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	01/28/2026-02/10/2026
	FEI NUMBER 3007373532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Mettu (M.) Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited, Unit VII	Unit-VII, Sy No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot S1 Part SEZ, TSIIC, Green Ind. Park
CITY, STATE, ZIP/POSTAL CODE, COUNTRY Polepally Jedcherla Mandal, Mahabubnagar Telangana 509302 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product 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:

FACILITY AND EQUIPMENT SYSTEM

OBSERVATION 1

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

Specifically,

A. The (b) (4) non-dedicated (b) (4) used in the manufacturing of (b) (4) (b) (4) drug products for the US market at your firm have not been appropriately cleaned since their installation several years ago. For example,

Table 1

(b) (4) ID No.:	(b) (4) installation date (b) (4)	Years since (b) (4) Duct not cleaned

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1. On 28-Jan-2026, we observed build-up of (b) (4) materials on (b) (4) HEPA Filter and its (b) (4) and throughout the (b) (4) Duct of (b) (4) of (b) (4) IDs: (b) (4) located in your (b) (4) block. (b) (4) (b) (4) through the (b) (4) HEPA filter (b) (4) Duct has the potential to carry these materials into the (b) (4) and contaminate the (b) (4) product undergoing (b) (4) The equipment usage status of these (b) (4) on 28-Jan-2026 was as follows:

Table 2

Sr. No.	Equipment number	Equipment status	Type of Cleaning	Last Cleaning Date	Pervious product
(b) (4)					

These (b) (4) are used in the manufacturing of the following examples of (b) (4) drug products at varying strengths that are sold into the USA market:

Table 3

(b) (4)

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(b) (4)

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(b) (4)

On 29-Jan-2026, your firm collected multiple swab samples from different locations of the (b) (4) (b) (4) HEPA filter (b) (4) as well as the (b) (4) duct and analyzed swab samples for chemical analysis by HPLC method to identify the presence of drug substances and related degradants of the previously manufactured drug products. Test data revealed the presence of different drug substances observed above the acceptance limit used for cleaning verification/cleaning validation indicating a potential risk for drug products cross-contamination with other drug products active materials (drug substances) that were manufactured using the (b) (4) IDs: (b) (4) Examples of swab sample test results for chemical analysis by HPLCs are tabulated as follows:

Table 4 (HPLC ID: HPLC0008)
Acceptance Limit: (b) (4) mcg/swab

Sampling location	Results of (b) (4) (Analyses Date 29/01/26)	Unknown Peaks identified on 31/01/26	Results of Unknown Peaks
(b) (4)			

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Sampling location	Results of (b) (4) (Analyses Date 29/01/26)	Unknown Peaks identified on 31/01/26	Results of Unknown Peaks
(b) (4)			

^ *The swab analyses results were found as high as approximately 250 times the acceptance limit.*

Table 5 (HPLC ID: HPLC0001)
Acceptance Limit: (b) (4) mcg/swab

Sampling location	Results of (b) (4) (Analyses Date 29/01/26)	Results of (b) (4) (b) (4) (Analyses Date 29/01/26)	Unknown Peaks identified on 31/01/26	Results of Unknown Peaks
(b) (4)				

^ *The swab analyses results were found as high as approximately 380 times the acceptance limit.*

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Table 6 (HPLC ID: HPLC0002)
Acceptance Limit: (b) (4) mcg/swab

Sampling location	Results of (b) (4) (Analyses Date 29/01/26)	Unknown Identified status on 31/01/26	Results of Unknown Peaks
(b) (4)			

Following the swab sample chemical test results for (b) (4) IDs: (b) (4) on 30-Jan-2026 your firm reported Field Alerts for (b) (4) drug products that are manufactured in (b) (4) block.

On 05-Feb-2026, your firm collected additional swab samples from (b) (4) IDs: (b) (4) (b) (4) for chemical analyses and analyzed swab samples using a newly validated swab samples test method by HPLC (APL/GT/O026-01), which is supposed to detect all active components (drug substances) (b) (4) analysis. The swab sample test results obtained using this method further confirmed potential for carryover and cross-contamination between drug products that were manufactured using these non-dedicated (b) (4) Examples of the swab sample analyses include the following:

Table 7 (HPLC ID: HPLC0008)
Acceptance Limit: (b) (4) mcg/swab

(b) (4)

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(b) (4)

[redacted]

^ *The swab analyses results were found as high as approximately 545 times to the acceptance limit.*

Table 8 (HPLC ID: HPLC0008)
Acceptance Limit: (b) (4) **mcg/swab**

(b) (4)

[redacted]

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Additionally, the swab sample test results (**Tables 4 to 8**) are artificially low by approximately 50% as the swab stick could not adsorb/retain large amount of (b) (4) materials that were present on the (b) (4) X (b) (4) surface area that was swabbed for each swab sample.

