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
11/03/2025-11/14/2025

FEI NUMBER
3009883410

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

FIRM NAME
EUGIA Pharma Specialities Limited

STREET ADDRESS
Unit - 2, A - 1128 & B - 1127 Bhiwadi

CITY, STATE, ZIP CODE, COUNTRY
Riico Industrial Area, Rajasthan, 301019, 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

The responsibilities and procedures applicable to the Quality Unit are not fully followed.

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

For example, during inspection of aseptic filling lines (b) (4) it was observed that multiple corrective interventions (b) (4) 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.

Interventions include:

1. On filling line (b) (4) critical aseptic connections are not visible to monitoring systems, specifically the aseptic connection of the manifold to the (b) (4) tank and (b) (4) tubing connections for the (b) (4) component. These connections represent the most critical control point in the process as they establish the pathway from the product-containing tank to the (b) (4) used for finished vial filling.

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2. On filling line (b) (4) activities at the (b) (4) stoppering station cannot be viewed via CCTV, including stopper bowl assembly operations and any interventions occurring after vial filling but prior to stoppering.

3. On filling line (b) (4) activities at the (b) (4) stoppering station cannot be viewed via CCTV, including maintenance interventions such as (b) (4) track adjustments or cleaning of vial filling machine (b) (4) conveyor belt.

Lack of a continuous and comprehensive visual monitoring system that allows for clear observation of all critical operations within the ISO 5 zone during production compromises the ability to detect potential aseptic technique deviations and undermines assurance of sterility for the finished products. Moreover, the objectionable conditions noted throughout the inspection suggest that your Quality Assurance unit has not exercised adequate oversight of aseptic operations to ensure that operators practice consistently maintain aseptic conditions.

OBSERVATION 2

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

Specifically,

During aseptic filling operations, procedure EP2-PRD-SOP-002, "Personnel Behavior in Aseptic Area" and line specific intervention procedures were not followed:

A. Aseptic filling on filling line (b) (4) Injection batch (b) (4)

1. On October 16, 2025, during line assembly and filling for ROW (b) (4) batch (b) (4) (b) (4) Injection, (b) (4) gram/vial), operators performed (b) (4) checks and challenge tests in the Grade A area. During the (b) (4) checks, the operator's arms and upper torso were observed reaching over the line, blocking laminar airflow. The

operator's gowning is sampled for environmental monitoring at the end of setup and held to Grade B limits.

B. Airflow visualization study #E2-MIS-VSP-0066, effective June 19, 2023 (Line (b) (4) Filling).

During interventions (b) (4) (Transfer of Manifold from (b) (4) LAF (b) (4) LAF-06 to Filling Line) and (b) (4) (b) (4) (Connecting Manifold to (b) (4) Tank and Fixing (b) (4) Tubing) in the Grade A area of filling line (b) (4) the following sterility breaches were observed:

1. Intervention (b) (4) When the manifold was placed inside the filling line, sterile wrapping cover on (b) (4) was not on the (b) (4) but inside the sterile outer wrapping. The operator retrieved the cover from inside the outer wrapping and replaced the covering before removing the outer wrapping. Subsequently, during manifold placement near (b) (4) tubing, the sterile covering on (b) (4) was pulled off due to contact with tubing, leaving the (b) (4) exposed throughout the remainder of the intervention. At some point prior to Intervention (b) (4) the cover was replaced.

2. Intervention (b) (4) At the start of this intervention, (b) (4) were observed missing their sterile wrapping, while (b) (4) had been re-covered. (b) (4) remained uncovered for the duration of the manifold connections.

C. Airflow visualization study #E2-MIS-VSP-0195, effective March 28, 2024 (Line (b) (4) Filling).

1. Intervention (b) (4) (Removal of Broken Vial from (b) (4) Conveyor Before (b) (4) Stoppering): During removal of a broken vial from the (b) (4) conveyor, a wipe contacted an open vial still on the conveyor track. During additional wiping, the operator's hand and forearm covered the same open vial, blocking first air.

