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	10/10/2022-10/18/2022*
	FEI NUMBER 3008316085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vikram Shukla, Site Head and VP Operation

FIRM NAME	STREET ADDRESS
Pfizer Healthcare India Private Limited	Plots 116-117-118-119-111-123(Part), Jawaharlal Nehru Pharma City - SEZ, Parawada
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam, Andhra Pradesh, 531019 India	TYPE ESTABLISHMENT INSPECTED Sterile 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

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

a) Qualification of vial and ampoule (b) (4) used for cleaning of primary containers are inadequate. Your firm has initiated three (3) recalls and filed over 30 Field Alert Reports from January 2019 to October 2022, due to observed particles (fiber, black particles, insects, etc.) inside the drug products distributed in the US commercial market and the retain samples. Performance Qualification of (b) (4) vial (b) (4), and (b) (4) ampoule (b) (4) were not performed to challenge (b) (4) ability to remove particles that are stuck inside and outside the vials and ampoules. For example, investigation on black particles found in the retain samples of Propofol Injectable Emulsion 10mg/mL batch # DX9067 (recall date: July 14, 2022), manufactured in Line-(b) (4), identified black particles as residuals of a beetle wing which was stuck on the inside wall of the vial. This investigation also stated that this particle was not removed by washing and was (b) (4) in (b) (4). Your firm's engineering and validation department head also confirmed that during the qualification of the (b) (4), particle challenge

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Yasamin Ameri, Investigator - Dedicated Drug Cadre Junho Pak, Investigator	X Yasamin Ameri Investigator - Dedicated Drug Cadre Signed By: 2001565939 Date Signed: 10-18-2022 03:10:21	10/18/2022

studies using different types and sizes of particles were not performed.

b) Your maintenance program for production equipment is deficient in that you failed to take proper action for the observed rust inside the (b) (4) vessels. For example, OOS report No. 6462795 was issued on October 26, 2021, for brown stains observed on the shaft and the manhole lid of (b) (4) Vessel #02 in Line-(b) (4), during the (b) (4) process of this vessel. Your investigation confirmed that the brown spots were Iron Oxide. Your immediate corrective action was to clean the brown stains and check the vessel (b) (4) use, however, failed to perform preventative actions. Your firm failed to follow maintenance/Engineering procedure, SOP-106270, "Visual inspection of Manufacturing vessel" to correct the problem by (b) (4) and (b) (4), to ensure that Iron Oxide from rusty equipment does not leach into the drug products made in this vessel. Vessel #02 in Line-(b) (4) is used for production of (b) (4) Injection, (b) (4) Injection, (b) (4) Injection, (b) (4) (b) (4) Injection and (b) (4) Injection. Your firm has manufactured (b) (4) batches of these drug products from October 2021 to October 2022 and distributed in the US commercial market.

***DATES OF INSPECTION**
10/10/2022(Mon), 10/11/2022(Tue), 10/12/2022(Wed), 10/13/2022(Thu), 10/14/2022(Fri), 10/17/2022(Mon), 10/18/2022(Tue)

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