DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 02/10/2026-02/20/2026
	FEI NUMBER 3014362214
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Bhaskar Krishna, Chief Executive Officer	
FIRM NAME Maiva Pharma Private Limited	STREET ADDRESS No 32 Sipcot Industrial Complex Phase I
CITY, STATE, ZIP CODE, COUNTRY Hosur, Tamil Nadu, 635126, 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

Production records do not contain complete information relating to the production and control of each batch.

On February 10, 2026, during the initial walkthrough of your facility, numerous original CGMP documents associated with the manufacture of U.S. marketed drug products were observed discarded in trash bags located in the scrap area. These documents were not marked as copies, voided through an established procedure, or otherwise reconciled as part of an approved document control system. The discarded records included, but were not limited to:

A. Discarded gloves containing handwritten Environmental Monitoring (EM) sampling details (settle plates exposure time) related to activities performed February 8, 2026, for (b) (4) Injection, Commercial Batch No. (b) (4)

B. In-process leak test equipment reports, including (b) (4) sample results, for US marketed product (b) (4) USP (b) (4) mg/mL), Commercial Batch No. (b)(4), signed by Production and IPQA personnel on February 09, 2026, found torn into multiple pieces.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	February 20, 2026

C. Two (2) weighing verification printout of intact API bags prior to transfer into the aseptic area for US marketed product (b) (4) USP (b) (4) mg/mL), Commercial Batch No. (D)(4), generated February 9, 2026, using balance PROD/(b) (4) G-016.

D. A (b) (4) sterilization (b) (4) containing handwritten time entries documenting aseptic interventions times (e.g., forceps transfer, (b) (4) transfer, (b) (4) sanitization, and forceps fixing) performed on February 8, 2026, US marketed product (b) (4) Injection USP, Commercial Batch No. (b) (4)

E. A (b) (4) fill volume weighing report for (b) (4) vials generated at (b) (4) on February 9, 2026, using balance PROD/MFG/4-007, for US marketed product Batch (b) (4) (b) (4) USP (b) (4) mg/mL), Commercial Batch No. (D)(4).

F. Printed (b) (4) measurement data recorded at 12:14 on February 9, 2026, for Line (b) (4) for the manufacturing of (b) (4) USP Units, Exhibit Batch No. (D)(4), which was strike-marked and discarded. Printout was found with value of (b) (4) which is below the batch manufacturing record established limit range of (b) (4) to (b) (4)

G. Four (4) dispensing weight balance printouts for issued raw materials and excipients for (b) (4) (b) (4) USP Units, Exhibit Batch No. (b) (4) generated February 7, 2026, using balances RMS/094 and RMS/007.

H. Three (3) weight check print reports generated at (D)(4) (2) and (D)(4) (1) on February 8, 2026, for (b) (4) vessel PROD/MFG (b) (4) 001 used in the manufacture of (b) (4) (b) (4) USP Units, Exhibit Batch No. (D)(4), using balance PROD/MFG (b) (4) 010.

In combination, these findings demonstrate a failure to maintain and control original manufacturing records. Currently, original raw data printouts generated in the manufacturing areas are not subject to adequate controls, reconciliation or retention, allowing for uncontrolled disposal of CGMP documentation with no Quality Unit oversight. Additionally, documentation of aseptic interventions (e.g., (b)(4) setup and EM interventions) is not being documented contemporaneously, as required to maintain reliability and integrity of data.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

A. Your firm failed to ensure that aseptic processing activities are performed in accordance with established procedures and that deviations from approved practices are investigated. For example, during review of Deviation Investigation Report DV/001/25/035, initiated following a microbial excursion observed on February 28, 2025, a (b) (4) CFU/Plate was recovered from the vial sealing LAF (Grade A) area, (b) (4) ID: (b) (4) Line (b) (4) Capping and Sealing zone during environmental monitoring associated with the manufacture of (b) (4) Injection, USP (b) (4) % (Batch No. (b) (4)

As part of the investigation DV/001/25/035, a GEMBA walkthrough was conducted by your Quality Unit in the sealing area of Line (b) (4) on March 03, 2025, during the manufacture of (b) (4) Injection (b) (4) mg/mL, (No USA), Batch No. (b) (4) In this walkthrough, operators located in the Grade B area were observed performing (b) (4) RABs) interventions during sealing operations in the Grade A area. During the same walkthrough, operators were also observed failing to perform required (b) (4) sanitization for periods exceeding (b) (4) while conducting aseptic interventions in the Grade A area. In addition,

forceps used in the Grade A area were observed being introduced into the Grade B area and subsequently returned to the Grade A environment.