2. Intervention (b) (4) (Collection of Sterile (b) (4) Stopper Samples for Sterility Testing): During collection of sterile stoppers for testing, the (b) (4) made direct contact with the sterile stopper bowl and stoppers within the bowl.

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REPEAT OBSERVATION

OBSERVATION 3

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

Specifically, airflow visualization (smoke studies) of Grade A laminar flow do not demonstrate there is appropriate air laminarity during commercial operations:

A. (b) (4) Line Airflow Study (b) (4) Protocol #E2-MIS-VSP-0195, effective March 28, 2024, is not representative of actual commercial production conditions:

1. Manifold Connection Intervention Discrepancies: CCTV review of Intervention (b) (4) (Connecting Manifold to (b) (4) Tank and Fixing (b) (4) Tubing through (b) (4) for batch (b) (4) (filled November 5, 2025) showed the operator sanitized their hands twice before finger dab monitoring. The intervention includes connecting the manifold to the (b) (4) tank containing the product, then (b) (4) tubes connecting (b) (4) to the manifold are connected. Finger dabs occur after the (b) (4) tube connection, not after manifold connection to the (b) (4) tank. Multiple activities during this intervention showed the operator's entire forearm inside and directly over the connections. Similar activities were observed during line assembly for batch (b) (4) however these activities were not simulated in airflow visualization study E2-MIS-VSP-0195.

2. Transfer and Removal of Sterilized Equipment: During Intervention (b) (4) (Transfer of Sterilized Material from (b) (4) Room to Filling Room) of laminar airflow study #E2-MIS-VSP-0195, the (b) (4) LAF was transported into the filling room with (b) (4) However, during production of batch (b) (4) the (b) (4) LAF was transferred to the room with (b) (4) making contact with the surface monitoring stand and a (b) (4) Production involves (b) (4) operators conducting simultaneous activities with the (b) (4) LAF (b) (4) continuously (b) (4) from (b) (4) whereas the

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smoke study showed multiple unloading activities during which the LAF (b) (4) were (b) (4) (b) (4) after each equipment removal.

3. Airflow study #E2-MIS-VSP-0195 Interventions (b) (4) through (b) (4) (Transfer and Assembly of (b) (4) Manifold): During transfer and installation of (b) (4) smoke flowed out of the LAF Grade A area, across a (b) (4) and commingled with air from the line after (b) (4) was (b) (4) for (b) (4) transfer. This demonstrates compromised airflow patterns creating direct pathways for contaminants to reach critical sterile operations and product contact surfaces. In addition, during batch (b) (4) production, one operator assembled (b) (4) while another loaded additional (b) (4) onto the line. In the airflow study, all operations for unloading and installation of the (b) (4) was done by a single operator.

B. (b) (4) Line Airflow Study (b) (4) Protocol #E2-MIS-VSP-0066 effective June 19, 2023, showed turbulence during Intervention (b) (4) (Handling of (b) (4) Conveyor Personnel Movement), under dynamic conditions. Smoke was observed eddying around the conveyor and operator in the Grade A area. This conveyor transfers (b) (4) vials from the (b) (4) stoppering station to the (b) (4)

C. (b) (4) Line Airflow Study (b) (4) Protocol #EP2-GST-P-0053-01, effective July 2, 2025, showed turbulence during Intervention (b) (4) (Transferring of (b) (4) Stopper Bag from (b) (4) LAF to Table near Conveyor), under dynamic conditions. While moving the Grade A (b) (4) LAF containing stoppers to the filling line (b) (4), smoke flowed out of the (b) (4) LAF, eddying up into the Grade B clean room. As the operator pulled the (b) (4) LAF to the (b) (4) of Line (b) (4) (Grade A), smoke continued to eddy up and contact the operator's gowning. Once docked, the operator removed stoppers from the (b) (4) LAF and placed them on a table in the Grade A area, with arms and torso extending over a conveyor used to transfer (b) (4) (b) (4) vials from the (b) (4) stopper station to the sealing area. This intervention occurs (b) (4) during each commercial production batch: (b) (4).

