DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	06/10/2026-06/19/2026
	FEI NUMBER 3027357163

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Girish Harani, Site Head	
FIRM NAME Eugia Steriles Private Limited	STREET ADDRESS Plot Nos.1, 2, 2a & 2b, Industrial Park, Parawada Phase-III Anakapalli
CITY, STATE, ZIP CODE, COUNTRY Andhra Pradesh, 531021, 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 I OBSERVED:

(b) (4)

OBSERVATION 1

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

Specifically,

A. A (b) (4) trial run was conducted on June 16 - 17, 2026 to simulate the aseptic filling and (b) (4) process for (b) (4) injection, USP (b) (4) mg/vial and (b) (4) injection (b) (4) mg/vial. The following deficiencies were observed:

1. The vial sampling tray used to conduct manual fill weight verification of (b) (4) filled vials were removed from the Grade A filling area after hand sanitization at approximately 12:03:21 on June 16, 2026, using (b) (4) intervention. The vial sample tray located in the Grade B environment was moved to a (b) (4) then to the sampling weighing station located at (b) (4) (b) (4) and then returned until approximately 14:54:38 (almost 3 hours later). The vial sampling tray comes into direct contact with forceps stationed on the filling line for unplanned interventions of stoppered/unsealed vials. However, there is no detailed cleaning procedure ensuring that each of the (b) (4) in the sample vial tray are adequately sanitized prior to reentry in the Grade A filling line.

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2. On June 16, 2026 at approximately 14:25:06 the operator removed his gloved hands from the filling line (b) (4) after unloading (b) (4) stoppers and made direct contact with the Grade B environment. However, he did not sanitize his gloved hands prior to re-entering his gloved hands into the Grade A environment to directly pulling out the (b) (4) from the (b) (4) near the (b) (4) stopper bowl at approximately 14:25:32.

3. On June 17, 2026 at approximately 11:10:50 the (b) (4) leading to the Grade A environment of the (b) (4) Unloading System (b) (4) was unintentionally (b) (4) by the operator after (b) (4) Two operators were in the process of pulling out the (b) (4) from beneath the (b) (4) separating the Grade A and Grade B environments. The (b) (4) is used to load and transfer (b) (4) vials to the (b) (4) However, the (b) (4) was not sanitized after being exposed to the Grade B environment. The unplanned intervention was not documented until CCTV review during the current inspection.

4. There is no defined limit on how far above the (b) (4) of the Grade A filling line an operator may extend his gloved hands and within the (b) (4) used to store the (b) (4) vials. The (b) (4) of the (b) (4) was not sanitized after coming into direct contact with sanitized gloved hands from the Grade B environment at approximately 8:51:20 on June 17, 2026.

B. On June 10, 2026, the following deficiencies were observed within the Grade A (b) (4) Vial Liquid (b) (4) Product Filling and Stoppering Machine in Line (b) (4)
   1. Unsmooth (b) (4) surfaces on the (b) (4) used to store filling tubes during the vial filling process.
   2. Visible scratches on the interna (b) (4) adjacent to the product filling area.
   3. Visible gaps between the (b) (4) used to cover HEPA filters.
   4. Peeling tape and proliferated surfaces covering the (b) (4) directly above the product filling area.
   5. Unsmooth and rusted (b) (4) surfaces on the (b) (4) media plate stands stationed throughout the Grade A environment.
   6. Multiple visible (b) (4) scratches on the (b) (4) of the vial filling line.
   7. Multiple visible black and (b) (4) marks/scratches on the (b) (4) empty vial (b) (4) machine.

8. Indented hole and extraneous black material observed on the camera mount surface stationed within the Grade A filling line and above the empty vial (b) (4) machine.

   In addition, the (b) (4) Laminar Air Flow (LAF) used to stored (b) (4) materials in the Grade B environment was very rusted.

C. No dynamic air flow visualization studies have been performed for interventions within the (b) (4) Unloading System (b) (4) used for loading and moving (b) (4) vials prior to (b) (4) This includes the lack of airflow studies for planned interventions, such as changes in environmental monitoring (EM) settle plates and active air sampling plates, which occur approximately (b) (4)

   In addition there is no environmental monitoring on the opposite side of the (b) (4) (Length: (b) (4) and Width (b) (4) used to (b) (4) load (b) (4) vials for approximately (b) (4) at a time prior to being moved and transferred to the (b) (4) machine.

