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	1/27/2026-2/6/2026*
	FEI NUMBER 3008461619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Atul Shastri, President - Operations

FIRM NAME	STREET ADDRESS
Eugia Pharma Specialities Limited	Unit-III, Plot No: 4, 34 to 40, 41P, 44 to 48, EPIP, TSIIC, IDA, Pashamylaram Village, Patancheru Mandal
CITY, STATE, ZIP CODE, COUNTRY Sangareddy, Telangana, 502307 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Product 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

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

Specifically,

A. Procedures to prevent microbiological contamination of drug products are not established and followed. Poor aseptic practices and inadequate glove monitoring was observed during review of CCTV recordings of sterile production. For, example,

   a. On January 9, 2026, the sterile operator (b) (6) made direct contact with the (b) (4) using his gloved hands on multiple occasions while installing the (b)(4) during assembly of the aseptic filling line (Block (b) (4) Line (b) (4) RABS; Equipment ID PN (b) (4) -001), prior to the manufacture of (b)(4) (b) (4) Injection (b) (4) mg (b) (4) mL, batch (b)(4) intended for the U.S. market. According to procedure EP3-PR-SOP-027-07, "Handling of Interventions During Filling and Stoppering Activities, Line (b) (4) sterile gown parts shall not come into contact with Grade A areas of the machine.

   b. Operators did not ensure that empty vials were cleared from the filling line prior to performing (b) (4) (b) (4) interventions. On January 9, 2026, while removing environmental monitoring (EM) plates from the (b) (4) location of Block (b) (4) Line (b) (4) the EM technician did not ensure that all empty vials were cleared

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prior to the activity. Open vials were present in close proximity to the EM technician during the activity. According to procedure EP3-PR-SOP-027-07, only filled vials are required to be cleared from the track prior to performing an intervention.

c. Operators did not ensure that stopper bags did not contact the interior of the (b) (4) during stopper transfer. On January 9, 2026, during the filling operation of (b)(4) Injection (b)(4) mg (b) (4) mL, batch (b)(4), the operator placed a bag of stoppers over the (b) (4) to transfer the stoppers. The exterior of the stopper bag was sanitized in Grade B prior to introduction into the Grade A area. The representative activities performed during smoke studies (document E3-UTL-RQ-0181, dated February 18, 2025) and media fill batch (b)(4) manufactured on September 6, 2025, for Block (b) (4) Line (b) (4) were not representative of routine commercial manufacturing, as the stopper bag did not contact the (b) (4) during those activities.

d. An approved intervention for Block (b) (4) Lin (b) (4) Intervention C4 – Removal of empty, fallen, jammed, or broken vials from the (b) (4) or filling conveyor by (b) (4) requires the use of forceps. However, during filling of batch (b)(4), the operator used both gloved hands and forceps to remove a jammed vial. During this activity, the vial broke, and broken glass fragments were scattered near empty vials on the track. The operator did not ensure that all empty vials were removed following the accidental vial breakage. The operator used a sterile wipe from Grade B to clean the broken vial. While cleaning the track, the wipe came into contact with empty vials on the track. The operator did not ensure that all empty vials were cleared prior to resumption of filling. In addition, these activities were not simulated during smoke studies.

e. During review of the smoke study video (dated November 5, 2024) of an approved intervention for Block (b) (4) Line (b) (4) RABS, Equipment ID PN (b) (4) -001 (Interventions I1 and I2 – Assembling of (b) (4) by

(b) (4) the operator contacted the tip of a sterile forceps with his elbow and gloved hands on multiple occasions. The activity was not clearly visible due to the current camera location within the filling room while we reviewed the video recording for the batch (b)(4). There is no assurance that Quality review of the intervention is adequately performed for routine commercial batch production.

f. During review of smoke study videos dated November 5, 2024, associated with Block (b) (4) Line (b) (4) aseptic setup of the (b) (4) stopper bowl (b) (4) Interventions I1 and I2), unidirectional airflow was blocked by the operator's hand while removing the (b) (4) cover from the stopper bowl. In addition, during the intervention "(b) (4) stopper (b) (4) and stopper loading (b) (4) " (b) (4) the outer surface of the (b) (4) cover contacted the loading (b) (4) No incident related to these observations was documented in the smoke study report (E3-UTL-RQ-R-0185, approved on March 21, 2025).

g. On January 8, 2026, complete outer surface of (b)(4) containers containing equipment located in Grade B (b) (4) room was not properly disinfected prior to placement in the Grade A filling line during (b) (4) set up for (b) (4) Injection, USP (b) (4) g/vial, Batch # (b)(4) in Block (b) (4) Line (b) (4)

h. After filling set up for (b) (4) Injection, USP (b) (4) g/vial, Batch # (b)(4) in Block (b) (4) Line (b) (4) Aseptic operator was observed to thoroughly disinfect hands, enter Grade A to perform minor activities such as moving a (b)(4) container containing forceps prior to glove monitoring performed by AQA. Glove monitoring after (b) (4) assembly was not performed immediately to ensure that

microbial contamination if present on the aseptic operator gloves can be accurately detected and recovered.