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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.

A. Aseptic processing operations conducted in filling line (b) (4) are deficient in design and controls to prevent microbiological contamination of sterile drug products.

On November 05, 2025, we evaluated the filling operation in (b) (4) Line (b) (4) for (b) (4) Injection (b) (4) g; Batch (b) (4) (USA market). During the batch filling operation, we observed the manufacturing operator performing corrective Intervention Code (b) (4) Lubrication of (b) (4) intervention) multiple times. During this intervention, the manufacturing operator (b) (4) to lubricate them. According to your VP Operations, this intervention is carried out (b) (4) (b) (4) since they should ensure the (b) (4) have smooth movement during the filling process. The distance between the (b) (4) and the conveyor where the empty vials are exposed is approximately (b) (4) (b) (4) Intervention (b) (4) has a maximum allowable frequency of (b) (4) times and duration of NMT (b) (4) This referenced validated frequency suggest that the operation repeatedly must reach into the ISO 5 (Grade A) filling line area indicating the filling process relies on multiple operators' interventions inside the aseptic zone.

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

On November 06, 2025, we evaluated the filling operations in Production Formulation Line (b) (4) for (b) (4) Injection (b) (4) g/vial; Batch (b) (4) (No-USA market). During the batch filling operation, we observed the manufacturing operators frequently moving from Grade B area to Grade A area thru the (b) (4) conveyor to perform inherent interventions such as transfer of (b) (4) stopper bags for (b) (4) or EM monitoring. This continuous flow of personnel from Grade B to Grade A and the other way round disrupts the Grade A environment. Additionally, no personnel monitoring is conducted after movement from Grade A to Grade B.

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OBSERVATION 5

Aseptic processing areas deficient regarding system for monitoring environmental conditions.

Your environmental monitoring program is inadequate in assessing and monitoring all the potential critical surfaces, conditions and equipment in your aseptic processing areas.

A. Non-viable particle count (NVPC) (b) (4) monitoring in Grade B areas is performed only once during product batch activity as per step (b) (4) of procedure EP2-PLA-SOP-012-08, "Environmental Monitoring" Version: 08, Effective Date: 14-Jun-2025. On November 5, 2025, during the manufacturing of (b) (4) Injection (b) (4) g, filling line (b) (4) Batch: (b) (4) (USA market), the microbiologist performed the NVPC monitoring approximately (b) (4) before completion of the batch filling activity. Failure to perform sequential (b) (4) NVPC monitoring during an aseptic batch activity does not ensure that the Grade B environment will remain under control for the entire duration of the aseptic filling activity.

   Additionally, your firm does not perform continuous NVPC monitoring of the (b) (4) laminar airflow (LAF) unit used when transferring (b) (4) stoppers from the sterile material receiving area to the aseptic filling lines for (b) (4) As per procedure EP2-PLA-SOP-012-08, "Environmental Monitoring", Version: 08, Effective Date: 14-Jun-2025, step (b) (4) NVPC monitoring of (b) (4) LAF units is performed (b) (4) (b) (4) On October 14, 2025, during the assembling process of (b) (4) Batch: (b) (4) on the filling line (b) (4) operators were observed transporting (b) (4) LAF unit (b) (4) LAF-12) containing sterile parts and components from Grade B corridor into the aseptic fill room (b) (4) with the LAF (b) (4) There is no assurance the (b) (4) LAF units maintain Grade A conditions throughout their entire use.

B. Your EM program fails to include settle plate monitoring for the (b) (4) laminar airflow (LAF) units located in (b) (4) On October 14, 2025, during the assembling process of (b) (4) Batch: (b) (4) on the filling line (b) (4) operators were observed transporting (b) (4) LAF unit (b) (4) LAF-12) containing sterile parts and components from Grade B corridor into the aseptic fill room (b) (4) with the LAF (b) (4) This practice compromises the sterility assurance of exposed components and undermines aseptic controls designed to prevent microbiological ingress into Grade A/B environment.

