DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration 1240 Parklawn Drive Room 2032 Rockville, MD 20857 ORAPHARMInternationalResponses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	07/25-29/2022, 08/01-02/2022
	FEI NUMBER 3004611182

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Satchithanandam Madhan Kumar, Associate Vice President of Operations

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited, Unit XI	61 - 66 Survey No.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pydibhimavaram, Andhra Pradesh, 532409, India	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM I (WE) OBSERVED:

OBSERVATION 1

Procedures for the cleaning and maintenance of equipment are deficient regarding the removal or obliteration of the previous batch identification.

Specifically,

1) Re-cleaning operations for (b) (4) was logged for being initiated on July 04, 2022 within Equipment Cleaning and Usage Log Record, Equipment No. (b) (4), Book No. 22-00161, Issued On: 04/12/2021. However, the equipment re-cleaning operations has not been completed as of July 25, 2022, which is approximately twenty-one (21) days later.

In addition, during the inspectional walkthrough on July 25, 2022, a build-up of visible white powder and brown rust was observed throughout the (b) (4) feeding line port connecting (b) (4) used to manufacture (b) (4) API batches. This is despite cleaning and (b) (4) operations being last logged for completion on June 22, 2022 after the manufacture of (b) (4) API, Batch # (b) (4) on the same day. Furthermore, a sample swab of the observed white product residue was taken on 07/25/2022 during the inspection, which resulted in recovery of (b) (4) ppm of (b) (4) API.

2) Re-cleaning operations for (b) (4) was logged for being initiated on July 03, 2022 within Equipment Cleaning and Usage Log Record, Equipment No. (b) (4), Book No. 22-00190, Issued On: 04/12/2021. However, the equipment re-cleaning operations has not been completed as of July 25, 2022, which is approximately twenty-two (22) days later.

In addition, during the inspectional walkthrough on 07/25/2022, visible white powder residue was observed inside the (b) (4) used to manufacture (b) (4) API batches. This is despite visual inspection and

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		Guerlain Ulysse, Investigator Jeffrey P. Raimondi, Investigator	08/02/2022

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cleaning operations being last logged for completion on June 19, 2022 after the manufacture of (b) (4) API, Batch # (b) (4) on June 18, 2022. Furthermore, a sample swab of the observed white product residue twas aken on 07/25/2022 during the inspection, which resulted in recovery of (b) (4) API.

OBSERVATION 2

There is a failure to thoroughly investigate any unexplained discrepancy whether or not the batch has been already been distributed.

Specifically,

1) From July 1, 2022 to August, 1, 2022, approximately six thousand three hundred thirty-seven (6337) error messages have been logged for HPLC and GC equipment used to routinely perform release and stability testing for API batches manufactured for the U.S market. However, there has been no holistic investigation, trending, or corrective actions performed to prevent further recurrences of such errors. This includes the following HPLC and GC equipment error messages generated within the (b) (4) timeframe:
A) Approximately Four hundred and eleven (411) logged messages of "Instrument Failure."
B) Approximately thirteen (13) logged messages of "Sequence stopped because of error" and "sequence stopped by user."
C) Approximately twenty (20) logged messages of "Failed to get the newest information of the batch queue because of the communication failure."

2) A market complaint #MC-CAD-003860 was received pertaining to black particles observed in a finished product (tablet) which was manufactured using the API, (b) (4) batch # (b) (4) produced by your firm. However, the investigation did not include evaluation of retention samples for the presence of black particles.

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OBSERVATION 3

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

Specifically

1) Deviations are not always initiated within (b) (4) (b) (4) of its observation as required by procedure: ZQA006, Handling of Deviation. For example, the following deviations are a few instances where they were not initiated within (b) (4) (b) (4) of observation:
A) DE-U11-002931 was observed on 16-Oct-2021, but the deviation was not initiated until (b) (4)
B) DE-U11-002954 was observed on 09-Dec-2021, but the deviation was not initiated until (b) (4)
C) DE-U11-003063 was observed on 30-April-2022, but the deviation was not initiated until
D) DE-U11-003073 was observed on 09-May-2022, but the deviation was not initiated until

2) Laboratory data is not always recorded contemporaneously as per GMP and standard operating procedure requirements. For example:
A) During the inspectional walkthrough on July 25, 2022 at approximately 12:48 pm, (b) (4) bottles of (b) (4) water samples were stationed but not recorded or logged for receipt by the Microbiology laboratory. This is despite the water samples being delivered to the laboratory at approximately 10:55 am, which is approximately two hours prior to the inspectional walkthrough being conducted.

B) The (b) (4) run for (b) (4) Equipment No. QACM003, which is used to destruct culture media from the microbiology laboratory, started at 11:16:06 on July 25, 2022. However, the equipment start time was not recorded within the Destruction Record for Culture Media Equipment Logbook, Book No. 22-00002, Issued Date: 05/12/2021 as of the inspectional walkthrough at approximately 12:45 pm on July 25, 2022.

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