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	10/23/2025-10/30/2025 FEI NUMBER 3005292384

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Jiangyu Fu, Plant Leader

FIRM NAME	STREET ADDRESS
GE Healthcare Shanghai Co. Ltd.	No. 1 Niudun Rd. Pilot Free Trade Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Shanghai, 201203 China	Sterile Drug 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.

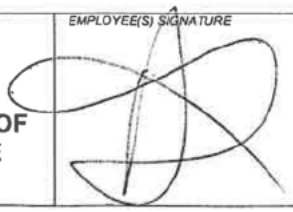
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Approved drug product container closures are not retested or reexamined as appropriate for identity, strength, quality, and purity after exposure to conditions that might have an adverse effect with subsequent approval or rejection by the quality control unit.

Specifically,

On February 22, 2024 your firm initiated DEV-11527 which found visible foreign black particles on the (b) (4) wall in (b) (4) Injection filled in (b) (4). During the investigation it was found that two types of black particles are present which are called Type I (embedded in the (b) (4) wall) and Type II (adhered on the inner surface of the (b) (4)). The investigation found that the black particles also extended to the (b) (4) products. Both the (b) (4) effected batches were manufactured on multiple manufacturing lines. The inspection concluded and determined that the root cause of the black particles is rooted from the supplier of the (b) (4). The investigation found (b) (4) batches of (b) (4) products that contained black particles (Batches: (b) (4) (b) (4) were rejected and (b) (4) batches were shipped to the US. Prior to shipping of the (b) (4) batches, your firm visually re-inspected the (b) (4) batches.

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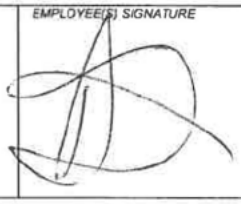
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(b) (4)

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After the initial re-inspection of the (b) (4) batches was complete, your firm found additional (b) (4) with adhered and embedded particles in (b) (4) batches (b) (4) (b) (4) Your firm only conducted an AQL test (b) (4) from each of the total batch) and a 100 % re-inspection of the remaining (b) (4) was not conducted although black particles are found present in (b) (4) batches.

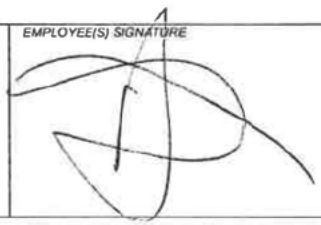
OBSERVATION 2

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

Specifically,

A- On October 27, 2025, I witness the manufacturing of (b) (4) Injection filled in (b) (4) (b) (4) (Batch # (b) (4) intended for the US market. The product is manufactured in Line (b) (4) with a target of (b) (4) units. During manufacturing, I witnessed the following:

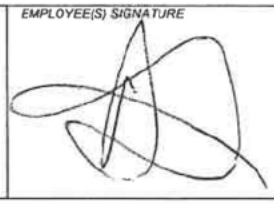
a. On multiple occasions I observed, two employees removing goggles after entering the Grade A filling area. After removing the goggles, the employees would hang the goggles on the (b) (4) hanger where the goggles contacted the wall of the facility. In addition, employees would also place the goggles on (b) (4) benches near manufacturing activities would take place. According to Line (b) (4) Production Manager inside the filling area is Grade A environment and outside the filling area is Grade C environment.

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b. An employee wearing googles improperly while replenishing stoppers by filling the (b) (4) with (b) (4) stoppers. The employee's forehead and eyebrows were exposed. According to section 18 of QID.020.02_f19, effective date September 15, 2025, states "Particular emphasis shall be placed on the following: All hair is covered". Additionally, when the stopper bag was sprayed with (b) (4) the bottom was never sprayed. That bag was then placed next to the (b) (4) area during manufacturing.

B- Your firm does not have equipment numbers for each equipment used in the filling line. For example, equipment such as (b) (4), forceps, scissors, etc. are not identified and thus cannot be traced. During the inspection, I observed that your firm uses (b) (4) of (b) (4) for manufacturing line (b) (4) (b) (4) of a (b) (4) was observed to be dented during manufacturing. According to Line (b) (4) Injectable Manager, after the visual inspection of (b) (4) was conducted, they would replace the dented (b) (4) By not having identification on each equipment, there is no way of tracking which (b) (4) in which (b) (4) needs to be replaced. In addition, your firm uses Logbook, titled 'Production (b) (4) Hose / (b) (4) tube Change', Logbook # ID163.17, form # QID.053.13_f2. Ver. 3 to document the changing of visually inspect components prior sterilization and record sterilization cycle information. That logbook states that (b) (4) are defined by different identification (b) (4)

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OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

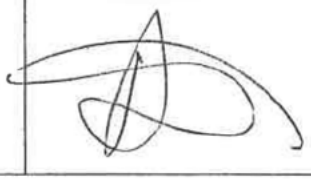
Specifically, your firm uses (b) (4) unprotected storage drives to backup quality manufacturing data from manufacturing equipment.

A- Equipment such as:
1- Filling Lines (b) (4) Equipment # 90275, 82712, and 90278
2- Filling Line (b) (4) Environmental Monitoring System (EMS), Equipment # 90287
3- Filling Line (b) (4) Process Control System, Equipment # 56508

According to Engineering Manager, Quality Assurance (QA) do not verify any data that are backed up from manufacturing equipment. Additionally, QA is not present during any backup process.

B- Your firm's SOP, QED.010.23, effective date September 15, 2025 is inadequate because it does not explicitly define that QA needs to be present during backup process, documenting what data has been backup.

***DATES OF INSPECTION**
10/23/2025, 10/24/2025, 10/25/2025, 10/27/2025, 10/28/2025, 10/29/2025 & 10/30/2025.

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