Your firm does not have a written procedure that defines whether (b) (4) interventions in the sealing area are permitted or prohibited, nor does it define the conditions, controls, or limitations under which such interventions may be performed. Your Deputy General Manager stated that (b) (4) interventions can be performed in this area; however, these interventions are not limited in frequency, may be performed "N" times during operations and are not documented in the commercial batch records. In addition, no (b) (4) LAF is installed above the (b) (4) RABs (b) (4) in where the (b) (4) intervention is performed to protect the Grade A conditions in the sealing area from the Grade B background conditions from where the employee performs the intervention. Furthermore, the (b) (4) RABs (b) (4) in the capping/sealing area are not equipped with alarms or any electronic monitoring system to detect, record, or trend (b) (4) events. Note that from the vial stoppering zone to the sealing and capping zone, the conveyor length is (b) (4) According to your Deputy General Manager in this location (b) (4) interventions such as removal of broken and fallen vials might occur during aseptic filling operations.

Moreover, your Quality Unit has not performed airflow visualization (smoke) studies under dynamic conditions to evaluate the impact of (b) (4) RABs) interventions and personnel manipulations on unidirectional airflow and protection of the Grade A critical zone. The absence of such studies does not provide assurance that unidirectional airflow is maintained during (b) (4) (b) (4) interventions. In addition, your firm's media fill studies did not simulate or evaluate the maximum number of (b) (4) interventions that may be performed during routine production, nor did they represent worst-case conditions for interventions in this area.

The deviations observed by your firm during the GEMBA walkthrough, including (b) (4) interventions, inadequate (b) (4) sanitization, and movement of tools between Grade A and Grade B areas, were not independently investigated or assessed. Instead, these inadequate aseptic

practices were only referenced as possible contributing factors (Root Cause) for Deviation Investigation Report DV/001/25/035.

Additionally, during the inspectional walkthrough conducted on February 13, 2026, of Filling Line (b) (4) during filling operations of (b) (4) Injection (b) (4) mg (b) (4) mL, (aseptic filling), (No-USA), Batch No. (b) (4) we observed an operator introducing (b) (4) directly from the Grade B area into the (b) (4) RABS Grade A (Sealing) area to perform a sensor adjustment intervention. It is unknow how this intervention is classified (i.e., routine or corrective intervention) in your aseptic filling process. The operator did not use the sterilized (b) (4) from the (b) (4) and this intervention was not documented in the commercial batch record.

B. Laboratory Investigation Report (LIR) OOS/013/25/001 was initiated on March 07, 2025, for out-of-specification (OOS) assay results obtained during stability testing of (b) (4) Injection USP (b) (4) µg/mL) (b) (4) mL vial, stability Batches Nos. (b) (4) and (b) (4) at the 6-month stability interval under long-term (25°C/60% RH) and accelerated (40°C/75% RH) storage conditions; Expiration Date: (b) (4)

Batch No.	Orientation and Frequency	Condition	Assay Result (%) by HPLC
(b) (4)	Upright 6M	25°C/60 % RH	(b) (4)
	Invert 6M	25°C/60 % RH	
	Upright 6M	25°C/60 % RH	
	Invert 6M	25°C/60 % RH	

(b) (4)	Upright 6M	40°C/75 % RH	(b) (4)
	Invert 6M	40°C/75 % RH	
	Upright 6M	40°C/75 % RH	
	Invert 6M	40°C/75 % RH	
Specification Limits		**NLT (b) (4) % and NMT (b) (4) % of Label Claim**	

Although Phase I laboratory investigation did not identify an assignable cause, retesting confirmed the initial OOS assay results. A subsequent manufacturing investigation reported no discrepancies that could have contributed to the OOS results. Therefore, your QC laboratory performed multiple hypothesis analyses and identified two main contributing factors as root causes:

- Analytical error associated with the quantity and handling of USP reference standard vials used for (b) (4) content determination and assay standard preparation.

- Instrument-related variability associated with Shimadzu HPLC ID: I-538, specifically tubing diameter configuration impacting peak area responses relative to standard and sample concentrations.

Based on the identified root causes, your QC laboratory performed the retest analysis in a different HPLC and invalidated the initial OOS results. However, the investigation LIR OOS/013/25/001 does not provide documented evidence demonstrating that the analyst involved in the initial testing committed an error in the preparation or handling of the USP reference standard. In addition, the investigation does not establish when the Shimadzu HPLC ID: I-538 became unsuitable for assay

analysis. Moreover, as part of the investigation no documented retrospective assessment was conducted of other analyses performed using Shimadzu HPLC ID: I-538 to determine the potential impact of instrument-related variability on previously released products, stability samples, or other test results.

C. Failure to adequately investigate and determine the root cause of a significant microbiological contamination event associated with an aseptic process simulation (media fill), and failure to establish scientifically justified process controls to prevent microbiological contamination.

Specifically, on June 04, 2024, Media Fill Batch No. (b) (4) performed on Line (b) (4) Line) was aborted due to turbidity (microbial growth) observed in the (b) (4) media bulk solution held in the (b) (4) manufacturing tank (PROD/MFG/4-005).