Furthermore, swab sample testing of (b) (4) (refer to **Tables 4 to 8**) showed unknown peaks randomly eluting at different retention times in multiple swab samples tested by HPLC. These unknown peaks were not identified and accounted for in the above tables. There is a potential that the unknown peaks could be due to active and degradant materials of drug products manufactured using these (b) (4)

2. On 28-Jan-2026, we observed potential for growth of microbial contaminants due to the presence of bird droppings and layers of dust particles inside the (b) (4) filter (b) (4) of (b) (4) of (b) (4) ID: (b) (4) We also observed dust materials and potential microbial growth inside the (b) (4) filter (b) (4) with (b) (4) % filter efficiency) and (b) (4) HEPA filter (b) (4) % filter efficiency) (b) (4) of this (b) (4)

On 29-Jan-2026, your Microbiologists collected (b) (4) swab samples for microbial tests from the (b) (4) (b) (4) section of (b) (4) HEPA filter (b) (4) at (b) (4) Duct (b) (4) The testing revealed TNTC (Too Numerous To Count) fungal, mold, bacterial, and Total Viable Particulate Count (TVPC) colonies. There is a potential for microorganisms, fungal, yeast and mold grown inside the (b) (4) HEPA filter (b) (4) to get carried with the (b) (4) through the (b) (4) Duct into the (b) (4) and potentially contaminate the product while it is used for the manufacturing of (b) (4) drug products. The details of the microbial tests result are as follows:

Table 9

Microbial test	Plate method results	Confirmatory testing results
TAMC	**TNTC**	Not Applicable
TYMC		
Pseudomonas Aeruginosa	Growth Observed	Oxidase test found **Positive** indicates presence of ***Pseudomonas aeruginosa***.

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Microbial test	Plate method results	Confirmatory testing results
Staphylococcus Aureus	Whitish and yellow colonies observed.	Coagulase test found Negative for *Staphylococcus aureus* and indicated the presence of other members of Staphylococcus genus.
Salmonella	Pink Colonies with yellow zone observed on (b) (4) (b) (4) plates.	Results found Negative, However, growth on (b) (4) plates indicates presence of the other members of Enterobacteriaceae family.
Escherichia coli *(E. Coli)*	Whitish Pink mucoid colonies observed.	Indole test found **Positive** indicates presence of ***E. Coli*** along with other member of Enterobacteriaceae family.

TYMC: Total Yeast and Mold Count
TAMC: Total Aerobic Microbial Count

The evaluation of confirmatory testing results for Salmonella showed no indication of colony collection and transfer to the media as it was seen for positive control plate. This was indicative of potential lack of testing integrity while performing microbial testing.

B. Your Preventative Maintenance (PM) of (b) (4) is deficient for the following reasons:

1. Your procedure SOP No.: FU7-EN-MNP-007, Titled: "PREVENTATIVE MAINTENANCE PROGRAMME", Version: 15.0, Effective date: 24-Sep-2025 has no mention of Quality Unit responsibilities on the physical verification of the condition of (b) (4) Duct, (b) (4) HEPA filters and overall conditions of (b) (4) of (b) (4) during periodic preventative maintenance. Therefore, your Quality Unit failed to evaluate conditions of these areas of (b) (4) of (b) (4) and your Engineering unit simply focused on following the timelines for the replacement of (b) (4) HEPA filters without recognizing the excess (b) (4) materials present inside the (b) (4) Duct and the surrounding areas of (b) (4) HEPA filter inside the (b) (4) As a result, there were no investigation logged to determine the impact and risk of potential products cross-contamination.

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2. There is no mention of periodic maintenance requirement in your procedure (FU7-EN-MNP-007) for preventative maintenance. However, your maintenance department was conducting (b) (4) periodic maintenance of (b) (4) The evaluation of checklists (Document No.: FU7B-PMP-GEN-028) for (b) (4) preventative maintenance revealed requirement for the cleaning of all filters of (b) (4) Your Sr. General Manager (b) (6) Dy. General Manager (b) (6) Senior Technical Assistant (b) (6) and Executive (b) (6) of Engineering and Maintenance Department stated that they have cleaned (b) (4) (b) (4) only during (b) (4) preventative maintenance but they have never cleaned (b) (4) HEPA filter. The evaluation of (b) (4) for (b) (4) ID: (b) (4) on 29-Jan-2026 revealed the presence of large amount of bird dropping, dust and (b) (4) materials while these filters were Type-C (product changeover) cleaned on 22-Jan-2026. This (b) (4) was in "Cleaned" status during the inspection.

