DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	12/03-10/2025
	FEI NUMBER 3030304532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ashish Dange, Managing Director	
FIRM NAME Wizcure Pharmaa Private Limited	STREET ADDRESS H-881, Phase-III, RIICO Industrial Area
CITY, STATE, ZIP CODE, COUNTRY Bhiwadi-301019, Rajasthan India	TYPE ESTABLISHMENT INSPECTED Sterile 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,
Microbiologists responsible for performing sterility testing and collecting environmental monitoring, personnel monitoring, and (b) (4) samples confirmed they do not collect, test, and incubate all samples.

A. During inspection of the (b) (4) Biological incubators in the microbiology laboratory on December 5, 2025, (b) (4) personnel monitoring plates were observed and photographed with visible microbial growth.

   On December 6, 2025, (b) (4) of the (b) (4) plates previously observed with growth were observed with no growth. Upon examination, the plates on December 6, 2025 were missing the initials of the microbiologist who plated them, and the plates appeared to be different although the labeling information was the same (except for the missing microbiologist initials). The remaining (b) (4) plates were missing.

   When questioned about this discrepancy, Microbiologist (b) (6) stated that he had labeled unused plates with the same information and discarded the plates with growth.

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B. Upon inspection of the (b) (4) Biological incubators in the microbiology laboratory on December 3, 2025, sterility testing, personnel monitoring, environmental monitoring, and (b) (4) samples that were supposed to have been collected and under incubation were not present. Associated logbooks and analytical worksheets containing testing data were also incomplete or missing. Examples included:

1. There were samples in the incubators for approximately (b) (4) lots of products in varying stages of in-process sterility testing but no in-process test records. According to (b) (6) Microbiology Manager, sterility (b) (4) are examined (b) (4) Results of these examinations are not recorded (b) (4) but (b) (4) . This is also the date the record is created.

   In addition, Microbiology Manager (b) (6) explained that positive and negative controls for sterility testing methods have not been routinely conducted since October 2025 and there has not been any growth promotion testing done on the (b) (4) (b) (4) used for sterility testing for over a year.

2. There were no personnel monitoring samples in the incubators. Procedure MBP023 "Procedure for Personnel Monitoring by Contact Plate Method" requires personnel monitoring for all personnel (b) (4) A microbiologist confirmed none of the samples were collected.

3. Environmental monitoring settle plates are not collected according to Procedure MB021 "Procedure for Environmental Monitoring by Settle Plate Method". On December 3, 2025, only (b) (4) settle plates from (b) (4) were found in the bacteriological incubator, representing the following locations: (b) (4) (b) (4)

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(b) (4) Based on procedural requirements, a minimum of (b) (4) plates should be collected (b) (4) from Grade A locations and approximately (b) plates from Grade B locations. For the (b) (4) (b) (4) total plates should have been collected (b) (4) (b) (4)

4. During inspection of environmental monitoring records and media preparation documentation from (b) (4), a systematic review was conducted to assess the adequacy of media preparation relative to environmental monitoring (EM) and media fill testing performed. This analysis revealed discrepancies between documented media volume and recorded usage / testing results.

   i. Media Preparation vs Environmental Monitoring Results:

   (b) (4):
   (b) (4) plates prepared: (b)(4) (per Media Preparation Records)
   Environmental monitoring results recorded: (b) (4) results
   Discrepancy: (b) (4) results recorded without corresponding media preparation

   (b) (4):
   (b) (4) plates prepared: (b) (4) (per Media Preparation Records)
   Environmental monitoring results recorded: (b)(4) results
   Discrepancy: (b) (4) results recorded without corresponding media preparation

   (b) (4) media (b) (4) prepared: (b) (4) (per Media Preparation Records)
   Sterility Logbook: (b) (4) samples received (plus (b) (4) for controls (b) (4) sterility testing is initiated) = (b) (4) needed to conduct testing
   Discrepancy: (b) (4) results recorded without corresponding media preparation

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Microbiology Manager, (b) (6) confirmed that media is made (b) (4). A comprehensive review of all available media preparation records for the inspection period revealed no additional (b) (4) media preparation beyond the documented amounts.