Deviation Report DV-001-24-066 was initiated and disclosed that the (b) (4) media bulk solution remained in the manufacturing tank for approximately (b)(4) before initiation of (b) (4) The total (b) (4) hold time was reported as (b) (4) The media fill batch record specifies a (b) (4) hold time of Not More Than (NMT) (b) (4) In addition, the control procedure SOP/QA/GEN/044, "Aseptic Process Simulations," does not define a maximum allowable time to initiate (b) (4) after completion of media preparation. Samples collected from the manufacturing tank were sent to an external laboratory for identification. The recovered organism was reported as Bacillus alcalophilus. Your firm concluded that potential root causes included:

- Delay in initiation of (b) (4) after completion of manufacturing) within the established NMT (b) (4) hold time.
- Addition of sterile media (b) (4) into the manufacturing tank in a Grade C classified area, resulting in exposure of media and (b) (4) to the Grade C environment during material addition.

However, Deviation Report DV-001-24-066 did not provide documented scientific evidence demonstrating that the established (b) (4) hold time of NMT (b) (4) for bulk media solution is microbiologically justified or validated, and whether it is appropriate under actual manufacturing conditions, including environmental exposure during media (b) (4) addition. Furthermore, although the addition of sterile media (b) (4) occurs in a Grade C environment, the investigation did not provide evidence that this practice is supported by a risk assessment and validation demonstrating suitability for media solution preparation. According to your Deputy General Manager, previous media fills were reportedly prepared under similar Grade C conditions without observed growth; however, the investigation did not include a comprehensive comparative analysis to determine why contamination occurred in this instance. Previous event that Bacillus was recovered in your facility was in 2021.

D. Deviation Investigation Report DV/001/26/001 was initiated following an out-of-action-limit result of (b) (4) CFU/plate (Limit NMT (b) (4) CFU/plate) observed on January 03, 2026 (monitoring performed on December 28, 2025) at Location (b) (4) aseptic corridor (Grade B), Line (b) (4) associated with the aseptic filling of (b)(4) Injection, USP (b) (4) mg (b) (4) mL (Batch No. (b) (4) Your firm concluded that one probable root cause of the excursion was increased personnel movement in the aseptic corridor during the monitoring period.

However, the investigation did not include a comparative assessment of personnel movement in the same corridor during similar operations on other dates to determine whether personnel traffic on the date of the excursion was higher than typical or within normal operating conditions. There was no documented retrospective review of historical entry/exit logs, personnel flow data, or routine traffic patterns to substantiate that personnel movement on December 28, 2025, was abnormal.

Without objective comparison to baseline or historical data, the conclusion that increased personnel movement was the root cause is not adequately supported by documented evidence.

E. Your Quality Unit was not able to provide all supporting documentation related to Deviation Investigation Report DV/001/24/086, initiated on July 18, 2024. This deviation was initiated in response to an out-of-action-limit personnel monitoring excursion of (b) (4) CFU/plate (Limit NMT (b) (4) CFU/plate) for employee ID: (b) (6) in an aseptic processing area of Line (b) (4) (Grade B). Your Quality Unit concluded that the root cause was attributable to operator-related factors based on an interview with the production operator. The investigation report root cause states that the operator's forehead may have perspired due to stress while working in primary and secondary garments and that inadequate aseptic behavior on the day of the excursion may have contributed to the microbiological result.

However, although your Quality Unit stated that the root cause determination was based on an interview conducted with the involved operator, the firm was unable to provide any written record or documentation of the interview. There was no documentation describing the questions asked, the responses provided, the date and time of the interview, or how the information obtained was evaluated and verified by the Quality Unit. The absence of documented interview records prevents an evaluation on how your firm determined the root cause.

F. Your Quality Unit failed to initiate a deviation or investigation for an event observed during the "Method Validation of Bacterial Endotoxins Test by Kinetic Chromogenic Assay Using (b) (4) (b) (4) for (b) (4) – API," Protocol Reference Number: (b) (4) During analysis of the second study run on August 24, 2024, at the (b) (4) dilution, the test report was not captured in the (b) (4) software system. Your Quality Unit subsequently prepared the same sample solution and repeated the analysis without first documenting or investigating the initial failure of the software to capture the data.

Following this event, your firm contacted the equipment service provider to inform them of the observed deficiency and shared data retrieved from the instrument to determine a probable root cause. However, no response was received from the service provider, and your Quality Unit did

not initiate a formal investigation to determine the cause of the data capture failure, assess the potential impact on the validity of the method validation study, evaluate other runs or products tested using the system, or document a scientifically justified conclusion.

G. Your Quality Unit failed to conduct a thorough investigation of a complaint involving particulate matter reported on December 17, 2025. Market Complaint Investigation Report MC/006/25/006 for (b) (4) Injection USP (b) (4) mg (b) (4) mL, Batch No. (b) (4) describes a costumer complaint (ID: (b) (6) that was received related to the presence of particles observed in vials. However, just by solely reviewing previous complaint history of the same product your Quality Unit concluded that it could be reasonably assumed that the particles mentioned in the complaint may be related to (b) (4) precipitate observed in previously reported complaints for (b) (4) Injection USP (b) (4) mg (b) (4) mL, Batch No. (b) (4) reported on February 21, 2024.