C. Your Quality Unit lacked oversight on the cleaning of (b) (4) For example,

On 28-Jan-2026, your Executive (b) (6) from Engineering unit stated that all filters of (b) (4) (b) (4) HEPA filters) are cleaned by Type-C cleaning (product changeover cleaning) method. He demonstrated Type-C cleaning on (b) (4) ID: (b) (4) for (b) (4) HEPA filter (b) (4) by inserting his hands through the (b) (4) and mentioned to wipe-out (b) (4) materials using a lint free cloth until the length of hand reach which is roughly only about 15 to 20% of the total surface area of (b) (4) HEPA filter (b) (4) However, on 03-Feb-2026 the same Executive stated that there is no Type-C cleaning performed on (b) (4) HEPA filter (b) (4) and that his earlier statement about the cleaning of (b) (4) HEPA filter (b) (4) was not truthful.

Moreover, your firm has no documented procedure relating to Type-C cleaning for (b) (4) that (b) (4) (b) (4) to (b) (4) Additionally, there is no oversight of Quality Unit on the cleaning and maintenance of (b) (4) This was evident as build-up of (b) (4) materials was observed on (b) (4) HEPA Filter and its (b) (4) and throughout the (b) (4) Duct of (b) (4) IDs: (b) (4) and there was no quality events logged to investigate these issues which has potential to cause cross-contamination between (b) (4) drug products.

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PRODUCTION SYSTEM

OBSERVATION 2

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,

A. Multiple (b) (4) empty trial runs were observed prior to official batch production runs during the review of 2023-2024 backup data for equipment No (b) (4) without any documented explanation, batch record instructions, or standard operating procedures. In addition, the empty trial runs were not recorded within the (b) (4) equipment usage logbooks. For example, the following batch and audit trail reports were generated for (b) (4), Area: (b) (4) on July 6th, 2023:

File Name	Product Name (b) (4)	Batch Number and Lot Number	Start Date/Time (User)	End Date/Time (User)

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File Name	Product Name	Batch Number and Lot Number	Start Date/Time (User)	End Date/Time (User)
	(b) (4)			

However, there is no documented reasoning for the need to perform multiple empty trial runs between lots of the same campaign batch manufactured approximately (b) (4) apart from each other.

B. According to the Associate Vice President (AVP) of Quality Assurance, the (b) (4) Block (b) (4) Production Office (Room No. (b) (4) is routinely used to print and review alarm and audit trail reports of production equipment involving (b) (4) products. The printed reports are signed off and then attached to final batch production records. On January 28, 2026, an unplugged computer system was observed to be backdated to November 3, 2025, (b) (4) upon start-up. According to the Senior Executive of Production, the computer system has a shared username and password for the department. In addition, the same computer has permissions for deleting files and permanently delete files from the computer recycle bin. There is no documented explanation for the need for production officers to have deletion controls and access to additional applications, including a raster graphics editor for image creation and editing.

In addition, the Human Machine Interface (HMI) panel of the printer located in the same (b) (4) production office displayed multiple copy jobs logged between November 27 at (b) (4) and December 4 at (b) (4) (b) (4) According to the Associate Vice President (AVP) of Quality Assurance, there is no documented

reasoning or instructions for making unverifiable copies from the printer. In addition, the IT Administrator stated that he is unable to retrieve the document details or year in which the documents were copied (e.g. 2025 vs. 2022) due to software limitations.

C. The Industrial Panel Computer (IPC) of the Document Storage and Retrieval System (DSRS) in Zone (b) (4) and Zone (b) (4) area used to manage, generate, and print commercial batch production records (BPRs) was observed to have permissions for deleting files and permanently deleting files from the computer recycle bin. There is no documented explanation of the need for the Quality Assurance Senior Assistant to have permissions for deleting files, recycle bin capability, and access to additional applications in DSRS, including for:

1. Raster graphics editor for image creation and editing.
2. Creating digital notes directly on the desktop.

D. Your firm utilizes (b) (4) Electrolab Trust E Model dissolution apparatuses in the general block quality control laboratory for the dissolution testing of several products destined for the US market. Each instrument is capable of storing up to 1,000 methods and storing up to 10,000 test reports. On January 29, 2026, it was observed that electronic test reports were not available for the following dissolution tests conducted on January 28, 2026:

1. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on instrument ID: DISZ0038
2. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on instrument ID: DISZ0038
3. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on instrument ID: DISZ0040.
4. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on instrument ID: DISZ0040.

According to your instrumentation engineer, after 10,000 test results, the system will overwrite the previous results. This practice creates a significant risk of data loss and potentially leads to the loss of

critical analytical data required for product release. Your firm has failed to establish and implement adequate procedures for backing up analytical data from these dissolution apparatuses.

