following:

1. Collected substitute samples from the (b)(4) system located in the QCP Laboratory
2. Identified these laboratory (b)(4) samples as having been collected from the following scheduled Plant-(b)(4) sampling locations for (b)(4)
   - (b)(4) sampling points in Plant-(b)(4)
   - (b)(4) sampling points in Plant-(b)(4)

D. Your firm's microbial limit tests (MLT) for (b)(4) APIs are inadequate. Specifically, you allow averaging an out of specification (OOS) result with an in-spec result to achieve a passing average. Also, your dilution factor calculation is not included in LIMS to obtain accurate final cfu/g results. On 02/19/2026, I (EL) inspected MLT enumeration and recording of results in LIMS in the QCP Microbiology Laboratory. I found the following.

1. (b)(4) Tablet (b)(4) mg Batch (b)(4) (for ROW), 36-month long-term (LT) stability: A (b)(4) dilution of the tablet sample was prepared and used for MLT. The MLT was performed in duplication (TAMC Limit: ≤(b)(4) cfu/g). During the TAMC enumeration, one plate showed (b)(4) cfu while the 2nd plate showed (b)(4) cfu. I observed the QCP Microbiologist recorded colony counts on the lids of (b)(4) plates. The

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Microbiologist then mentally added the two counts together (b) (4) cfu) and took an average of the two counts (b) (4) cfu). The Microbiologist then entered (b) (4) cfu/g into LIMS. Because LIMS does not apply the (b) (4) dilution factor, the final reported result was (b) (4) cfu/g instead of the correct (b) (4) cfu/g (b) (4) cfu). I independently enumerated the plates and found (b) (4) cfu on the second plate, a count confirmed by the QCP Microbiology Deputy Manager. This represents a significant discrepancy from the (b) cfu recorded by your microbiologist. When corrected for the (b) (4) dilution factor (b) (4) cfu/g), the sample fails the specification limit of (b) (4) cfu/g.

2. (b) (4) API Batch (b) (4), 12-month stability under (b) (4)°C condition: Identical MLT practice of writing enumerations on the (b) (4) plate lids and mentally performing calculations was observed. The colony counts obtained were (b) (4) cfu and (b) (4) cfu. Your firm recorded an average of (b) (4) cfu/g in LIMS (b) (4) (b) (4) rounded to (b) (4) LIMS does not calculate or apply the (b) (4) dilution factor, resulting in a final reported result of (b) (4) cfu/g. When the dilution factor is applied, the correct result is (b) (4) cfu/g (b) (4) (b) (4) which is out of specification (TAMC Limit: ≤ (b) (4) cfu/g). Your firm was unaware this API batch failed stability testing until the FDA investigator identified the error during the inspection. This API batch was used to manufacture finished product (b) (4) Injection (b) (4) mg Batch (b) (4) (Mfg. 02/2025, Exp. (b) (4) This batch is currently in the U.S. market (shipment date (b) (4)

3. (b) (4) API Batch (b) (4) for ROW), 6-month stability under 2-8°C condition: A (b) (4) dilution of the API sample was prepared for MLT. The same inadequate practices were observed, with colony counts of (b) (4) cfu and (b) (4) cfu recorded. Your firm entered the average of (b) (4) cfu/g into LIMS (b) (4) (b) (4) cfu]. LIMS does not apply the (b) (4) dilution factor, resulting in a reported result of (b) (4) cfu/g instead of the correct (b) (4) cfu/g (b) (4) This result exceeds the TAMC specification limit of ≤ (b) (4) cfu/g. Your firm was unaware of this stability failure until the FDA investigator identified it during the inspection. According to your firm's management and QCP personnel, microbial limit testing for API and (b) (4) had never recovered any colony-forming units prior to the inspection on 02/19/2026. Your firm also stated that no cfu have been detected in MLT following 02/19/2026.

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E. Your firm's finished product sterility testing is inadequate in that the (b) (4) failed to maintain media anaerobic condition. Specifically, on 02/19/2026 we observed (b) (4) Injection (b) (4) mg/vial Batch (b) (4) (domestic market) (b) (4) sterility reading. We noted the entire (b) (4) vial was (b) (4) (b) (4) (b) (4) (b) (4) Use of compromised (b) (4) can produce false negative sterility results, failing to detect anaerobic contamination in products intended to be sterile.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically,

A. While observing a mock aseptic fill on February 24, 2026, the following deficiencies were noted:

1. Operators were observed obstructing unidirectional HEPA-filtered air flow over the stopper bowl and (b) (4) vials while refilling the stopper bowl
2. Operators observed obstructing unidirectional HEPA-filtered air flow by passing forceps over the (b) (4) (b) (4) and removing fallen vials from the (b) (4)
3. Operators observed obstructing unidirectional HEPA-filtered air flow while moving (b) (4) vials from the (b) (4) loading area to the (b) (4) loading area through the (b) (4) (b) (4)
4. Sterile forceps inside the holder had fallen over onto the bottom surface of the (b) (4) The sterile forceps tips touched the surface and were placed back upright and used for subsequent interventions.

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5. Approximately 5 NVPC alarms were encountered during the set up and filling operations. These alarms were triggered while manipulations were being made through the (b) (4) in several areas of the filling line. The observed operator response was to acknowledge alarms and continue operations after particle counts returned to specification, without discarding potentially affected vials or initiating investigations.

6. The (b) (4) holder used to support the (b) (4) tank exhibited visible wear, cracking, and broken edges, presenting a potential source of particulate contamination in the Grade A environment.