The investigation report MC/006/25/006 does not document any review of the batch production records, packing records, environmental monitoring data, or visual inspection records for the batch related to the particle complaint. Your Quality Unit firm evaluated this complaint as equivalent to previously reported (b) (4) precipitate complaints without documented justification. The investigation conclusion states that there was no definitive root cause, and the complaint was closed without adequate documentation supporting the assumption that particulate matter and precipitate were the same condition.

OBSERVATION 3

Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes.

A. Aseptic process simulations (media fills) performed on (b) (4) RABs filling Lines (b) (4) are not designed and executed to adequately simulate routine commercial aseptic filling operations.

Specifically, your firm performs aseptic process simulations (media fills) for sterile liquid and (b) (4) drug products; however, the simulations do not reflect actual commercial manufacturing conditions and interventions.

Manufacturing operators do not document (b) (4) process interventions and line stoppages occurring during routine aseptic capping/sealing operations in the commercial batch production records to ensure adequate review and evaluation by the Quality Unit.

Examples of interventions not recorded include, but are not limited to sensor adjustments, removal of fallen vials on the capping (b) (4) track, stuck/jammed seal, removal of broken vials on (b) (4) capping (b) (4) adjustment of the (b) (4) adjustment, (b) (4) adjustment, seal chute adjustment and removal of broken vials during capping operations. The manufacturing operator may perform (N) times such interventions during capping/sealing operations; however, the interventions and the filling line stoppages resulting from these interventions are not recorded in the commercial batch records. Therefore, since the capping and sealing interventions are not documented, there is no assurance that your current aseptic process simulations represent worst-case operating conditions and challenge the full range and frequency of interventions that occur during commercial production. Additionally, there is no documented evidence that manufacturing operators who might perform the process interventions in a commercial setting have been qualified for such aseptic operations.

B. Failure to document process interventions in batch production records and failure of the Quality Unit to adequately evaluate the impact of such interventions on product quality.

Specifically, during review of manufacturing operations for terminally sterilized products (i.e. filling Lines (b) (4) it was observed that manufacturing operators do not document process

interventions occurring during the Terminal Sterilization (TS) manufacturing process in the Manufacturing Batch Records (MBRs). Examples of unrecorded interventions that could potentially introduce contamination include but are not limited to removal of broken vials, removal of fallen vials, removal of stopper jammed, stoppage of the filling line and other interventions that may breach or temporarily compromise (b) (4) RABs system integrity. Moreover, your Quality Unit did not provide a risk-based approach to justify the current practice of not analyzing/monitoring/assessing routine or non-routine interventions for their potential to increase bioburden (the microbial load prior to sterilization).

C. We observed significant risks and inadequate aseptic practices during set-up process in preparation for commercial filling on Line (b) (4)

1) Review of the airflow visualization (smoke study) video for vial filling Line (b) (4) demonstrated that during setup operations within the aseptic core (Grade A area), (b) (4) manufacturing operators performed the routine intervention identified as "Machine Parts Transfer Main Load." During this intervention, (b) (4) (b) (4) (b) (4) During these activities, (b) (4) was observed repeatedly making direct contact with the interior (b) (4) frame of the aseptic core using (b) (4) This (b) (4) frame surface is not included in your current environmental monitoring (EM) program for surface monitoring. No sanitization of the interior surfaces of the aseptic core, including the (b) (4) framework, is performed following completion of the sterile filling parts transfer activities. Thus, your firm has not demonstrated that surfaces within the Grade A aseptic core that are routinely contacted during setup interventions have been adequately assessed for contamination risk.

2) Review of the airflow visualization (smoke study) video for vial filling Line (b) (4) demonstrated that during pre-assembling operations within the aseptic core (Grade A area), (b) (4) manufacturing operators performed the routine intervention identified as "(b) (4) transfer (b) (4) LAF to filling machine)." During this intervention, (b) (4) (b) (4) was observed repeatedly making direct contact with the interior (b) (4) (b) (4) frame of the aseptic core using (b) (4) during these transfer activities. However, your current environmental monitoring (EM) program does not include any EM monitoring during pre-assembling activities conducted within the Grade A aseptic core. No sanitization of the interior surfaces of the aseptic core, including (b) (4) and adjacent (b) (4) framework, is performed following completion of the (b) (4) transfer activities. Therefore, repeated contact with interior Grade A surfaces during pre-assembling activities, combined with the absence of monitoring and post-intervention sanitization, may compromise aseptic core conditions and increase the risk of microbiological contamination of product-contact surfaces.

3) Failure to adequately design and qualify aseptic processing operations to prevent microbiological contamination.

A. Specifically, airflow visualization (smoke) studies performed for (b) (4) RABs Filling Lines (b) (4) (b) (4) are not designed or executed to adequately evaluate aseptic processing risks under routine and worst-case operating conditions. The airflow studies do not simulate (b) (4) (b) (4) process interventions that occur during routine commercial aseptic capping and sealing operations. Our review of commercial batch production records indicates that operators perform multiple interventions during capping/sealing operations; however, these interventions are not incorporated into airflow re-qualification studies.