i. On January 18, 2026, during filling of (b) (4) Batch #(b) (4) I observed wipes exposed placed on a (b) (4) in the Grade B (b) (4) room that were used to sanitize materials prior to placement in Grade A.

j. Personnel monitoring performed after aseptic interventions did not adequately represent the activity performed. After completing filling line assembly, the Grade A operator sanitized his gloved hands prior to the collection of personnel monitoring samples. On January 9, 2026, the sterile operator (b) (6) after completing installation of the (b) (4) on Line (b) (4) Block (b) (4) for (b) (4) Injection (b) (4) mg (b) (4) mL, batch (b) (4) sanitized his gloved hands prior to the collection of personnel monitoring finger dab samples. According to procedure EP3-PR-SOP-027-07, gloved hands shall not be sanitized prior to finger dab sampling.

B. During aseptic filling operations, procedure EP3-QA-SOP-053-00, "General Clean Room Practices and Personnel Behaviour for Working in Aseptic Processing/ Sterility Testing Area" and line specific intervention procedures were not followed:

During set-up and aseptic filling of (b) (4) Solution (b) (4) % batch (b) (4) (US market) on (b) (4) the following was observed:

There was no environmental monitoring in the Grade A area where the connection from the Product

Transfer Line to the (b) (4) tank is made. Additionally, no finger dabs are collected after the aseptic connection and the operator is inside the Grade A area, yet his gowning is held to the Grade B limit.

b) During intervention I20: Addition of Bottles to (b) (4) the (b)(4) and the opened bag containing sterile bottles were observed over the sterile bottles and the (b) (4) In addition, the outer side of the bag containing the sterile bottles contacted the inner walls of the (b) (4)

c) The (b) (4) into which sterile bottles are loaded into remains on the line where it is sanitized but not sterilized. There is no environmental monitoring of the sides of the (b) (4) directly in contact with the open, sterilized bottles used in production.

d) The (b) (4) remains on the line where it is sanitized but not sterilized. There is no environmental monitoring of the sides of the (b) (4) directly in contact with the open, sterilized bottles used in production.

2. During aseptic filling of (b) (4) Injection Batch (b) (4) (US Market) on (b) (4) the following was observed:

During intervention C6-FG06: Adjustment of (b)(4) Through (b) (4) the operator was observed reaching over the exposed (b) (4) with the (b)(4) to adjust (b) (4) (b) (4)

b. During intervention C8-FG10: Clearing of Jammed Stopper Through (b) (4) at (b) (4) on January 14, 2026, the operator was observed using the handle of the forceps not the tips (jaws).

3. During aseptic filling of (b) (4) Injection, (b) (4) mg/Vial, Intervention C6 Clearing of Jammed Stoppers in Stopper Stoppering Track Through (b) (4) (b)(4), an operator was observed with the (b) (4) directly over stoppers on the tracks prior to vial stoppering. Similar practices were also observed in air flow visualization study EP3-UTL-RQ-P-0038 dated August 3, 2024.

4. During aseptic filling of (b) (4) Injection USP (b) (4) mg (b) (4) mL, on (b) (4) (b) (4) an operator was observed with the (b)(4) directly over stoppers on e chute stoppers fall onto from canister before being loaded into the (b) (4)

OBSERVATION 2

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

Specifically,

A. Your firm's procedures for interventions during aseptic filling operations on Block (b) (4) Line-(b) (4) (b) (4) machine, PN (b) (4) -001) do not ensure maintenance of appropriate enviro mental conditions or verification of environmental recovery prior to resuming sterile product manufacturing. During (b)(4) replacement and maintenance activities, your firm (b) (4) (b) (4) The filling zone is then cleaned while in Grade C conditions before attempting to re-establish the Grade A environment. Review of maintenance records from 2024-2025 revealed multiple instances of this practice, including Work Orders (b) (4) ENP/25/1141, (b) (4) 24/0022,

(b) (4) ENP/24/0296, and (b) (4) ENP/25/0478, where (b) (4) servicing were performed following (b) (4) and environmental degradation. Following these interventions (b) (4) your firm relies solely on a (b) (4) wait time for Non-Viable Particle Count (NVPC) to return to normal. However, your firm has not provided validated environmental recovery time based on qualification studies.