D. The Disinfectant Efficacy Validation study observed passing results and concluded the following contact time for (b) (4) Not Less Than (NLT) (b) (4) which is used for routine sanitization of gloves and cleanroom surfaces. However, operation and cleaning standard operating procedures list the contact time (b) (4) as: Wait Till Dry. There is no justification as to why the contact time listed in standard operating procedures for cleaning and sanitization differs from the validation report.

E. There is no environmental monitoring for non-viable particles directly after (b) (4) and (b) (4) empty vials from the (b) (4) This includes the lack of early detection for possible particles generated by (b) (4) conveyor belt, gears, and (b) (4)

F. On April 01, 2025, at approximately (b) (4) a (b) (4) integrity test failure was reported for (b) (4) '038 (b) (4) station) by Operator ID: (b) (6) . However, there is no written justification or investigation as to why the initial repeat test was performed and reported approximately (b) (4) later on April 02, 2025, between 15:45 - 15:52 by a different operator (Operator ID (b) (6) with passing results.

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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. According to the Quality Head, the following (b) (4) sensors, identified as part of the vial (b) (4) process, have not been calibrated or verified:

System	Component	P&ID (Sensor Names)
(b) (4) System	(b) (4)	(b) (4)

There is no calibration record for such sensors involving the (b) (4) and (b) (4) built in as part of the stoppering process for (b) (4) -45 and (b) (4) 20.

In addition, there is no sensor challenge test for the (b) (4) process and sensor locations. According to the Quality Head, (b) (4) stoppering is dependent on (b) (4) being maintained for (b) (4)

B. There is no formalized Operation Qualification protocol or report detailing quality unit and production review of (b) (4) alarm events, any challenges, and final outcomes. This includes the lack of detailed review for sensor and alarms used for (b) (4) signals, (b) (4) sensors used as (b) (4) sensors.

C. There is no detailed justification by the quality unit as to why planned media fill interventions dictated by the Aseptic Process Simulation (APS) master batch record are not uniformly performed for all (b) (4) campaign batches. For example:

In addition, one (1) out of the (b) (4) media fill batches fo (b) (4) mL media fill vials did not include the following intervention: Intervention No. NI-4-H: Transfer of forceps, forceps holder for (b) (4) (b) (4) side). There is no scientific or written justification as to why Media Fill Batch No. (b) (4) was carried out with one fewere planned intervention involving (b) (4) compared to (b) (4)

The Quality Manager stated the operator, along with the production supervisor, makes the final determination as to which interventions list in the media fill master batch record will be disregarded (write NA annotation) without any final input decision from the quality unit.

OBSERVATION 3

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

Specifically,

A. During my walkthrough on June 10, 2026, I observed that two (2) CCTV cameras were offline. In addition, I observed an outlined circle on the filling machine (b) (4) The Quality Head stated that this was due to future plans to install an additional camera inside the Grade A environment. The firm's CAPA report further states that some of the interventions, which are performed from filling to (b) (4) loading/unloading are not clearly visible from CCTV camera and there is no feasibility of view panel to verify aseptic intervention execution (behaviour and technique). However, activity is now monitored by real time reviewer from aseptic area.

Based on the above evaluation, below are the actions to be taken for clear visibility of interventions through CCTV:

Room Name and No.	Camera Adjustment /New Camera
Vial Filling and Stoppering area and (b) (4)	New CCTV Camera required at stoppering station

Vial Filling and Stoppering area and (b) (4)	(b) (4) CAM-2 Camera angle to be adjusted for better view of (b) (4) connections
(b) (4) Loading and Unloading area and (b) (4)	New CCTV Camera required at (b) (4) station
(b) (4) Loading and Unloading area and (b) (4)	(b) (4) CAM-5 (b) (4) loading shall be relocated to (b) (4) station
(b) (4) Loading and Unloading area and (b) (4)	(b) (4) CAM-6 Camera angle to be adjusted for better view

For example: At approximately 10:55 am on June 16, 2026, I observed the operator to be adjusting the sensor for the (b) (4) stopper bowl during the (b) (4) trial simulation. However, operator behavior and adjustments are not clearly visible from the CCTV cameras.

B. Breakdown report for Line (b) (4) Vial Filling and Stoppering Machine, Equipment ID: PR-VFSMC-002, (b) (4) Injection (b) (4) mg/vial, Batch No (b) (4) Batch End Date: May 25, 2025, was reported due to Breakdown Description: During filling (b) (4) Motor Failure Alarm occurred. The breakdown maintenance record remained opened during the 2nd batch run, Batch No. (b) (4) (Batch Date: (b) (4) to June 02, 2025) and the troubleshooting: (b) (4) motor occurred on June 01, 2025. However, according to the batch record checklist for review of Batch No (b) (4) Sr. No 25, Work orders/Maintenance request if any is closed. Result: No. There is no written justification as to why the open work order was not referenced in the batch record.