Examples of process interventions not simulated during airflow studies include, but are not limited to sensor adjustments, removal of fallen vials on the capping (b) (4) track, stuck or jammed seals, removal of broken vials on (b) (4) capping (b) (4) adjustment of (b) (4) (b) (4) adjustments, (b) (4) adjustments, seal chute adjustments, and removal of broken vials during capping operations. These interventions may involve (b) (4) RABs (b) (4) stopping the line, reaching into the critical zone, or otherwise disrupting unidirectional airflow. Because these routine and repeated interventions are not incorporated into airflow studies, your firm has not demonstrated that unidirectional airflow and first-air protection are maintained during actual operating conditions.

B. The airflow visualization (smoke study) performed for Filling Line (b) (4) does not include assessment of a routine process intervention identified as "(b) (4) conveyor for personnel movement." During batch filling operations, manufacturing personnel move between the Grade B area and the Grade A critical zone via a (b) (4) conveyor system to perform environmental monitoring activities. This movement involves frequent transition of personnel and associated equipment (e.g., (b) (4) between classified areas during ongoing aseptic operations.

However, the airflow study does not assess the potential disruption of first-air protection caused by repeated (b) (4) repositioning of the (b) (4) conveyor. Additionally, no personnel monitoring is performed upon re-entry from Grade A to Grade B following such movements. The continuous movement of manufacturing operators, including the microbiologists between Grade B and Grade A during aseptic filling operations, without qualification of airflow pattern impact and without appropriate monitoring controls, may disrupt the Grade A environment and increase the risk of microbiological contamination.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	02/10/2026-02/20/2026
	FEI NUMBER: 3014362214

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Bhaskar Krishna, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Maiva Pharma Private Limited	No 32 Sipcot Industrial Complex Phase I
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hosur, Tamil Nadu, 635126, India	Sterile Drug Manufacturer

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

There is no assurance that the current flow of personnel within the vial filling Lines (b) (4) is designed to prevent microbial contamination.

Filling Line (b) (4)

A. On February 13, 2026, during observation of aseptic filling operations for (b) (4) Injection, (b) (4) mg (b) (4) mL, Batch No. (b) (4) (non-U.S. market), on Filling Line (b) (4) it was noted that the microbiology analyst accessed the rear of the sealing and capping machine by (b) (4) moving the (b) (4) conveyor to perform environmental monitoring (EM).

The (b) (4) conveyor is positioned under a (b) (4) unidirectional airflow (LAF) zone intended to provide Grade A protection. When (b) (4) a portion of the conveyor assembly (b) (4) into the surrounding Grade B classified area. Upon (b) (4) the conveyor returns under the (b) (4) LAF zone without any sanitization, or environmental monitoring of the surfaces that were exposed to the Grade B environment. Therefore, the current sealing machine configuration and operational practice do not provide adequate assurance of contamination control during aseptic processing.

Filling Line (b) (4)

B. During batch filling operations, the manufacturing personnel routinely move between the Grade B area and the Grade A critical zone via a (b) (4) conveyor system to perform the intervention identified as "(b) (4) conveyor for personnel movement." This intervention involves frequent transition of personnel and associated equipment (e.g., (b) (4) between classified areas during ongoing aseptic operations to perform inherent activities such as environmental monitoring. This practice

results in repeated movement between classified areas during active aseptic filling operations. However, no personnel monitoring is performed upon re-entry from Grade A to Grade B following such interventions. The routine and repeated transfer of personnel and equipment between Grade B and Grade A areas during aseptic processing, without documented monitoring, may increase the risk of microbiological contamination.

C. During filling line setup activities, manufacturing personnel routinely move between the Grade B area and the Grade A (ISO 5) critical zone via a (b) (4) conveyor system to perform the intervention identified as "(b) (4) LAF transfer thru (b) (4) conveyor." This intervention involves multiple transitions of personnel and associated equipment, including a (b) (4) Laminar Airflow (LAF) unit, between classified areas during setup operations. The manufacturing operators use this intervention to transfer sterilized filling parts from the (b) (4) LAF unit into the aseptic core of the filling line (ISO 5) area. This practice results in repeated movement of personnel and equipment between Grade B and Grade A areas during active setup activities. However, no personnel monitoring is performed upon re-entry from Grade A to Grade B following such interventions. The routine transfer of personnel and (b) (4) equipment between classified areas during aseptic setup operations, without appropriate monitoring or documented control measures, may compromise the microbiological integrity of the Grade A critical zone.

OBSERVATION 5

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

A. Your firm failed to provide a scientific justification for the established frequency of settle plate monitoring for anaerobic microorganisms on Lines (b) (4) Additionally, your firm did not provide a scientific rationale for performing environmental monitoring under either static or dynamic conditions without defined criteria or preference, as described in the procedure titled

"Microbiological Environmental Monitoring Programme (EMP) of Cleanrooms and Controlled Environments", SOP No. SOP/QCM/GEN/007, Version 07, Effective Date: May 15, 2025.

