DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/27/2022-1/10/2023* FEI NUMBER 3006419237

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Simon W Scholte, Vice President

FIRM NAME	STREET ADDRESS
Piramal Pharma Solutions Inc	1500 Bull Lea Rd Ste 250
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lexington, KY 40511-1267	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

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

The following deficiencies are related to the stability batches of (b) (4), (b) (4) ((b) (4)), you discovered during your preparation for this FDA inspection:

Specifically,

A) Your SOP MQC-100033 on Sterility Testing requires closure of interior airlock door after (b) (4) cycle is complete. Your analyst repeatedly marked the interior airlock door as open instead of close. This was not identified during the initial review.

B) Your analyst failed to enter Active Viable Air (AVA) sample end-time during Environmental Monitoring of (b) (4) for sterility testing of stability batches as required by your SOP MQC-100036. This was not identified during the initial review.

C) Your test method MTM0213-003.00 requires use of (b) (4) and your analyst failed to follow the SOP. This was not identified during the initial review.

D) Your analyst over (b) (4) the EM and Bio-burden testing plates beyond the required duration. This was not identified during the initial review.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator Paranthaman SenthamaraiKannan, Investigator	1/10/2023

Rafeeq Habeeb -S Digitally signed by Rafeeq Habeeb -S Date: 2023.01.10 16:27:21 -05'00'

X S. Paranthaman

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/27/2022-1/10/2023* FEI NUMBER 3006419237

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Simon W Scholte, Vice President	
FIRM NAME	STREET ADDRESS
Piramal Pharma Solutions Inc	1500 Bull Lea Rd Ste 250
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lexington, KY 40511-1267	Manufacturer

E) The Result of Analysis for sterility testing of (b) (4) batches were released without raw data review.

OBSERVATION 2

Deviations from written specifications, test procedures and laboratory mechanisms are not recorded and justified.

Specifically,

A) Your test method TM-0213-007 for identity by FTIR of finished drug product (b) (4) requires identification and comparison of wave numbers of both standard and test samples, however analytical results of all (b) (4) batches of (b) (4) are derived just from visual observation without wave number comparison or identification.

B) Your SOP PHL-LEX-SOP-MQC-100023 for (b) (4) testing describes procedure for (b) (4) microbial assay which requires removal of (b) (4), however all (b) (4) microbial plates in the (b) (4) on (b) (4) and (b) (4) showed (b) (4) covering approximately (b) (4) of the surface.

C) Your SOP PHL-LEX-SOP-MQC-100076 on data review requires all data to be reviewed within (b) (4), however more than 38 entries in your Microbiology Laboratory Sample Record Logbook and nine entries in your incoming material logbook were incomplete even after (b) (4) as required by your SOP.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator Paranthaman SenthamaraiKannan, Investigator Rafeeq Habeeb -S Digitally signed by Rafeeq Habeeb -S Date: 2023.01.10 16:27:21 -05'00' X S. Paranthaman	1/10/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/27/2022-1/10/2023* FEI NUMBER 3006419237

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Simon W Scholte, Vice President	
FIRM NAME Piramal Pharma Solutions Inc	STREET ADDRESS 1500 Bull Lea Rd Ste 250
CITY, STATE, ZIP CODE, COUNTRY Lexington, KY 40511-1267	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically,

A) Your hose used to transfer (b) (4) for drug formulation in room number 1814 was stored in a box labeled as (b) (4) Hoses. The hose was found unwrapped and lacking (b) (4) date and status.

B) Your (b) (4) labeled released were stored along with unlabeled (b) (4) having unknown release and expiry status in the manufacturing area.

C) Your equipment wash room number 1814 in the drug manufacturing area had hoses that lacked cleaning status and identity. These hoses were used for (b) (4) washing.

D) Your external (b) (4) washer connected to the (b) (4) had standing water on the washer floor for approximately 12 hours during media fill batch (b) (4) on (b) (4)

OBSERVATION 4

Laboratory records do not include the initials or signature of the person who performs each test.

Specifically,

A) Your microbiology sample receiving logbook is incomplete and does not record both the initials of the person who initiated the test and the person who reviewed the results at more than 15 instances.

B) Your (b) (4) log book does not record sample entry for (b) (4) on at least two instances including December 14th and 24th.

C) Your chemistry lab notebook recording (b) (4) results for (b) (4) lacks initials and signature of the person who performed the test and the second person who reviewed the results.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator Paranthaman SenthamaraiKannan, Investigator X Rafeeq Habeeb -S Digitally signed by Rafeeq Habeeb -S Date: 2023.01.10 16:27:21 -05'00' S. Paranthaman	1/10/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/27/2022-1/10/2023*
	FEI NUMBER 3006419237

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Simon W Scholte, Vice President

FIRM NAME	STREET ADDRESS
Piramal Pharma Solutions Inc	1500 Bull Lea Rd Ste 250
CITY, STATE, ZIP CODE, COUNTRY Lexington, KY 40511-1267	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 5

Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected.

Specifically,

Your firm stored substances labeled quarantine and released along with unlabeled substances in the same flammable cabinets in the receiving area.

OBSERVATION 6

Complaint records are deficient in that they do not include the findings of the investigation.

Specifically,

Your complaint (b) (4) related to empty (b) (4) of (b) (4) mg (b) (4) (lot:(b) (4)) was not completely investigated to include review of operator's training records related to visual inspection.

*DATES OF INSPECTION

12/27/2022(Tue), 12/28/2022(Wed), 12/29/2022(Thu), 12/30/2022(Fri), 1/04/2023(Wed), 1/05/2023(Thu), 1/06/2023(Fri), 1/10/2023(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator Paranthaman SenthamaraiKannan, Investigator X Rafeeq Habeeb -S Digitally signed by Rafeeq Habeeb -S Date: 2023.01.10 16:27:21 -05'00' S. Paranthaman	1/10/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."