B. Airflow visualization E3-UTL-RQ-P-0043 dated November 1, 2024 (smoke study) of Grade A laminar flow for Block (b) (4) Line (b) (4) do not demonstrate there is appropriate air laminarity during commercial operation

1. Intervention I2 Assembling of (b) (4) the smoke appears to eddy up and around by (b) (4) during this intervention. This location is where open unfilled vials will move to the fill station then will have the (b)(4) (b) (4) before moving to either the good track or the rejection track.
2. Intervention I2 Aseptic Set Up of (b)(4) Chute (b) (4) the smoke appears to eddy up and around by the (b) (4) This is where the filled vials will have the (b)(4) (b) (4) before moving to the (b) (4) station.

C. The following deficiencies were observed during review of air flow visualization study EP3-UTL-RQ-P-0038 dated August 3, 2024 (smoke study) for Block (b) Line (b)

1. Intervention C26 Removal of Broken Vial on (b) (4) Through (b) (4) the simulation of broken vial removal was performed without vials present on the (b) (4) line. The operator simulated the hand and forceps motions of grasping and removing a vial without physically handling an object. This simulation approach does not adequately represent actual operational conditions and may not demonstrate worst-case airflow disruption that occurs during intervention activities.

2. Intervention C8 Removal of Fallen-Clearing of Jammed Vials at (b) (4) Through

(b) (4) the simulation shows the (b) (4) directly over (b) (4) (b) (4) vials at the (b) (4)

3. Intervention C5 Removal of Fallen Vials from the Filling Machine Conveyor Through (b) (4) (b)(4): the simulation shows the (b) (4) directly over filled vials leaving the filling zone.

D. The following deficiencies were observed during review of air flow visualization study E3-UTL-RQ-R-0180 dated November 14, 2024(smoke study) for Block (b) (4) ine (b) (4)

1. Intervention C22 Removal of Fallen Filled Vials rom the Block Through (b) (4) (b) (4) and C13 Removal of Fallen Filled Vials from the Block Through (b) (4) (b) (4) do not simulate wiping spilled liquid from the conveyor track.

2. Intervention I3: Transfer of (b) (4) stoppers from (b) (4) Stopper Canister to (b) (4) (b) (4) Stopper Bowl by (b) (4) Through observed directly over chute stoppers fall onto from canister before being loaded into the (b) (4) In addition, the operator created turbulent air when he shook the canister in quick and short motions to release (b) (4) stoppers to the (b) (4) This intervention is performed during (b) (4) manufactured on Line (b) (4) Block (b) (4)

3. Intervention C8A: Removal of Fallen Vials from (b) (4) Through (b) (4) (b) (4) reaches over open exposed vials yet no vials were removed. This intervention has been performed approximately (b) (4) times during the past 6 months during batches including but not limited to: (b) (4)

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Injection USP (US Market).

OBSERVATION 3

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

Specifically,

Aseptic processing operations are not designed to provide sufficient visual monitoring of critical interventions and aseptic manipulations to ensure compliance with current good manufacturing practice (CGMP) requirements.

During inspection of aseptic filling lines, it was observed that some set up activities as well as corrective interventions cannot be monitored through existing viewing windows or closed-circuit television (CCTV) camera systems. The CCTV system serves as the primary method for Quality Assurance personnel to review filling operations and identify potential breaches in aseptic practices.

For example:

A. On Block (b) (4) Line (b) (4)

1. Asepti (b) (4) connections are not visible to monitoring systems, specifically the aseptic connection of the product transfer line to the (b) (4) tank and the (b) (4) tank to the filling manifold. These connections represent the most critical control point in the process as they establish the pathway of the product (b) (4) from the product transfer line to the (b) (4) tank and on to the manifold which is then connected to the (b) (4) used for finished vial filling.

2. Any interventions that occur through (b) (4) including but not limited to: C16 - Removal of Empty (b) (4) Bottles Jammed on the Conveyor Through (b) (4) (b) (4) and C17 - Removal of (b) (4) Bottles from (b) (4) Through

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(b) (4)

B. On Block (b) (4) Line (b) (4)

1. Interv(4) tion I1 Aseptic Setup of (b) (4) (Removal from (b) (4) Through (b) (4) (b)(4). This intervention is done after the (b) (4) has been performed. (b) (4) (b) (4) the (b)(4) are moved from the (b) (4) to the filling line.

2. Intervention C21 Clearing of Jammed Stopper in Stopper Bowl Through (b) (4) This intervention has been performed (b) (4) times during the past 6 months during batches (b) (4) Injection USP (US Market).

C. On Block (b) (4) Line (b) (4)

1. Interv(4) tion (4) FG01 Removal of Fallen Vials from (b) (4) This intervention has been performed (b) (4) times during the past 6 months during batches including but not limited to: (b) (4) g/Vial. The location of the fallen vials on the (b) (4) determines visibility since only a portion of the (b) (4) is visible.
2. Intervention C3FG03 Removal of Fallen Empty Vials from the Filling Machine Conveyor Through (b) (4) (b) (4) This intervention was performed during batch (b) (4) Injection, (b) (4) mg/Vial

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy and 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.