B. Your Quality Unit does not perform any Environmental Monitoring (EM) during (b) (4) transferring and pre-assembly activities conducted in the (b) (4) Restricted Access Barrier System (b) (4) RABs) of Lines (b) (4) used in the manufacture of aseptic filling and terminally sterilized drug products. Specifically, personnel monitoring, settle plates, active air sampling, or non-viable particles is not performed. Fixing the sterile (b) (4) in the (b) (4) represents an intervention in the Grade A critical aseptic processing area; however, your current practice is to not perform EM monitoring, including viable and non-viable during this pre-assembly intervention to ensure that aseptic conditions are continuously maintained.

C. Your Quality Unit does not ensure that appropriate aseptic technique is followed during interventions in the Grade A aseptic processing area. On February 13, 2026, during observation of operators performing interventions on Line (b) (4) during aseptic filling operations of (b) (4) (b) (4) Injection, (b) (4) mg (b) (4) mL, (b) (4) (No-USA) Batch No. (b) (4) operators were observed (b) (4) (b) (4) According to your Microbiology Management, your environmental monitoring program includes only fingertip sampling (finger dabs) and does not include monitoring of (b) (4)

D. Your Quality Unit environmental monitoring (EM) program is inadequate in that it does not include routine microbiological monitoring of high-traffic and frequently handled equipment located within classified manufacturing areas. Specifically, (b) (4) electronic devices (e.g., (b) (4) used during operations on Filling Lines (b) (4) are not included in your environmental monitoring program. These items are routinely accessed by operators during manufacturing operations and represent potential sources of microbial contamination; however, your firm has not established procedures to monitor or assess the microbiological state of these surfaces.

E. Your firm does not adequately monitor and validate equipment classified as Grade A used in aseptic processing operations. On February 13, 2026, during setup of Line (b) (4) aseptic filling operations for (b) (4) Injection, (b) (4) mg (b) (4) mL, (No USA) Batch No. (b) (4) (b) (4) a (b) (4) laminar airflow (ID: PROD/FR/131) unit classified as Grade A, containing (b) (4) bags with sterilized equipment and utensils, was observed in use without any environmental monitoring during operations. Specifically, no viable air monitoring (e.g., active air sampling) or settle plates were performed while the unit was in operation.

In addition, your firm has not validated any (b) (4) LAF (b) (4) n total) unit to establish the maximum equipment and/or utensil load configuration or load pattern necessary to ensure the maintenance of Grade A aseptic conditions. Additionally, there is no risk assessment that demonstrates with scientific evidence that the current sampling locations are representative of worst-case operational conditions.

F. Your firm decrease the active (volumetric) air sampling frequency in Grade A areas based on the document titled "Quality Risk Assessment & Management For Reduction of Environmental Monitoring Sampling Locations for Line-(b) (4) & Line (b) (4) Clean and Controlled Areas", Document Number: MAIVA/QRAP/23/022, approved July 29, 2023.

This quality risk assessment is inadequate in that the detectability score was assigned a value of (b) (4) based on the firm's rationale that contamination could be immediately detected through microbiological monitoring techniques (settle plates, active air, and surface monitoring). However, this justification is inappropriate because the risk assessment was performed to reduce active (volumetric) air monitoring itself as a control measure. Assigning the highest detectability rating while simultaneously reducing the monitoring frequency of that same detection method undermines the validity of the risk assessment. When a more appropriate detectability value of (b) (4) is applied, the recalculated risk score changes the risk classification from "minor" to "major." According to your firm's risk management report, risks classified as "major" is not acceptable.

G. On Filling Line (b) (4) the (b) (4) intervention area where operators (b) (4) during aseptic processing is not included in your environmental monitoring program. Specifically, no viable environmental monitoring (active air) sampling is performed in this area during operations or NVPC. Although a non-viable particle counter (NVPC) is installed in the vicinity (approximately (b) (4), it is positioned opposite to the area where the (b) (4) intervention is performed and is not representative of the critical intervention zone.

H. During observation of smoke studies for Line (b) (4) (Vessel Assembly Line-1), the (b) (4) tank aseptic connection performed under Grade A conditions was not supported by non-viable particle count (NVPC) monitoring at the time of the intervention. Your firm does not perform non-viable particle count monitoring during the aseptic connection activity, which represents a worst-case intervention. Although an active air sampler is installed near the (b) (4) tank, the system is programmed to collect samples at (b) (4) Your firm does not ensure that the active air sample is being collected during the actual performance of the aseptic connection. Therefore, there is no assurance that environmental monitoring data is representative of the conditions at the time of the most critical aseptic intervention. In addition, the (b) (4) tank aseptic lines were observed not to be (b) (4) and were not disinfected with (b) (4) prior to connection to the filling line. These lines were exposed to the Grade B environment prior to transfer into the Grade A core area and subsequent aseptic connection.

