

**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 10/18/2021-10/27/2021*
	FEI NUMBER 3003901862

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Paul Michael Smullen, Site Leader

FIRM NAME Pfizer Asia Manufacturing Pte Ltd.	STREET ADDRESS 31 Tuas South Avenue 6
CITY, STATE, ZIP CODE, COUNTRY Singapore, 637578 Singapore	TYPE ESTABLISHMENT INSPECTED API 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

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

The dispensing room is not being used adequately to ensure API dispensed remain free from cross-contamination. For example, during my walk through of your facility on 10/18/2021, white powder was observed around the room, which included the floor and wall surfaces. The room was confirmed to be in clean status by firm personnel. Approximately 48 hours later, on 10/20/2021, your firm stated that further investigation determined that the white powder observed was a result of painting the room during maintenance operations, providing a handwritten in-house maintenance order form. Per your firm's change control procedure, no change control was issued for this maintenance activity.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

- A. Investigations do not always include complete data derived from all tests necessary to assure compliance with established specifications and standards. During review of laboratory data, I observed multiple sequences where interrupted sample injections were injected and showed that

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Arsen Karapetyan, Investigator - Dedicated Drug Cadre	<small>Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan-8 Date Signed: 10/27/2021</small> X _____	DATE ISSUED 10/27/2021

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the sample did not run, instead showing “Data Incomplete” samples injected were not documented to be performed, in order to determine whether the samples injected had any discrepancies or appeared to be out of trend. This discrepancy in your firm’s ability to retrieve, review and investigate all electronic raw data is a gap in your Data Integrity system.

B. Your firm does not adequately review ^{(b) (4)} TOC and conductivity trend data available within a data collecting application with respect your water system. During my review of your ^{(b) (4)} conductivity trend data in March and April of 2021, excursions above the action limit were observed on multiple occasions. These excursions were not observed by your firm personnel under current review procedures performed in March and April of 2021. Water from your firms ^{(b) (4)} water system is used as a component during API manufacturing operations.

C. Electronic Batch Records (EBR) are generated by your production personnel and attached with production batch records for review by the Quality Unit. In addition, automation personnel have access to batch history where manufacturing raw data is stored. My review found that, the process of generating these reports from your report studio application and capabilities of the batch historian application are not detailed in any procedures. Furthermore, EBR reports stored in report studio application, and raw data stored in batch historian are not reviewed or reconciled by either the Production or Quality units for completeness, consistency, and accuracy of all manufacturing raw data generated by the Production Unit.

***DATES OF INSPECTION**

10/18/2021(Mon), 10/19/2021(Tue), 10/20/2021(Wed), 10/21/2021(Thu), 10/22/2021(Fri), 10/25/2021(Mon), 10/26/2021(Tue), 10/27/2021(Wed)

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