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Specifically,

a. A critical investigation, PNC-EP3-MB-24-0012, was initiated on April 19, 2024, to investigate and identify the root cause of turbidity observed in aseptic process simulation (media fill) vials, batch (b)(4), executed on Line (b) (4) Equipment ID PN (b) (4) -001 (Grade A (b) (4) located within a Grade C room). Turbidity was observed in (b) (4) of (b) (4) after (b) (4) of incubation. The investigation identified that (b) (4) integrity test (b) (4) failures were reported, and the operator attempted to troubleshoot a potential leak in accordance with procedure EP3-PR-SOP-070-07. The investigation further concluded that, while troubleshooting the leak during the (b) (4) the manufacturing operator adjusted (b) (4) located (b) (4) of the (b) (4) system and used non-sanitized (b)(4) tools without performing glove sanitization. At the time, the firm's procedure required (b) (4) to be performed after the (b) (4) and the (b) (4) were open during the (b) (4) activity. Troubleshooting activities performed (b) (4) of the (b) (4) during (b) (4) testing could have compromised the aseptic boundary due to potential ingress of Grade C air into the (b) (4) Based on the investigation, during commercial batch manufacturing, the (b) (4) is performed prior to (b) (4) Any troubleshooting during this period is performed using (b) (4) without opening the (b) (4) The investigation was extended to batches manufactured within the previous aseptic process simulation batch and concluded that no risk was identified. Your firm followed the same manufacturing procedure used for the media fill study for commercial batch manufacturing prior to December 2022. After December 2022, the procedure for (b) (4) integrity testing was updated following implementation of a (b) (4) agent change from (b) (4) to (b) (4) However, the investigation did not extend to all products manufactured prior to December 2022. It was also noted that (b) (4) failures occurred in approximately (b) (4) batches manufactured in 2022, during which troubleshooting activities may have been performed by

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manufacturing operators, creating a potential contamination risk. No Field Alert was initiated for this media fill failure.

b. Work order (b) (4) ENP/25/0495 was initiated on (b) (4) during the filling of (b) (4) Injection, batch (b)(4) (expiry (b) (4) on the (b) (4) line at Bloc (b) (4) Line (b) (4) RABS), Equipment ID PN (b) (4) 001. The (b)(4) machine is a Grade A system located within a Grade B room. The filling operation started on (b) (4) at (b)(4) and was completed on (b) (4) at (b)(4). During the filling operation on (b) (4) at (b)(4), the filling operator initiated the work order after a timeout was observed at the (b) (4) Two engineering personnel entered the filling room at (b)(4) and identified that the (b) (4) used for the "(b) (4) assembly" was not functioning as required. They determined that a (b) (4) was missing at one location on the (b) (4) and replaced the (b) (4) This maintenance activity was performed inside the Grade A area of the filling unit. The intervention record documented that the work was performed from (b)(4) to (b)(4) ((b)(4) (b)(4)). IPQA signed the work order and determined that a deviation and subsequent investigation should be initiated. However, no deviation was initiated to assess the impact of the maintenance activity on the filling operation or on (b) (4) that had already been filled prior to the maintenance event. The batch was subsequently released and shipped to the U.S. market.

c. Work order (b) (4) ENP/24/0296 was initiated on (b) (4) during the initial setup for (b) (4) Solution, batch (b)(4) (expiry (b) (4) on the (b) (4) line at Block (b) (4) Line (b) (4) RABS), Equipment ID PN (b) (4) -001. The (b)(4) machine is a Grade A system located within a Grade C room. Following line clearance, (b) (4) was started on (b) (4) at 12:19. On (b) (4) at 13:00, the filling operator initiated the work order after continuous dripping of solution was observed from (b) (4) Engineering personnel performed maintenance activities from (b)(4) to (b)(4). According to the work order, the (b) (4) unit

was removed from the machine and repaired; however, this activity was not an approved intervention. A trial run using (b)(4) was performed to verify the functionality of the (b) (4) To perform this activity, laminar airflow to the filling unit was turned off, resulting in the filling unit being maintained in a Grade C environment. A (b) (4) of the (b) (4) was performed prior to restarting the filling operation, from (b)(4) on (b) (4) The filling operation was resumed on (b) (4) at (b)(4). This maintenance activity was not documented in the executed batch record. Additionally, no line clearance was performed to ensure appropriate cleaning of the filling unit prior to restarting the filling process, despite the (b) (4) unit being maintained under Grade C conditions during the maintenance activity. The batch was subsequently released and shipped to the U.S. market.