OBSERVATION 6

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

A. Specifically, your Quality Unit has not conducted a thorough evaluation of significant variation in total batch production time for (b) (4) Injection (b) (4) mL; Batch size (b) (4) aseptic filling on Line (b) (4)

Review of batch production records indicates that batch manufacturing duration varies substantially, ranging from approximately (b) (4) to (b) (4) for the same product and filling process. Your Quality Unit has failed to investigate the causes of the extreme variability in filling and production time and to identify process parameters, equipment performance factors, interventions, or operational practices contributing to such variation. Since the variability in batch production time has not been evaluated, your Quality Unit cannot demonstrate that the filling process is in a state of control.

Similar variation has been observed for the following filling process:

- Filling Line (b) (4) Injection USP (b) (4) mg (b) (4) mL; Batch size (b) (4) TS process. The batch manufacturing duration varies from approximately (b) (4) to (b) (4)

- Filling Line (b) (4) Injection USP (b) (4) mg (b) (4) mL; Batch size (b) (4) TS process. The batch manufacturing duration varies from approximately (b) (4) to (b) (4)

B. Your (b) (4) Vial Inspection Machine, Equipment ID: PROD/INSP/122, was qualified in accordance with "Performance Qualification for (b) (4) Vial Inspection Machine – With Product (b) (4) Protocol Number VAL/PQ/PROD/24/036-PV01, approved March 13, 2024. This equipment is used to conduct visual inspection of (b) (4) mL (b) (4) vials for, but not limited to particles, glass fragments, fibers, low/high volume, and empty vials. The performance qualification challenge set (b) (4) used for this qualification contained vials with particles of various sizes including, but not limited to, (b)(4) (b)(4) (b)(4) (b)(4) (b) (4) (b)(4) (b)(4) (b) (4) (b)(4) The (b)(4) (b) (4) was prepared in accordance with "Protocol for Preparation of (b) (4) Document Number: QD/PQ/QA/23/002/PV02, with an expiration date of (b) (4) and the particle sizes of this kit were certified by a contract laboratory. However,

your firm is currently performing a (b) (4) inspection challenge tests of the (b) (4) (b) (4) Inspection Machine using a separate challenge kit prepared in-house according to "Protocol for Defects Challenge Test Kit Preparation," Protocol Number: VAL/PROD/25/001-PV01. This in-house kit does not establish or verify particle sizes for the defects and has not been certified by a contract laboratory for particle size.

On February 17, 2026, during the inspectional walkthrough of your visual inspection area, the (b) (4) Vial Inspection Machine, Equipment ID: PROD/INSP/122, was observed being challenged with the in-house verification kit. During this challenge, the equipment failed to reject two (2) defective vials identified by your firm as containing a fiber and a glass particle. Your procedure titled "(b)(4) Vial Inspection Machine (b) (4)" SOP Number: SOP/PROD/INSP/009 V04, Section: (b) (4) states that if the challenge kit is not inspected or identified, the test is to be performed a second time. Your operators proceeded to perform a second (b) (4) visual inspection for the two (2) vials that were not rejected during the first inspection. During this second (b) (4) inspection both vials were now detected and rejected by the equipment. We asked your firm officials whether production vials are also inspected twice to ensure detection of all defects, consistent with the challenge test that can be repeated to ensure rejection of all defects. Your firm officials stated that (b) (4) visual inspection for manufactured products is only performed once.

Additionally, review of the (b) (4) visual inspection challenges performed on February 06, 2026, and February 07, 2026, respectively for the (b) (4) Vial Inspection machine for (b) (4) Injection USP, (b) (4) mg/mL, Batch No. (b) (4) revealed that in both challenges the (b) (4) visual inspection equipment failed to reject a total of three (3) defective vials from the challenge kit. Specifically, the (b) (4) inspection challenge failed to reject one (1) defective vial, and the (b) (4) inspection challenge failed to reject two (2) defective vials. The challenge was not repeated by your operators as required by your procedure, the specific types of defects that were not rejected were not documented, and no deviation was initiated. This

batch was subsequently released by your Quality Unit on (b) (4), and still within expiration date.

Your firm follow the same deficient scientific approach for the (b) (4) visual inspection of (b) (4) Injection USP (b) (4) mg/mL (b) (4) mL (b) (4) vial). The challenge kit used for this product does not establish or verify particle sizes for the defects and has not been certified by a contract laboratory for particle size.

Review of previous (b) (4) visual inspection challenges for (b)(4) Injection USP (b) (4) mg/mL, Batch No. (b) (4) revealed that the (b) (4) inspection challenge performed on November 7, 2025, failed to reject one (1) defective vial. No second challenge was performed as required by your procedure SOP/PROD/INSP/009 V04, Section: (b) (4) and no investigation or deviation was initiated.

C. Your firm's visual inspection qualification program is inadequate in that inspectors are qualified despite not meeting the acceptance criteria established in your written procedures.

Your protocol, titled "Visual Inspector Initial Qualification", Protocol Number: VAL/PQ/PROD/25/083-PV03, states in Section (b) (4) that the acceptance criteria require the operator to identify (b) (4) % of critical and major defect units in the challenge kit. It also states in section (b) (4) that the inspector shall not identify more than (b) (4) % of false rejects. A false rejection is defined in your procedure as misidentifying the nature of the defect leading to inaccurate rejection.