C. There is no standard operating procedure or written justification for the following trials captured in the audit trail for (b) (4) vial liquid (b) (4) product filling and stoppering machine in Line (b) (4) since February 2025: Post Media Fill Trials, Machine Trials, Trials (b) (4) Trials (b) (4) Tube Trial, and Fill Volume Trials.

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D. There is no equipment logbook in place for the (b) (4) vial liquid (b) (4) product filling and stoppering machine as per SOP EP5-PR-SOP-036-01 Equipment Usage Log, Effective Date: December 21, 2023 requirement. According to the Quality Head, the current electronic e-log has not been synchronized to collect, query and log batch data as originally planned. In addition, there is no manual equipment logbook in place in order for the quality unit to review and verify all Line (b) (4) activities in chronological order.

OBSERVATION 4

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

Specifically,

A. PNC-EP5-EN-25-0006 was initiated on June 07, 2025 due to power failure for all plant loads and during the (b) (4) process involving (b) (4) injection (b) (4) mg/vial, batch No. (b) (4) However, the investigation report did not include details surrounding the change in (b) (4) and its effect on the (b) (4) process. In addition, there is no software limitation, internal limit, or study as to how long a (b) (4) cycle can remain interrupted prior to continuation as per MSAT Manager. According to the Quality Head, batch No. (b) (4) was initiated after the power failure incident. However, the batch No. (b) (4) was ultimately rejected due to observed solution leakage from the product transfer line (b) (4) filling area. There was no attempt to repeat the (b) (4) batch thereafter.

B. OOS Number ESOOS240002 was initiated for R&D (b) (4) Injection USP (b) (4) mg/Vial, Test: Gross Content by HPLC, Date Initiated: February 03, 2024., Batch No. (b) (4) Results: (b) (4) mg/vial (Specification Limit: NLT (b) (4) and NMT (b) (4) . The manufacturing investigation attributed the most probable root cause to potential issues with connections to manufacturing vessels during (b) (4) calibration that may not have been accounted for during

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final volume make-up. Additionally, (b) (4) present in the vesse (b) (4) during calibration may have been drained prior to final volume make-up. The operator stated that he likely forgot to add the vessel lid for (b) (4) of the batch during the compounding stage. However, the investigation did not extend to other (b) (4) mg vial batches in the same campaign to see if there were any similar manufacturing issues and trending of results. The (b) (4) mg and (b) (4) mg are (b) (4) and manufactured in campaigns in order to maximize the usage of (b) (4) e.g. reduced (b) (4) (b) (4) and cleaning time).

Product Name	Start Date	End Date	Type of Product	Batch No.	Batch Size	Market
(b) (4)		13/01/2024	(b) (4)			USA/EU
		16/01/2024				USA/EU
		21/01/2024				USA/EU
		24/01/2024				USA/EU
		27/01/2024				USA/EU
		29/01/2024				USA/EU

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In addition, CAPA-EP5-PR-24-0029-OA-0003 was opened on May 27, 2024, to extend the investigation to identify the exact root cause for gross content failure. However, a trial run for Line (b) (4) was conducted to conclude the functionality and replacement of (b) (4) pumps with (b) (4) pumps instead. Issues concerning the filling line machine pumps was not documented as part of the initial investigation root cause analysis. In addition, there was no hypothesis testing or scientific justification documented to support the need to replace the (b) (4) material of construction with (b) (4) for the (b) (4) mg and (b) (4) mg vial filling pumps.

OBSERVATION 5

The reproducibility of test methods have not been established.

Specifically,

(b) (4) Injection, (b) (4) mg/ml) analytical methods and process was directly transferred from the (b) (4) However, the analytical methods were transferred under, Direct Analytical Method Transfer, in which an analyst from (b) (4) laboratory came on-site to conduct testing of the homogeneous sample along with an analyst from the receiving laboratory. However, there was no verification or review of the external and operational variables between both sending and receiving sites, including differences in environmental conditions and instrument models.

***DATES OF INSPECTION**
06/10/2026 (Wed), 06/11/2026 (Thu), 06/12/2026 (Fri), 06/15/2026 (Mon), 06/16/2026 (Tue), 06/17/2026 (Weds), 06/18/2026 (Thurs), 06/19/2026 (Fri).

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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."