7. Inadequate surface finishes were observed in multiple critical areas, including non-uniform sealant surrounding HEPA filter housings in the (b) (4) loading and (b) (4) loading areas. These rough, irregular surfaces do not meet cleanable surface requirements and may harbor contamination.

B. During the inspection, I (EL) reviewed aseptic process simulation (APS) / media fill (MF) conducted in Plant-(b) (4) injection line. The following deficiencies were noted.

1. Your MF did not simulate the worst-case conditions relating to intervention frequency and duration. Specifically, you did not track or trend interventions occurred during commercial manufacturing. Currently, intervention durations are not simulated. In addition, each intervention type is performed only once unless more is needed during MF regardless of worst-case conditions.

2. Your MF did not include the simulation of sealing activities. During MF, sealing operation was performed but activities i.e., sealing assembly, set-up, and interventions such as (b) (4) and removal of jammed units were not simulated. The sealing operation represents a critical closing operation that must be evaluated for its potential impact on container closure integrity.

C. During the inspection, I (EL) reviewed videos of airflow visualization studies (smoke studies) performed in 09/2023 for Plant-(b) (4) injection line. The lack of adequate smoke coverage, turbulent airflow, or poor aseptic practice were observed. Examples include but are not limited to:

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1. During (b) (4) of (b) (4) stoppers, the stopper bag was positioned over the stopper bowl, blocking HEPA-filtered first air to sterile stoppers.

2. During removal of fallen/broken vials from (b) (4) the aseptic operator's hand and arm were positioned over open vials on the (b) (4) blocking HEPA-filtered first air to sterile open vials. The impacted vials were not rejected. Your firm lacks procedure defining requirements for rejecting vials when HEPA-filtered air is blocked.

3. During vial collection in the (b) (4) loading area and (b) (4) loading into the (b) (4) the operator's hand and arm were observed obstructing HEPA-filtered first air to (b) (4) vials.

4. During (b) (4) loading into the (b) (4) (b) (4) updrafts of airflow were observed between (b) (4) containing (b) (4) vials.

5. During at-rest conditions, the (b) (4) next to the (b) (4) did not appear to adequately (b) (4) from the (b) (4) The (b) (4) facilitates (b) (4) ensuring HEPA-filtered air flows unidirectionally across the work zone to maintain a sterile environment.

D. Your firm's (b) (4) integrity testing, cleaning, and monitoring procedures are inadequate to ensure aseptic processing conditions. Specifically:

1. (Plant (b) (4) RLS-PD06-SOP-0134, Cleaning of Filling Line (b) (4) instructs the operator to "Wipe the inner surface of (b) (4) with clean room wipes soaked in (b) (4)." Neither the wipes nor the (b) (4) is sterile. In addition, no disinfectant is used to reduce microbial bioburden. The cleaning check performed by production and verified by QA only assesses the inner surface of (b) (4) for "satisfactory" or "not satisfactory" cleanliness. The procedure lacks defined acceptance criteria for what constitutes "satisfactory".

2. (Plant-(b) (4) RLS-PD13-SOP-0025, Operation and cleaning of (b) (4) filling and capping machine, instructs operators to "Clean the (b) (4)." This cleaning is done with non-sterile wipes and

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(b) (4) There are no detailed instructions for cleaning the (b) (4) or for visually inspecting to ensure they are cleaned. The (b) (4) on the (b) (4) filling machine are not subject to leak testing.

3. The review of your firm's (b) (4) integrity testing in Plant (b) (4) revealed the following deficiencies:

Your firm lacks data to demonstrate how many leak tests and (b) (4) cycles the (b) (4) material (b) (4) can withstand before degrading.

The leak testing equipment has inadequate software controls:

- Data on the unit overwrites after (b) (4) tests (batches) are completed
- Saved data reports can overwrite previous reports if they share the same file name
- System audit trails lack sufficient detail to capture data creation or deletion and are not reviewed by anyone

Your procedure RLS-PD06-SOP-0219, Operation and cleaning of (b) (4) leak tester, allows up to (b) (4) additional re-tests with variations before initiating an investigation for a failed leak test, but your firm has not provided scientific justification for this number of allowable retests. Failed leak tests also cannot be tracked in your system audit trail if they are overwritten.

The (b) (4) assessment records document when (b) (4) are replaced but fail to identify the reason for replacement (e.g., visual inspection failure versus integrity test failure). This prevents a root cause analysis of (b) (4) failures, trending of failure modes, or identification of systemic issues with (b) (4) quality or handling.

(b) (4) are sampled for environmental monitoring on only (b) (4) This practice fails to adequately assess microbial contamination on all product-contact surfaces and provide assurance that (b) (4) of the (b) (4) maintain aseptic conditions

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OBSERVATION 3

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up. Specifically,

Your firm's deviation management system is inadequate and does not capture equipment issues that may affect product quality. Since March 2024, your firm has created approximately 50 service work orders in Plant (b) (4) for critical manufacturing equipment, including but not limited to (b) (4) (b) (4) Your firm did not initiate deviations for several of these equipment issues.

According to firm management, deviations are only initiated for equipment malfunctions that occur during production that have an immediate product impact. Equipment issues are frequently identified and corrected solely through the service work order system and not evaluated through your deviation process.

This practice is inadequate because:

- Equipment malfunctions are not assessed for potential impact to product quality regardless of when they occur (set up, during production, etc.)
- Issues are not tracked, trended, or investigated to identify root causes
- Corrective and preventive actions (CAPAs) are not implemented or verified for effectiveness
- Your firm cannot ensure that critical manufacturing equipment remains in a qualified and validated state

Examples of service work orders with no corresponding deviations include the (b) (4) leak rate test not maintaining and the filling machine (b) (4) not working.

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