However, review of the mock qualification performed on February 17, 2026, for one visual inspector using (b) (4) vials and Test Kit Reference (b) (4) revealed that the inspector misclassified four (4) critical defects during the challenge set evaluation. Specifically, the inspector classified two (2) (b) (4) vials as Loose Seal defects and two (2) Loose Seal vials as (b) (4) defects. During the inspection of a total of (b) (4) vials (b) (4) good vials and (b) (4)

rejects), the inspector misidentified four (4) defects, and this represents a false rejection rate of approximately (b) (4) %, which exceeds the maximum allowable limit of (b) (4) %. Despite not meeting the established acceptance criteria, the inspector was documented as having passed the qualification.

Additionally, a second visual inspector who underwent the same mock qualification on the same date using (b) (4) vials and Test Kit Reference (b) (4) documented a cracked vial as "good" on the inspection record. A cracked/broken vial is classified by your "Visual Inspection/ Rejection Classification Details Logbook", Document Number: FMT/PROD-INSP/001/001 V09, as a critical defect. Although the vial was grouped with the rejected units during the qualification exercise, the inspection documentation reflects the vial was recorded as "good". With no investigation performed to find why the investigator did not accurately document a segregated vial on the inspection record, your Quality Unit assigned a passing qualification even when the operator failed to document a (b) (4) % of critical and major defect units in the challenge kit.

Your practice of granting qualification despite failure to accurately identify and document critical and major defects in accordance with established acceptance criteria does not ensure inspectors are adequately qualified to correctly detect and classify critical defects. Since their last qualification in (b) (4) your (2) two inspectors have been performing visual inspection duties for U.S.-marketed products, and each have individually inspected a total of (b) (4) lots.

OBSERVATION 7

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

Your firm has not established and followed adequate written procedures to ensure maintenance of appropriate pressure differentials and airflow patterns during shutdown (Preventive Maintenance) and restart of Air Handling Units (AHUs) supporting classified areas. Procedures SOP/ENGG/PM/015 V05,

titled "Air Handling Units (Line (b) (4) Effective Date: August 25, 2025 and SOP/ENGG/PM/044 V04, titled "Air Handling Units Line (b) (4) Effective Date: February 17, 2024 does not define a documented sequence for shutdown or restart of Air handling Unit (AHUs) in order from less controlled areas to more controlled (maintain positive pressure) areas during preventive maintenance (PM) activities. The procedures do not include a defined sequence to prevent reversal or loss of pressure differentials between areas of differing classifications or controls to ensure positive pressure gradients during maintenance. Failure to establish adequate procedural controls for AHU shutdown and restart may result in loss of pressure cascade, uncontrolled airflow between classified areas, and potential compromise of environmental control conditions.

OBSERVATION 8

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

On February 11, 2026, during observation of the Bacterial Endotoxins Test (BET) sample preparation performed for (b) (4) samples (Bacterial Endotoxins Test Report No. 080), the analyst did not follow proper micro-pipetting technique during the addition of lysate for two (b) (4) samples (tubes (b) (4) and (b) (4)

Specifically, the analyst was observed aspirating and dispensing lysate improperly, resulting in visible air bubbles and inaccurate volume transfer during test preparation. The analyst did not ensure complete and accurate delivery of the required lysate volume. Two microbiology department officials were present during the test and confirmed that they also observed the analyst perform improper micro-pipetting practices during the addition of lysate. Lower volumes of lysate during sample preparation may decrease endotoxin test sensitivity (λ), and endotoxins present near the detection limit may fail to produce gel formation. Furthermore, inaccurate lysate volume can; therefore, result in false negative test results. Thus, failure to follow proper micro-pipetting technique during BET preparation may compromise the accuracy,

reliability, and validity of endotoxin test results used to support the release of (b) (4) Since September 2024, your analyst has performed a total of (b) (4) Bacterial Endotoxin Tests (BET).

OBSERVATION 9

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

According to your SOP/QA/GEN/001 V13, Titled: "Document Preparation, Approval, Issue, Control, Retrieval, Reconciliation & Destruction" Effective Date: January 13, 2026, Section 7.10 (Document Destruction), describes that documents approved for destruction are to be destroyed through the shredding machine after QA approval, and destruction activities are to be verified and documented in the "Shredding Machine Usage Logbook" (FTM/QA-GEN/001/026). The logbook requires verification of destruction activities to ensure appropriate oversight.

However, during review of the Shredding Machine Usage Logbook (FTM/QA-GEN/001/026 V01), it was observed that the individual who performed the document destruction also signed as the verifier of the same activity. The verification step was not performed by a second, independent individual as required to ensure appropriate control. Therefore, failure to maintain independent verification of document destruction activities does not ensure adequate oversight, segregation of duties, and control of GMP records subject to destruction.

02/20/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."