d. Work order (b) (4) ENP/25/0049 was initiated on (b) (4) during the filling and stoppering operation of (b)(4) Injection, batch (b)(4) (expiry (b) (4) on Line (b) (4) Block (b) (4) (b) (4) RABS), Equipment ID PN (b) (4) 002. The filling machine is a Grade A system located within a Grade C room. The filling operation started on (b) (4) at (b)(4) and was completed on (b) (4) (b) (4) at (b)(4). On (b) (4), at (b)(4), the filling operator initiated the work order due to improper stoppering of vials. Engineering personnel entered the filling room, and breakdown maintenance was performed from (b)(4) on (b) (4) Engineering personnel verified the stoppering track and identified a misalignment, which was corrected by performing a centering activity. IPQA signed the work order as critical and determined that a deviation should be initiated. However, in the maintenance activity log within the executed batch record, Manufacturing documented that the engineering personnel rectified the issue without entering the laminar airflow (LAF) area and therefore concluded that there was no impact. No investigation or risk assessment was performed. The batch was subsequently released and shipped to the U.S. market.

e. Assigned root causes determined for Grade A microbial excursions are not always supported by your investigations or properly identified. For example, EM/OOL/035/25 and EM/OOL/036/25 was covered in PNC-EP3-PR(b) (4)25-0187 involved a total of two microbial excursions(b) cfu during Grade A settle plate near the(b) (4) addition and(b) (4) cfu found on settle plate near the(b) (4) of the Grade B change room during the production of (b) (4) Solution USP(b) (4)% w/v, Batch (b) (4) Isolates recovered from both settle plates were identified and there was a microorganism isolated in the Grade A settle plate was also found in the Grade B settle plate. However, your root cause determined for these excursions were that settle plates were contaminated during handing and/or transport which was not supported by your investigation.

f. Consumer complaints received regarding drug product efficacy (sub-potent or super potent drug products) are not adequately investigated to determine the validity or substantiate the complaint. According to the SOP entitled, "PROCEDURE FOR MARKET COMPLAINTS MANAGEMENT SYSTEM", Document No. HO-CQA-SOP-212-04, Effective 01-Jan 2026, retains and complaint samples are tested for specific tests based on the nature of complaint received. However, complaints involving drug product efficacy was not tested for assay as part of your investigation. For example,

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MC EP3-24-0154 received on May 29, 2024, for (b)(4) Batch # (b)(4) stated that "it doesn't work for her...(b) (4)." This drug product is used to (b) (4) however, complaint and reserve samples were only tested for description and related substances despite complaint being due to a possible subpotent drug product.

2. MC EP3-24-0207 received on September 13, 2024, for (b)(4) (b)(4) Batch # (b)(4) stated that "the (b) (4) containers contained more than (b) (4) application, leading to excessive dosage" which caused a (b) (4) flare up that lasted three weeks which ceased two days after the patient was instructed by the (b) (4) to stop using the drug. However, complaint and reserve samples were only tested for description and related substances despite complaint being due to a possible super potent drug product.

OBSERVATION 5

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

Specifically,

a. Personnel involved in (b) (4) interventions during filling activities in (b) (4) RABS are not held to Grade A specifications. Personnel monitoring samples, including gloves and forearms, are collected at the exit of the filling room and evaluated against Grade B specifications, even when personnel have performed Grade A (b) (4) interventions using gloved hands. The QA Manager stated that personnel monitoring of gloves following (b) (4) interventions during aseptic filling operations is currently not performed, and that exit monitoring is assessed against Grade B specifications. The samples collected at the exit

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Atul Shastri, President - Operations

FIRM NAME	STREET ADDRESS
Eugia Pharma Specialities Limited	Unit-III, Plot No: 4, 34 to 40, 41P, 44 to 48, EPIP, TSIIC, IDA, Pashamylaram Village, Patancheru Mandal
CITY, STATE, ZIP CODE, COUNTRY Sangareddy, Telangana, 502307 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Product Manufacturer

monitoring is not a representation of the grade A activity performed. The following is a list of microbial recoveries from operator glove monitoring samples for personnel involved in filling activities:

Batch	Filling line	Date	Operator	Recoveries at exit		(b) (4) intervention
				Right glove (CFU)	Left glove (CFU)	
(b) (4), (b) (6)						Addition of (b) (4) stoppers
						Addition of (b) (4) stoppers
						Addition of (b) (4) stoppers
						Addition of (b) (4) stoppers

b. (b) (4) interventions are not documented in batch manufacturing records. Verification of startup is performed prior to filling operations. During this activity, checklist EP3-PR-SOP-013-F-07-00 (Line (b) (4) Block (b) (4) s executed and may involve (b) (4) interventions; however, the current checklist does not document the type of intervention performed during startup. On January 9, 2026, Intervention C16 – adjustment of the (b) (4) using gloved hands was performed as part of startup at 8:26 AM by the sterile operator (b) (6) This intervention was not documented in the executed batch record. Finger dab samples from the operator were collected in the Grade B aseptic corridor upon exit from the room at 8:42 AM. Video recordings confirmed that the operator sanitized his gloves twice while in the Grade B