Additional media concerns include dry and cracking media, growth on (b) (4) of the (b) unused plates in the (b) (4) incubator (b) (4), and (b) (4) plates & (b) (4) (b) (4) are not labeled with a batch number or date of preparation.

ii. You performed media fill batch (b) (4) on June 9th, 2025 requiring approximately (b) (4) units, each with a volume of approximately (b) (4) mls. Your media preparation records do not support this surplus in volume of approximately (b) (4) mls. Furthermore, your contract testing laboratory (b) (4) did not perform growth promotion testing after media fill unit testing performed at their laboratory.

5. EM plate data appears erroneous such that periodically clustered data is recorded for Grade B – Grade C spaces in your (b) (4) EM logs. Specifically, approximately all recoveries in Grade B plates are (b) (4) CFUs. Grade C data is as follows for the period of (b) (4) (b) (4):

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(b) (4)

The CFU data (n=(b) (4) showed concentration around particular values. The number (b) (4) appeared most frequently(b) (4) times), while (b) (4) each occurred(b) (4) times Together, these (b) (4) values comprised more than half of all recorded measurements (b) (4) observations).

6. There were no samples for (b) (4) in the incubator. According to the sampling schedule provided by the microbiology manager, approximately(b) (4) samples should be collected from the (b) (4) system (b) (4) (b) (4) Microbiology Manager (b) (6) confirmed the samples were not collected. For the (b) (4) (b) (4) (b) (4) total plates should have been collected

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In addition, there were no (b) (4) sample testing reports completed for any (b) (4) testing sample locations from (b) (4) (b) (4) is used as a raw material in the following US products: (b) (4)

7. On December 3, 2025, a (b) (4) analysis record for sampling point (b) (4) was observed in the laboratory with the following fields left blank: Sample Name, A.R. No., and Total Bacterial Count.

   When a photocopy of this same record was requested and subsequently provided by the firm, the previously blank fields now contained the following entries:
   - Sample Name: "(b) (4) "
   - A.R. No.: "(b) (4) "
   - Total Bacterial Count: "(b) (4) cfu/ml"

   An explanation for how these data fields were completed after the original record was observed during the inspection was not provided.

C. Documents observed in the microbiology room with results pre-filled include but are not limited to:
   1. Sterility test results are documented on "Sterility Test Observation Record, Format MBP014-F01". On December 03, 2025 when reviewing documents discovered in microbiology department, Sterility Test Observation Record Forms (Format MBP014-F01) were found with negative results, lot number of media used, remarks, and growth promotion information pre-filled out.

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2. Multiple Antimicrobial Effectiveness Test Reports (Format MB045-F01-00) were also discovered in the microbiology department with Observations at "(b) (4)", "(b) (4) (b) (4)", "(b) (4)", "(b) (4)", "(b) (4)" and "Log Reduction" information pre-filled out. Microbiology Manager (b) (6) confirmed that no anti-microbial effectiveness checks have been done for any product including those for the US market.

D. Prior to the inspection, no sterility failures have ever been reported, and no alert or action level findings have ever been reported for environmental monitoring, personnel monitoring, or (b) (4) samples. For samples that were inspected while under incubation during this inspection, failing results were observed:

1. Environmental monitoring locations –
   December 6th, 2025 EM locations (b) (4)

   December 5th, 2025 EM locations (b) (4)

   Note: December 5th, 2025 was the day we observed set-up for (b) (4) batch (b) (4)

   (b) (4) Sampling Locations (b) (4) show growth on the selective media (b) (4) used for (b) (4)

   December 4th, 2025 EM locations (b) (4)

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December 3rd, 2025 EM locations (b) (4)

December 3rd, 2025 PM locations (b) (4), (b) (6) (b) (4)

December 1st, 2025 EM location (b) (4)

For each of the above samples any growth is OOS.

2. On December 5th, 2025 the following plates exhibited failing results at (b) (4) of incubation – (b) (4), (b) (6) These plates were discarded and replaced with unused plates. Any growth for these sampling locations would be considered OOS.

E. Your Quality Control laboratory practices and documentation are deficient regarding your (b) (4) UV-VIS equipment and tests. Specifically, you could not produce any digital versions of your raw data sheets generated by these instruments and they are connected to their own PCs. You do not have any audit trail enabled on these systems and unique usernames and passwords for analysts have not been established. Your analysts harbor access and permissions to generate and print data sheets without Quality Unit oversight.

