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	2/16/2026-2/27/2026*
	FEI NUMBER 3011960448

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ch. V. V. Satyanarayana, Associate Vice President - Operations (Unit Head)

FIRM NAME	STREET ADDRESS
EUGIA Pharma Specialities Limited	Unit-1, Sy. No. 550, 551 & 552, Kolthur Village, Shameerpet Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal-Malkajgiri District, Telangana, 500101 India	Sterile Pharmaceutical 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 and followed.

Specifically,

1. Environmental and personnel monitoring within the Line (b) (4) LAF are not appropriately established. The aseptic connection for connecting the (b) (4) vessel to (b) (4) vessel for (b) (4) mg/mL drug product is performed within the LAF on Line (b) (4), and was reclassified as Grade A-Air in July 2025 with bacterial alert and action limits of (b) cfu/plate and (b) cfu/plate, respectively. The area is not held to Grade A classification during this critical operation with a specification of No Growth. In addition, there is no immediate personnel monitoring conducted for the individual after completing the aseptic connection.

2. The (b) (4) on the sterile filling lines in the (b) (4) blocks are installed by the operator (b) (4) the Grade A filling area then (b) (4) from within the Grade A filling area (b) (4) The operator's garment (b) (4) was observed to touch the Grade A exposed portion of the (b) (4) These (b) (4) are not further sanitized.

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	Matthew B Casale, Investigator - Dedicated Drug Cadre Joseph A Piechocki, Investigator	X Joseph A Piechocki Investigator Signed By: JOSEPH A. PIECHOCKI JR -S Date Signed: 02-27-2026 14:28:23	2/27/2026

3. The conveyor on Line (b) (4) that is maintained within the Grade A filling area after the stoppering station is (b) (4) by operations personnel through a (b) (4) (b) (4) intervention and entering the area to access the other side of the filling line. The following deficiencies were observed with this intervention:

    a. The intervention was not performed according to the smoke study or written procedure, which requires that only (b) (4)
    b. Operations personnel are not personnel monitored after this intervention during filling operations.
    c. The areas under the (b) (4) conveyer belt that interfere with the airflow are not completely disinfected after reassembly of the area.

    In addition, Line (b) (4) has a conveyer which is (b) (4), and similar deficiencies were observed with this intervention. This intervention on Line (b) (4) and Line (b) (4) is qualified up to (b) (4) and (b) (4) times, respectively, during batch set-up and filling operations.

4. During the review of CCTV footage for the manufacture of (b) (4) (b) (4) mg/mL Batch (b) (4) the following additional deficiencies were observed:

    a. During the aseptic connection, the operator leaned over and cover the opening of the sterile product transfer line prior to connecting to the (b) (4) vessel.
    b. Interventions, including removal of fallen vials on the (b) (4) do not ensure that (b) (4) do not go over open sterile vials.

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CITY, STATE, ZIP CODE, COUNTRY Medchal-Malkajgiri District, Telangana, 500101 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

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,

There has been no aseptic process simulation (media fill) conducted since July 2022 for (b) (4) mg/mL intended for the US market, which requires (b) (4) using Line (b) (4) requires an aseptic connection (b) (4) and is used when (b) (4) cannot be performed on the filing line. Since March 2024, at least (b) (4) batches of (b)(4) (b) (4) mg/mL have been shipped to the US market.

OBSERVATION 3

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.

Specifically,

Employees engaged in visual inspection of sterile finished pharmaceutical products work up to (b) (4) however, the qualification of the employee is only performed after (b) (4) of visual inspection the first time the employee is qualified to perform visual inspection and is not performed again at subsequent requalifications. Of the (b) (4) employees qualified for visual inspection, (b) (4) were first qualified in (b) (4) were first qualified in (b) (4) and (b) (4) were first qualified in (b) (4) with the remainder first qualified more recently, and none were challenged after (b) (4) since their first qualification.

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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.

Specifically,

Investigations into issues requiring the filing of Field Alert Reports are not always complete. For example,

1. Investigation MC-EP1-24-0107 was opened on 06/06/2024 due to a consumer complaint of an 18 mm glass piece found in a dispensed vial of (b) (4) Injection, USP (b) (4) mg per (b) (4) ml batch (b) (4) The investigation could not find the source of the glass; however, the root cause was attributed to vials breaking in the (b) (4) and leaving glass in intact vials. Corrective actions to the investigation included adding new preventative maintenance to the (b) (4) (b)(4), adding a review of (b) (4) rejected vials, and adding a new visual inspection challenge vial for larger glass pieces, and requalification of the visual inspection employees; however, there is no discussion of whether or not the glass vials used for the product are still acceptable or why the visual inspection was unable to see the glass in the time and conditions of the visual inspection operations, which were not changed.

2. Investigation MC-EP1-24-0197 was opened on 10/30/2024 due to a consumer complaint of a 15 mm glass piece found in a dispensed vial of (b) (4) Injection,

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USP (b) (4) mg per (b) (4) ml batch (b)(4). The investigation could not find the source of the glass; however, the root cause was attributed to vials breaking in the (b)(4) and leaving glass in intact vials. Corrective actions to the investigation included adding new preventative maintenance to the (b) (4) (b)(4), adding a review of (b)(4) rejected vials, and adding a new visual inspection challenge vial for larger glass pieces, and requalification of the visual inspection employees; however, there is no discussion of whether or not the glass vials used for the product are still acceptable or why the visual inspection was unable to see the glass in the time and conditions of the visual inspection operations, which were not changed.

3. There have been 388 complaints of (b) (4) in (b) (4) Injection USP (b) (4) mg/ml in the last two years, leading to the filing of 77 field alert reports, and there have been 231 complaints of (b) (4) problems in (b) (4) (b) (4) USP (b) (4) mg per ml in the last two years, leading to the filing of 57 field alert reports; however, there has been no review of the container closure systems of either product since they were initially marketed to determine if the container closure system was appropriate for the products in light of the complaints and field alert reports.

***DATES OF INSPECTION**

2/16/2026(Mon), 2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/23/2026(Mon), 2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri)

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