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C. Your firm failed to perform surface monitoring (contact plate monitoring) for the (b) (4) Unit and Human Machine Interphase (HMIs) panels, which act as the interface between your manufacturing operators and the (b) (4) filling line (b) (4) out of (b) (4) HMIs located in rooms (b) (4) are not considered as part of your surface sampling locations. There is no scientific justification for only performing contact surface monitoring on only one (1) HMI. On November 4, 2025, during the manufacture of (b) (4) Injection (b) (4) g, filling line (b) (4) Batch: (b) (4) (USA market), your operator was observed multiple times in direct contact with the HMI located adjacent to the filling line for vial filling activities.

Your firm also uses (b) (4) tables within the aseptic Grade B areas (b) (4) and Production Bulk lines) for documentation and material handling purposes. These tables are not considered as part of the surface monitoring program, as confirmed by firm management.

Additionally, your firm failed to include the (b) (4) handles of the (b) (4) (b) (4) located in (b) (4) building in the surface monitoring program (swab sample). These (b) (4) are used by your operators and microbiologists to transfer settle plates, NVPC counter and volumetric air samplers from Grade C to Grade B areas. Not performing the surface monitoring in the (b) (4) (b) (4) handles represents a potential contamination risk during aseptic transfer.

D. Your firm failed to identify with unique equipment number the (b) (4) located in the aseptic filling lines (b) (4) As per firm management, these (b) (4) are routinely used for the handling of materials (i.e. settle plate stands, cleaning and disinfecting materials) within the aseptic Grade B areas. On November 5, 2025, during the manufacturing of (b) (4) Injection (b) (4) g, filling line (b) (4) Batch: (b) (4) (USA market), approximately (b) (4) unidentified (b) (4) were observed in the aseptic fill room. There is no traceability of the cleaning and sanitization of the (b) (4) which impedes investigations of potential contamination and/or environmental deviation.

E. Your firm failed to perform adequate environmental monitoring (EM) excursion investigations to address the root cause of positive microbial contamination found during routine environmental monitoring and personnel monitoring during the manufacture of sterile (b) (4) drug products manufactured in (b) (4) (b) (4) Moreover, your firm trends the excursions as per the specific location and not considering other

impacted locations within the classified areas and equipment. The following are not an exhaustive listing of the inadequate investigations reviewed:

Out of Limit (OOL) Investigation	Product Manufactured, Batch#, Fill Line	Market	Grade & sampling location	Results	Microorganism	Probable Root Cause
EM/OOL/006/23	(b) (4)	USA	(b) (4)		Kocuria varians, Micrococcus luteus	Momentary personnel exposure with volumetric air sampler.
EM/OOL/007/23		USA			Staphylococcus hominis, Staphylococcus haemolyticus, Micrococcus luteus, Kocuria kristinae and Kocuria varians	Improper sanitization of air sampler (b) (4) or improper hands sanitization prior to performing air sampling activity which may lead to excursion.
EM/OOL/002/24		USA			Staphylococcus aureus and Kocuria varians	Personnel movement during entry of personnel in aseptic area at the time of

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	(b) (4)	(b) (4)		volumetric air sampling.
EM/OOL/016 /24		Europe	Kocuria flava	Rapid movement, poor technique during handling of media plate or air sampler i.e. improper sanitization of equipment before use, improper practices during (b) (4) sanitization before sampling.
EM/OOL/018 /24		USA	Staphylococcus pseudintermediu s	Media plate transferred from grade B to grade A without hand sanitization. Men can be the root cause.
EM/OOL/004 /25		USA	Staphylococcus epidermidis, Staphylococcus haemolyticus,	Root cause was identified as Men, as in view multiple number

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	(b) (4)		(b) (4)	Micrococcus luteus, Staphylococcus hominis and Kocuria varians	of personnel movement due to filling activity.
EM/OOL/014/25		USA		Staphylococcus epidermidis, Staphylococcus haemolyticus and Staphylococcus cohnii/ureilyticus	Probable root cause due to gown sleeve or forearm area missed or inadequate sanitization in aseptic area.