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F. You lack control over certificate of analysis creation such as version control or page numbering. Specifically, we observed uncontrolled access to your PC used to generate and print CoAs. This PC lacks usage logs and lacks an audit trail. Furthermore, we observed numerous CoAs discovered in your trash on December 3rd, 2025.

OBSERVATION 2

Equipment and utensils are not cleaned or maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

The following were observed throughout productions areas used to manufacture products for the US market.

A. The (b) (4) Line consisting of rooms (b) (4) (b) (4) used to manufacture for the US market:

1. Apparent rusty equipment, apparent rusty components (b) (4), apparent rusty machine parts on and around filling zone such as the (b) (4) parts and (b) (4) (b) (4) tracks
2. Stained / apparent rusty HEPA filters and / or HEPA filter (b) (4) as well as (b) (4) (b) (4)
3. (b) (4) with apparent rust is used to transport the (b) (4) product transfer vessel from (b) (4) room to filling room.

B. The (b) (4) Line consisting of rooms (b) (4) (b) (4) used to manufacture (b) (4) (b) (4)

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1. Apparent rusty equipment on the (b) (4) machine (Eq. ID – WPPL/BH/PD/EQP/100) including:
   i. (b) (4) used to (b) (4)
   ii. (b) (4) directly above location where finished product (b) (4)
   iii. Apparent rusty (b) (4) directly over (b) (4)
2. (b) (4) on the (b) (4) machine (Eq. ID – WPPL/BH/PD/EQP/100) is not easily cleanable and is replaced (b) (4). The assessment and replacement of the (b) (4) is not documented. (b) (4) was observed in the following location
   i. The entire (b) (4) where finished product (b) (4)
   ii. Under a (b) (4) used to (b) (4) (b) (4)
   iii. Beside the (b) (4) where (b) (4). Additionally, this (b) (4) (b) (4) appears to be secured with tape.
3. Apparent rusty equipment on the (b) (4) Filling & Sealing Machine (Eq. ID – WPPL/BH/PD/WQP/101) in the following locations:
   i. (b) (4) directly over the packaging (b) (4) This is immediately upstream of where the (b) (4) the finished product (b) (4)
   ii. (b) (4) for (b) (4) which (b) (4) (b) (4)

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Your firm aseptically fills OTC finished drug products (b) (4) for the US market. Your aseptic filling process includes:

A. After sterilization of your (b) (4) product transfer vessel via (b) (4) performed in Washing and Sterilization Area (b) (4) you move this vessel into your Grade A space located in (b) (4) Filling Room (b) (4) Your (b) (4) product transfer vessel is moved via your (b) (4) into your (b) (4) Filling Room (b) (4) Your Washing and Sterilization Area (b) (4) is a Grade B area, your corridor is a Grade B area and your (b) (4) Filling Room (b) (4) is a Grade B space with exception to your Grade A filling area located under your LAF. Your aseptic connection located on your (b) (4) product transfer vessel is not covered or protected during this transfer.

B. Your firm performs aseptic filling on (b) (4) Filling Line (Room (b) (4)). On December 5th we observed setup on this line. This filling line has no barrier protection separating the filling line, to include the filling zone that harbors the (b) (4) , area where (b) (4) are loaded, area the (b) (4) resides and the area whereby open sterile bottles pass, by design, between Grade A and Grade B spaces prior to being filled.

C. Contact surfaces of the sterile (b) (4) components are not sterilized. For example:
   1. The (b) (4) Filling Line (Room (b) (4)) (b) (4) bowl and (b) (4) track all contact sterile (b) (4) packaging components. These pieces of equipment are left in place between batches and disinfected but not sterilized.
   2. (b) (4) tubing connecting (b) (4) to the (b) (4) were not removed and are left in place between batches and disinfected but not sterilized.

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D. Media fills are not designed to ensure they provide a representative challenge to the aseptic filling process. The protocols do not:
   1. Establish and record the number of interventions that must occur
   2. Establish the limit for the number of personnel that may be present in the room during aseptic processing
   3. Establish the time(s) and attribution of personnel regarding aseptic connections

E. Comprehensive static and dynamic airflow pattern studies were not conducted for the (b) (4) (b) (4) Filling Line Rooms (b) (4)
   1. Static airflow studies were limited to areas immediately surrounding entry and exit doors and HEPA (b) (4) (within (b) (4) of these locations only).
   2. No dynamic smoke studies were performed to evaluate critical operational scenarios, including line set-up activities, aseptic connections and interventions during operations
   3. The studies did not include evaluation of Grade A spaces, which are critical areas requiring the highest level of air quality control.

