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	3/28/2024-4/5/2024*
	FEI NUMBER 3027357163

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Yugandhar Puvvala, CEO and Executive Director

FIRM NAME	STREET ADDRESS
Eugia Steriles Private Limited	Plot Nos.1, 2, 2a & 2b, Industrial Park, Parawada Phase Iii
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Anakapalli, Andhra Pradesh, 531021 India	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:

OBSERVATION 1

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

Specifically,

a. On April 2, 2024 during post production manual cleaning of line (b) (4) RABS ID PR (b) (4) RABS-001 used in the manufacture of (b) (4) injection USP (b) (4)% (b) (4) mg/mL) (b) (4) mL (b) (4) vial) batch (b) (4) the employee performing the cleaning was observed cleaning the (b) (4) conveyor and other filling station surfaces located at the (b) (4) of the (b) (4) RABS prior to cleaning surfaces located at the (b) (4) such as (b) (4) (b) (4) Upon further review document EP5-PR-SOP-043-00-Procedure for Operation and Cleaning of (b) (4) Restricted Access Barrier System in Line (b) (4) Make: (b) (4) section 4.2.24 does not include instructions for operators to perform cleaning the (b) (4) following a (b) (4) (b) (4) approach, and it does not include instructions for cleaning the (b) (4)

b. Per your summary report for disinfectant efficacy validation performed under protocol ES-GEN-P-101 approved on January 28, 2024, your firm only tested the effectiveness of (b) (4) on (b) (4) RABS (b) (4) the effectiveness of (b) (4) sporicidal agent) on this surface was not verified. A review of document EP5-PR-SOP-023 (b) (4) Procedure for Operation, Cleaning, and Changeover of (b) (4) Ampoule/vial Filling and Stoppering Machine in line (b) (4) make: (b) (4) show that disinfectant (b) (4) is used to

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	Teresa I Navas, Investigator - Dedicated Drug Cadre	X Teresa I Navas Investigator - Dedicated Drug Cadre Signed By: Teresa I. Navas -S Date Signed: 04-05-2024 15:43:13	4/5/2024

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clean these surfaces with a contact time of NLT (b) (4) Effectiveness of the disinfectant solutions was also not evaluated on material noted as (b) (4) which is the material for the (b) (4) holding in place the (b) (4) RABS (b) (4)

c. On April 1, 2024 during the line clearance of filling line (b) (4) for of (b) (4) injection USP (b) (4) % (b) (4) mg/mL) (b) (4) mL (b) (4) vial) batch (b) (4) the employee performing the line clearance did not document one bottle of (b) (4) spray not working and the out of calibration status of (b) (4) RABS PR (b) (4) RABS-001 (b) (4) ES-PR- (b) (4) (location filling zone (b) (4) and ES-PR- (b) (4) (location filling zone (b) (4) In addition, the employee also did not verify the sterilized equipment (forceps, tubes, (b) (4) etc.) and stoppers held in (b) (4) laminar airflow chambers were within the established hold time.

d. During review of your (b) (4) sterilization cycle performance qualification studies I noted that the biological indicators lot (b) (4) manufacturer's COA states a maximum incubation time of (b) (4) at (b) (4) ºC however your incubation time for these BIs was (b) (4) Per the manufacture's recommendation if incubation was to be extended beyond (b) (4) precautions such as (b) (4) (b) (4) However these precautions were not provided during your incubation as your incubators only provide continuous monitoring information associated with the temperature conditions and not the (b) (4) conditions.

e. Production employees noted that they must climb inside the (b) (4) sterilization chamber without shoes or shoe covers to perform manual cleaning of the inside of the chamber.

f. (b) (4) time and conditions to remove (b) (4) present on the (b) (4) of (b) (4) sterilized (b) (4) injection USP (b) (4) % (b) (4) mg/mL) (b) (4) mL (b) (4) vial) (b) (4) have not

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been established. During the manufacture of batch [(b) (4)] residue was observed to be present on vials on April 3rd during visual inspection, the vials were offloaded from the [(b) (4)] sterilization chamber on April 2, 2024.

g. Corrective actions enacted in response to EM/OOL/001/23 289CFU obtain from environmental monitoring settle plate located in grade C area inside change room for filling line [(b) (4)] did not have effectiveness to check that the corrective actions were adequate.

h. Environmental contact plates used to [(b) (4)] of [(b) (4)] after filling of [(b) (4)] [(b) (4)] injection USP [(b) (4)]% [(b) (4)] mg/mL) [(b) (4)] mL [(b) (4)] vial) batch [(b) (4)] do not appear to have made contact with the surface of the [(b) (4)] In addition there are no instructions for minimum contact time with the [(b) (4)] plate for this type of surface monitoring.

OBSERVATION 2

Input to and output from the computer and records or data are not checked for accuracy.

Specifically,

a. During review of raw chromatography data for of submission batches of [(b) (4)] [(b) (4)] USP [(b) (4)]%, I observed raw including but not limited to related substance (RS) of finished product, API RS, stability RS testing reprocessed without a reason

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provided in empower. These findings were not included in your executed audit trail review performed for the data obtained during October, November 2022 and March 2023.

b. Calibration certificates issued on Monday April 1, 2024 of (b) (4) ES-PR-(b) (4) (location filling zone (b) (4) and ES-PR-(b) (4) (location filling zone (b) (4) of (b) (4)RABS ID PR (b) (4)RABS-001 show that calibration was performed using (b) (4) ID (b) (4)09 which provides a direct reading of (b) (4) however the service employee noted that he used equipment (b) (4)02 which measured the (b) (4) from the (b) (4) and does not provide directly an (b) (4) value, instead it requires a calculation conversion. The calculation and use of equipment (b) (4)02 was not documented or noted in the calibration certificate.

c. Review of (b) (4) integrity tester serial number (b) (4) revealed that (b) (4) integrity test programs (b) (4) were aborted on September 27th and 29th respectively, the list of programs in the equipment does not show if the (b) (4) associated with this tests were completed successfully.

OBSERVATION 3

Control procedures are not established which 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, on 4/3/24 I observed the manual visual inspection process of (b) (4) (b) (4) USP (b) (4)% batch (b) (4) for approximately (b) (4) during this time I observed all (b) (4) operators observe vials that appeared to have white visible particles and classify them as good vials. During this time I also observed that during manual visual inspection the vials remained (b) (4) after the (b) (4) sterilization process, however there is no evaluation on how the presence of (b) (4) on the

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outer surface of vials affects the performance of visual inspection for defects. On 4/5/23 at approximately 11:30 AM I observed again the visual inspection process and noted that one operator classified a vial with visible white particles as a good vial. I also requested employees to examine the vials from visual inspection qualification kit ID1 and two of the (b) (4) employees performing visual inspection failed to detect the white particles defect from the test kit.

***DATES OF INSPECTION**

3/28/2024(Thu), 3/29/2024(Fri), 4/01/2024(Mon), 4/02/2024(Tue), 4/03/2024(Wed), 4/04/2024(Thu), 4/05/2024(Fri)

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