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filling room. Therefore, the glove samples collected would not be representative of the (b) (4) intervention performed in the Grade A area. The filling line was used to manufacture (b) (4) Injection, USP, batch (b) (4) for the U.S. market. The QA Manager stated that (b) (4) interventions performed during setup are currently not documented and that personnel monitoring samples collected at exit are evaluated against Grade B specifications. Recoveries were reported from personnel glove samples collected at exit following filling line setup; however, no investigations were initiated, as the firm applies Grade B limits (alert level > (b) (4) CFU and action level (b) (4) CFU) to these samples. The following is a list of recoveries from operator glove monitoring samples for personnel involved in filling line setup activities:

Batch	Filling line	Date	Operator	Recoveries at exit	
				Right hand glove (CFU)	Left hand glove (CFU)
(b) (4), (b) (6)					

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(b) (4), (b) (6)

c. Appropriate actions were not taken when non-viable particle count (NVPC) levels exceeded action limits during aseptic filling operations of (b) (4) products. According to SOP EP-PR-SOP-017-03, "Operation and Monitoring of (b) (4) NVPC Using the FMS Facility Monitoring System," when NVPC excursions occur, filling activities are required to be stopped and the cause of the excursion evaluated. Any exposed open, filled, or unfilled containers on the filling machine are required to be discarded.

On January 10, 2026, during the filling operation of (b)(4) Injection (b) (4) mg (b) (4) mL, batch (b) (4) an NVPC alarm was recorded at the filling station from (b)(4) to (b)(4). The operator did not stop the filling line and instead acknowledged the alarm by adding the comment "no interventions." It was noted that an intervention involving removal of a jammed vial occurred at the (b) (4) station between (b)(4) and (b)(4).

A list of batches in which NVPC alarms were reported during filling operations without appropriate actions taken within the past twenty-one days is provided below.

Product	Batch	Filling line	Mfg date	Number of NVPC alarms	Action taken or not
(b) (4)					

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(b) (4)

[redacted]

d. Aseptic activities were performed while non-viable particle count (NVPC) results were out of specification. Your firm uses (b) (4) non-viable particle monitors while performing aseptic activities, including but not limited to connecting product transfer lines after (b) (4) Although NVPC results were out of specification during these activities, the excursions were reported as "pass," and aseptic activities continued. No investigations were initiated for these excursions. Quality failed to adequately evaluate these excursions and implement appropriate corrective actions. Some incidents are shown below:

Product	Batch	Date	Activity	Location (Grade A)	≥(b) (4) m (spec MT (b) (4) particles/m3)	≥(b) (4) m µ (spec NMT (b)(4)	Reported as Pass/Fail	Comment

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Sangareddy, Telangana, 502307 India	Sterile Drug Product Manufacturer

						particles/m3)		
(b) (4) njection (b) (4) mg(b) (4) mL	(b)(4)	November 6, 2025	Aseptic connection inside LAF of product transfer line	Block (b)(4)	(b) (4)	(b) (4)	Pass	Tube touched NVPC probe
(b) (4) Injection (b) (4) mg(b) (4) mL	(b) (4)	November 21, 2025	Front side of the filling machine (b) (4) at (b) (4) near to filling station	Block (b)(4)	(b) (4)	(b) (4)	Pass	(b) (4) spray towards NVPC funnel
(b) (4) injection (b) (4) mg(b) (4) ml	(b)(4)	January 1, 2026	Aseptic connection inside LAF of product transfer line	Block (b)(4)	(b) (4)	(b) (4)	Pass	Personnel movement
(b) (4) injection (b) (4) mg(b) (4) ml	(b)(4)	February 1, 2026	Aseptic connection inside LAF of product	Block (b)(4)	(b) (4)	(b) (4)	Pass	Personnel movement

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CITY, STATE, ZIP CODE, COUNTRY Sangareddy, Telangana, 502307 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Product Manufacturer

			transfer line					

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

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A.Destructive testing is performed on sterile drug products that are difficult to inspect such as but not limited to (b) (4) dispensed in (b) (4) containers and sterile drug products dispensed in glass (b) (4) vials to ensure that there are no visible critical defects such as particulates or foreign matter present in the product sample. On January 30, 2026, a demonstration of the firm's destructive testing method was performed, and the visual operator was observed manually tapping the contents of a (b) (4) vial against a glass test tube measuring approximately (b) (4) tall numerous times to transfer all the contents of the (b) (4) vial in the glass tube. It is not known whether this method of tapping of the contents is appropriate to ensure that there is no loss or spillage of drug product during transfer or if there are drying/evaporation issues as the drug product travels down the length of the glass test tube before being inspected for visible particulates and foreign matter. Furthermore, the SOP entitled, "ACCEPTABLE QUALITY LIMIT (AQL) TESTING OF 100 PERCENT STERILE INSPECTED CONTAINERS" Document No. EP3-QA-SOP-080-01, Effective January 16, 2026 does not describe in detail how destructive testing is performed for difficult to inspect sterile drug products such as size of test tube used and manner in which drug product is transferred. At least eight unsubstantiated complaints regarding adverse drug events such as (b) (4) irritation and/or (b) (4) pain which may be attributable to particles in the product that were not assessed for particulates as part of their investigation. Approximately (b)(4) batches of sterile (b) (4) drug products dispensed in (b) (4) vials and at least (b)(4) batches of sterile (b) (4) drug products were dispatched since January 2024. For (b) (4) drug products dispensed in (b) (4) containers, supplemental destructive testing is the only test for visible particulates and foreign matter.