OBSERVATION 6

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.

There is no assurance that your laboratory test methods have been validated or demonstrated to be suitable for their intended use to consistently produce accurate and reliable results.

For example, repeated Out-of-Specification (OOS) results have been observed during the HPLC assay analyses of (b) (4) Crude and sterile materials. Although low sample injection volume was identified as the root cause, the recurrence of these events indicates insufficient analytical method controls to ensure assay reliability.

Investigation #	Date	Product Name	Batch #	OOS Result	Specification Range	Conclusion
E2OOS240003	(b) (4)					OOS observed is due to material variability.
E2OOS240012						Invalid initial OOS due to less injection volume
E2OOS240013						Invalid initial OOS due to less injection volume
E2OOS240019						Invalid initial OOS due to less injection volume
E2OOS240022						Invalid initial OOS due to less injection volume

OBSERVATION 7

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, your firm relies exclusively on the vendor's Certificate of Analysis (COA) to ensure the sterility of (b) (4) used on filling line (b) (4) for (b) (4) (b) (4) Following an initial analysis conducted in March 2024, your firm has purchased over (b) (4) bottles of sterile (b) (4) across (b) (4) separate shipments without conducting any re-validation of the vendor's sterility test results. This practice means your firm has been accepting sterile (b) (4) for critical aseptic manufacturing operations without independent verification of sterility for an extended period, encompassing

multiple shipments and (b) (4) of individual units, creating significant risk that non-sterile material could be introduced into sterile manufacturing processes.

OBSERVATION 8

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.

Specifically,

A. Operators conducting (b) (4) for in-process testing on filling line (b) (4) filling) lack training and qualification. Operators are trained by reading procedures without hands-on experience using (b) (4) Additionally, your firm does not maintain (b) (4) with reference standards to train and qualify operators' ability to (b) (4) This deficiency compromises the consistency and reliability of (b) (4) detection during manufacturing operations.

B. Standard Operating Procedure EP2-PFB-SOP-038-02 "In-Process Checks During Batch Operation" fails to establish adequate control procedures for (b) (4) assessment. While firm management states that in-process (b) (4) is performed to evaluate (b) (4) made from (b) (4) the procedure and associated (b) (4) "(b) (4) Verification Record" focus solely on (b) (4) (b) (4) detection. The procedure does not establish methodology, acceptance criteria, or documentation requirements for (b) (4) evaluation. Additionally, while the procedure defines corrective actions for (b) (4) identification, it fails to specify actions to be taken when (b) (4) are encountered during (b) (4) testing.

C. The (b) (4) Verification Record (b) (4) provides inadequate documentation for critical quality attributes. The form only captures (b) (4) identification (Yes/No) without fields or instructions for documenting (b) (4) observations (b) (4) assessments, or other (b) (4) characteristics that management identifies as critical quality parameters for the product.

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OBSERVATION 9

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

Your firm's cleaning and sanitization practice performed on filling line (b) (4) are inadequate to follow the cleaning and sanitization sequence from top to bottom of your filling line. For example, on November 04, 2025, your operators failed to follow a top to bottom cleaning approach during the post cleaning and sanitizing activities for (b) (4) Injection USP (b) (4) g/vial, Batch: (b) (4) (USA). Your operators began cleaning from the (b) (4) located in Grade A area and subsequently proceeding towards the filling zone without first cleaning and sanitizing the (b) (4) LAF that is located above the filling line. This deficiency does not ensure directional flow of the cleaning activities to prevent a potential cross contamination between uncleaned and cleaned zones.

Furthermore, when reviewing the cleaning process for (b) (4) Injection USP (b) (4) g/vial, Batch: (b) (4) (USA market), your operator was observed placing an uncleaned (b) (4) stand (used for Environmental Monitoring activities) directly onto the conveyor belt that had been previously cleaned. This inadequate practice was also noted during the sanitization process of the filling line.

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