F. Line design with (b) (4) bottles from Grade A where they are (b) (4) loaded through Grade B then back to Grade A where they enter the track to move to the filling station.

G. You use (b) (4) to clean and sanitize equipment used in your aseptic (b) (4) filling room prior to filling. You lack documentation supporting the (b) (4) is sterilized. Furthermore, the bulk (b) (4) drum observed in your basement and usage records / logs are also absent.

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OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

A. On December 5th, 2025, while observing set-up on (b) (4) Filling Line (Room (b) (4) for the aseptically filled finished drug product (b) (4) batch (b) (4) poor aseptic processing behavior was observed. This filling line is used to manufacture US market product. Examples of poor aseptic behavior include:

1. An operator exited the filling room and returned with (b) (4) for the (b) (4) filling apparatus, these (b) (4) in total) are affixed to this filling apparatus in close proximity to aseptic connections, approximately (b) (4)

2. Operators were specifically observed moving freely between Grade A and Grade B spaces without any record of their movements and activities throughout the entire setup process.
3. Operators were observed with exposed skin while performing maintenance activities on the (b) (4) assemblies in close proximity to the filling station and / or while performing aseptic connection.

4. Operators were observed wearing safety glasses with exposed skin around the glasses. In addition, operators were observed moving their protective eyewear (glasses) such that they rested on their forehead while their head was inside the Grade A area.

5. Operators were observed reaching into the open bag containing sterile bottles multiple times to remove bottles from the bag and place them on the (b) (4) This technique was used to place all bottles on the (b) (4)

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6. During the aseptic connection between the sterile transfer manufacturing tank (b) (4) and the manifold for the filling line, an operator was observed touching the opening of the tubing and tubing connections on the manifold and (b) (4) apparatus prior to making the connection, touching the approximate (b) (4) gasket used to aseptically connect the transfer tank and manifold.

7. Direct contact with HEPA filters by operators' heads was observed.

8. Two power failures occurred during setup operations at approximately 11:40am and 12:40pm which were not documented. Upon resumption of power, operations continued without removal of potentially compromised materials and cleaning was not performed.

9. During (b) (4) interventions for filling the (b) (4) bowl, operators were observed with their gowning directly over and in contact with the interior surfaces of the bowls. Additionally, operators touched the grasping ends of forceps (the portions that directly contact (b) (4) and then used the same contaminated forceps to adjust (b) (4) on the (b) (4) track and operators were observed touching the (b) (4) track with their gloved hand directly. These practices create multiple contamination pathways that could compromise the sterility of product-contact components.

10. Operator gowning appeared with tears / holes and markings / writing on it such as dates / places where zippers are coming away from the fabric

11. An operator was observed unzipping his protective equipment to remove and use his mobile phone.

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B. On December 8th, 2025, while observing set-up, filling, and transfer of equipment and components on (b) (4) Filling Line (Room (b) (4)), for the aseptically filled finished drug product (b) (4) batch (b) (4) Lot (b) (4), poor aseptic processing behavior was observed. This filling line is used to manufacture US market product. Examples of the observed poor aseptic behavior include:

1. The (b) (4) bag with the manifold and attached tubing was observed unsealed and open to the outside environment. Operator (b) (6) (emp ID # (b) (6) stated the manifold is (b) (4) "as is".

2. From 10:43-10:50 AM, Aseptic Connections from manifold to (b) (4) and manifold to sterile manufacturing transfer tank. During these connections, we observed multiple instances of the operator touching the (b) (4) on the (b) (4) assemblies used to connect the (b) (4) tubing to the (b) (4) assembly and touching the gasket used during the connection of the manifold tubing to the sterile manufacturing tank. In addition, the (b) (4) were already in place at the time of this observation.