B. On February 2, 2026, I observed the (b) (4) visual inspection process for (b) (4) Injection (b) (4) mg/ml, Batch No. (b)(4), a sterile (b)(4) drug product. Visual inspectors were observed (b) (4) However, only the front of the vials of (b)(4) drug products were inspected. Vials were not rotated 360 degrees against the contrasting black and white backgrounds to ensure that there are no visible particulates or foreign matter present. Approximately (b)(4) batches of sterile (b)(4) drug products were shipped to the United States since January 2024.

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OBSERVATION 7

Employees are not given training in the particular operations they perform as part of their function.

Specifically,

Visual inspectors are not adequately qualified to perform visual inspection for all the sterile (b) (4) drug products that are manufactured for distribution or intended for distribution to the United States. For example,

a) The firm does not have physical destructive testing defect kits for difficult to inspect sterile products that are dispensed in (b) (4) containers, (b) (4) vials or drug product suspensions which are transferred to glass tests tubes during supplemental destructive testing such as but not limited to (b) (4) Destructive testing is performed in glass test tubes that are (b) (4) may require careful manipulation during the visual inspection process to detect visible defects.

b) There is no defect kit or library available on site to train visual inspectors to detect visual particulates or foreign matter for (b) (4) Injection (b) (4) mg/vial, a (b)(4) drug product which appears to be (b) (4) According to the DGM QA, the (b) (4) Injection (b)(4) defect kit is used to train/qualify visual inspectors for (b) (4) Injection (b) (4) mg/vial. The (b) (4) background may pose a challenge as there may not be enough contrast to properly identify visual defects. Furthermore, this training procedure is inadequate because the kit is not representative, the (b) (4) for (b) (4) Injection is (b) (4)

c) (b) (4) Injection, USP is a sterile drug product that is dispensed in (b) (4) glass ampoules; however, the firm does not have a representative physical defect kit to adequately train your

visual inspectors. According to the Visual/Packing IPQA, the firm uses a schematic to train their employees on ampoule glass defects. Complaint MC EP3-24-0173 received on November 19, 2025 for (b)(4) Injection USP, (b) (4) mg/ml, Batch No. #(b) (4) regarding defective ampoules, specifically that they were "not sco" d, difficult to open, and caused an injury to one of the nurses" was unsubstantiated. Approximately(b) (4) batches of (b)(4) Injection, USP were released and dispatched to the United States since January 2024.

OBSERVATION 8

Test procedures relative to appropriate laboratory testing for pyrogens are not followed.

Specifically,

On January 27, 2026, I observed a microbiologist performing the gel clot LAL (limulus amebocyte lysate) endotoxin test for the following sterile drug products:

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- (b) (4) Injection (b) (4) mg (b) (4) ml (b) (4) mg/ml) Batch No. (b) (4)
- (b) (4) Injection (b) (4) mg/vial Batch No. (b) (4)
- (b) (4) Injection (b) (4) mg (b) (4) ml (b) (4) mg/ml) Batch No. (b) (4)

The SOP entitled, "HANDING OF LAL REAGENTS AND BACTERIAL ENDOTOXIN TESTING BY GEL-CLOT TECHNIQUE" Document No. EP3-MB-SOP-088-00 states that after the addition of lysate to test tubes containing samples, microbiologists are to "gently mix the tubes" prior to incubation. However, the microbiologist was observed vigorously shaking a white test tube rack used to hold the product samples, spike samples, positive and negative controls prior to incubation. The purpose of gently mixing the samples after the addition of lysate is to homogenize the mixture and to prevent air bubbles/foam which may interfere with the formation of a gel clot to detect low levels of endotoxin if present. Bacterial endotoxin is a critical release test for sterile (b) (4) drug products and the test must be performed adequately to prevent releasing finished drug products that may not meet endotoxin specifications. According to Microbiology Supervisor, there have been no endotoxin failures since January 2024 and approximately (b)(4) batches of sterile (b) (4) drug products have been dispatched to the United States.

OBSERVATION 9

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

Your firm uses (b)(4) tape to secure the (b) (4) under the HEPA filters of (b) (4) RABS units utilized for the aseptic filling of (b) (4) products. Rough surfaces and exposed adhesive areas of the tape

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were observed at multiple locations. The ease of cleanability of the tape and the potential for contamination have not been evaluated. In addition, the potential obstruction of unidirectional airflow resulting from the use of the tape has not been assessed. These conditions were observed on filling lines including (b) (4) (b) (4) Your firm manufactures (b) (4) products for the U.S. market using these filling lines.

OBSERVATION 10

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy.

Specifically,

On January 27, 2026, I, observed how the firm reads environmental monitoring plates collected from but not limited to Grade A classified areas during the production of (b) (4) Injection, (b) (4) mg/vial for Batch No. (b)(4). The Head of Quality explained that a duplicate set of environment records are generated to facilitate an independent secondary review or verification. The initial reading of microbial plates is performed by the "Observer" and the secondary reading/verification is performed by the "Reviewer" using separate but identical records. However, the raw data obtained from both records are not compared or reviewed against one another accuracy or discrepancies by the "Checker". To ensure that there are no microbial excursions in the critical Grade A zones where the action limit is not more than (b) (4) fu, it is critical that records are compared to ensure the integrity and reliability of microbial data generated. According to the Head of Quality, microbial data is verified by a QC Supervisor in CaliberLIMS prior to release. However, this practice is inadequate because the raw data must be reviewed for accuracy prior to entry or transcription into CaliberLIMS. For example, the readings

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documented by observer and reviewer for (b) (4) Injection, Batch No. (b)(4) were not compared or verified for accuracy.

OBSERVATION 11

Established laboratory control mechanisms are not followed.

Specifically,

Approximately 35% of the invalidations of out-of-specification (OOS) results were recorded at the Quality Control Chemistry laboratory. Of these invalidations, 57% were attributed to analyst error and 18% were attributed to equipment-related errors. The identified root causes for these OOS results were not always supported by adequate scientific justification. For example,

a. An out-of-specification (OOS) result for related substances by HPLC was reported on May 6, 2024, for (b) (4) Solution (b) (4) % w/v, batch (b)(4) (9-month long-term stability sample). The HPLC test for related substances showed that the level of (b)(4) impurity at relative retention time (RRT) (b) (4) exceeded the specification limit of NMT (b) (4) %, with a reported result of (b) (4) %. (b) (4) batches were tested together, and the subject batch was the only batch that failed. Phase 1a and Phase 1b investigations confirmed the OOS result, and instrumentation malfunction, vial contamination, and dilution errors were ruled out. No obvious assignable root cause was identified. A Phase 2 manufacturing investigation was conducted; however, no definitive root cause was determined. An extended laboratory investigation was subsequently performed. The sample was sent to an external laboratory for LC–MS analysis, which concluded that the molecular weight of the identified impurity was

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(b) (4) g/mol. The firm reviewed products tested in the laboratory during the previous (b) (4) and identified (b)(4), which has a molecular weight of (b) (4) g/mol, as a potential source of contamination. The firm tested (b)(4) USP working standard at the same concentration using the (b)(4) related substances method; however, no peak was observed at RRT (b)(4), confirming that the impurity peak was not attributable to (b)(4) and further ruling out contamination. Retesting was performed using three samples on a different HPLC system and with a different column, and all results met specifications. The firm invalidated the initial results and concluded that the initial OOS result may have been due to improper cleaning of glassware without adequate scientific justification.

b. An out-of-specification (OOS) result for the assay test by HPLC was reported on September 2, 2024, for (b)(4) Injection (b) (4) mc (b) (4) mL, batch (b)(4) (initial release). The assay result was (b) (4) %, against a specification of (b) (4) %. Re-injection from the same vial resulted in (b) (4) %, and analysis of a re-filled sample from the original solution also resulted in (b) (4) %. Phase 1 laboratory investigation did not identify any obvious or assignable root cause. A Phase 2 manufacturing investigation was conducted; however, no definitive root cause was identified. The extended laboratory investigation concluded that the analyst may have overfilled the HPLC vial above the shoulder level, potentially resulting in abnormal results. This conclusion was not supported by the re-filled sample results. In addition, based on feedback from external service personnel, the (b) (4) time used for the sample loop (b) (4) was considered insufficient for the subject analysis. It was suggested that insufficient (b) (4) could have allowed air bubbles to be trapped in the loop, resulting in assay variability, and a (b) (4) time of (b)(4) was recommended. However, the laboratory had analyzed approximately (b) (4) samples since 2018 using this validated method and had not previously experienced similar issues. Retesting was performed using three samples on a different HPLC system with the same column, and all results met specifications.

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Based on these results, the firm invalidated the initial failed results and concluded that the initial OOS result may have been due to overfilling of the sample solution in the HPLC vial and insufficient (b) (4) time without adequate scientific justification.

***DATES OF INSPECTION**

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X Patty P Kaewussdangkul
Investigator
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