3. At 11:13, first air violations were observed during (b) (4) and replacement of the (b) (4) Operators were observed removing the (b) (4) from (b) (4) and (b) (4) commenced. At the conclusion of (b) (4) the (b) (4) were replaced with the operator's hand directly above the (b) (4)

4. 10:58 – 11:13, operators were observed reaching into the open bag containing sterile bottles multiple times to remove bottles from the bag and place them on the (b) (4) (b) (4) This technique was used to place all bottles on the (b) (4)

5. Direct contact with HEPA filters by operators' heads was observed.

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12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483responses@fda.hhs.gov	12/03-10/2025
	FEI NUMBER 3030304532
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ashish Dange, Managing Director	
FIRM NAME Wizcure Pharmaa Private Limited	STREET ADDRESS H-881, Phase-III, RIICO Industrial Area
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6. During (b) (4) interventions for filling the (b) (4) bowl, operators were observed with their gowning directly over the interior surfaces of the bowls.

7. At 11:40, 11:54 and 11:57, an operator was observed slapping the (b) (4) apparatus, which is approximately 12" from the filling station.

8. During filling, operators were observed routinely removing (b) (4) from the (b) (4) with their hands. In addition, operators were seen reaching over and touching the (b) (4) track used to (b) (4)

9. Operators were observed with their gowning unzipped and ink pens affixed to their unzipped but buttoned gowns.

10. Operators were observed wearing safety glasses with exposed skin around the glasses.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

A. Personnel monitoring program has not been implemented for any aseptic operations. Personnel monitoring regarding aseptic connections has never been conducted.

B. Surface monitoring has never been performed on any equipment surfaces including critical product contact surfaces such as (b) (4) product contact locations including (b) (4)

C. Active viable air sampling has never been implemented in any aseptic processing areas.

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D. Passive air monitoring is only performed regarding (b) (4) during aseptic processing in your Grade A space and the location is not clearly defined in your quality system.

E. Non-viable particle monitoring was not performed during setup operations observed on December 5, 2025. Furthermore, your QA Manager (b) (6) reported you do not perform NVP measurements during any filling operations and only perform NVP monitoring prior to setup and filling operations.

OBSERVATION 6

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

A. You do not perform visual inspection of your aseptically filled product, and you have not established written procedures regarding this critical process. Your QA Manager reported you inspect the outside of each unit for defects to include particles but do not inspect the contents.

B. You lack control over critical elements of your terminally sterilized (b) (4) process for the following:

C. You lack recordation of critical process parameter(s) in your BPRs regarding your (b) (4) process such that (b) (4) is not recorded. Your production personnel reported (b) (4) was required for (b) (4)

1. Enumeration of rejects is absent regarding your in-process visual inspection of filled (b) (4) for your (b) (4) process, instead, your BPRs read in part, "OK". Furthermore, critical attribute of (b) (4) integrity is apparently incorporated into your

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"other" rejects category. I observed at least one reject regarding (b) (4) during inspection of approximately (b) (4) units.

OBSERVATION 7

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

A. You do not document quality system events such as deviation, OOSs and changes.
   1. No deviations or OOS were generated for the EM/PM deficiencies nor for any discarded QC records identified during the inspection.
   2. (b) (4) testing forms changes were made approximately (b) (4) per Microbiology Manager, (b) (6) subsequently causing you not to collect over (b) (4) samples. No Change control nor other quality record was opened to capture this event.
   3. You performed a change to your method validation for your (b) (4) on (b) (4) and did not document this revalidation via any change control.

B. At the initiation of this inspection on December 3, 2025, we found GMP documents that were disposed inside a bag which was inside a box collected from QC Documentation Room (b)(4). The evaluation of the contents of the bag revealed presence of (b) (4) Analysis sheets from (b) (4), (b) (4) validation data summary sheets from 2019, certified copy of the validation certificate for the Bacteriological Incubator from 2022. Other items in the bag included vials of (b) (4) Injection USP, unlabeled (b) (4) (b) (4) containing a (b) (4) liquid, unlabeled vials containing a (b) (4) liquid, among other scraps of paper.
   1. Logbooks (b) (4) Testing Lob Book and Bulk Sample Testing Log Book) for year 2025 were observed with missing sample received entries.

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2. Log Book for gross QC calculations was observed and your QA Manager stated it was not a GMP logbook and reported the logbook is not controlled via any written SOP per your quality system.

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