E. During the review of the dissolution analytical package for (b) (4) Tablet USP (b) (4) mg, it was observed that your employee shared their login credentials on several occasions with other employees to perform dissolution test runs. Sharing login credentials compromises the traceability and accountability of analytical data, as it becomes impossible to determine which individual performed the testing or reviewed the results. The following are the examples where employees shared their login credentials, but are not limited to:

1. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on January 28, 2026, using instrument ID: DISZ0038
2. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on January 23, 2026, using instrument ID: DISZ0041
3. A.R. No. (b) (4) (b) (4) Tablet (b) (4) mg, Batch No. (b) (4) dissolution test was performed on December 12, 2025, using instrument ID: DISZ0041

F. On January 29, 2026, the Executive of (b) (4) Blister (b) (4) Packaging Area had logged in to the desktop of the weighing balance integration system IPC ID No. SPCB0027 using the login ID of another person (Senior Executive of (b) (4) Packaging). There is no documented reasoning of the need for packaging personnel to share user login IDs and passwords.

OBSERVATION 3

Master production and control records lack complete manufacturing and control instructions, sampling and testing procedures.

Specifically,

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A. During the inspection it was observed that the executed batch production records for tablet compression operations do not include designated fields or provisions for recording the time when stratified samples are collected during the compression process. The absence of sampling time documentation prevents verification that samples were collected at appropriate intervals throughout the compression run, that the stratified sampling strategy was properly executed, and that adequate process control was maintained during critical manufacturing steps. Additionally, the calculation for the stratified sampling plan was not available in the batch records. The following are examples of batch records; we observed that stratified sample collection times are not recorded, but are not limited to:

- (b) (4) Tablets USP (b) (4) mg, Lot #(b) (4)
- Tablets USP mg, Lot #
- Tablets USP mg, Lot #

B. According to the AVP of Quality Assurance, production operators are responsible for visually determining the rate at which the(b) (4) increases from the start to the end of the(b) (4) process involving(b) (4) Tablet (b) (4) mg. There is no defined (b) (4) limit, master batch record instructions or standard operating procedure for the (b) (4) limit of the (b) (4) and rate at which production personnel are allowed to increase the variable (b) (4) between the qualified operational range of (b) (4) Approximately, (b) (4) batches of(b) (4) Tablet(b) (4) mg have been manufactured since March 2023 and intended for the U.S market.

QUALITY SYSTEM

OBSERVATION 4

Complaints records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

A. Approximately 52 out of 127 (~41%) complaints received for all U.S. products since January 2026 consisted of (b) (4) USP (b) (4) mcg. This includes ten (10) consumer complaints received for (b) (4) and six (6) complaints received for (b) (4) Mfg. Date: July 2025, Expiry Date: (b) (4) involving the following issues:

1. (b) (4)
2. (b) (4)
3. Difficulty separating blister units
4. Poor perforation quality
5. (b) (4) loose in packaging

However, the following deficiencies were observed during the current inspection for (b) (4) (b) (4) USP (b) (4) mcg, (b) (4) Commercial Manufacturing Start Date: (b) (4) and during review of the Final Investigation Report for seven (7) recent complaints of (b) (4) Malfunction – (b) (4) and packaging not tearing along the perforated line for (b) (4) USP (b) (4) mcg, Batch No. (b) (4) Report Closed On: January 22, 2026:

1. There have been no shipment studies performed (e.g. via air, sea and road) to ensure that physical stresses, such as vibrations, shocks, temperature fluctuations, and pressure changes do not compromise the (b) (4) functionality, integrity, or the stability of the drug (b) (4) during transit.

2. No drop test study has been performed as of the current inspection to evaluate the durability and functionality of drug (b) (4) packaging after simulated accidental falls.

3. No detailed risk assessment was performed to analyze potential failure modes, including (b) (4) (b) (4) malfunctioning, and perforation failure. And no

assessment of risk mitigation strategies (e.g. completing a risk mitigation plan, verification of mitigation effectiveness, and management approval of residual risks).

4. The (b) (4) analysis did not include assessment of similar products for public data of complaints, regulatory history (recalls, warning letter etc.), and performance benchmarks.

5. As part of May 2022 (b) (4) Testing (b) (4) as per specification), (b) (4) samples were collected from (b) (4) stability CRT lot (Batch No. (b) (4) However, there was no statistical justification for selection of the sample size of (b) (4) and sample pool of (b) (4) batch for evaluating the (b) (4) of (b) (4)

B. Customer Complaint No. APL-FU7-2024-USA-PCM-00105 was received on February 27, 2024, for "Something metallic inside the pill" of (b) (4) Tablets USP (b) (4) Mg (b) (4) (b) (4) Batch No (b) (4) Expiration Date: (b) (4) The complaint sample was received by your U.S site for further evaluation and testing. However, there was no attempt to perform further identification or chemical analysis prior to concluding that the observed metallic material embedded in the tablet was instead oil lubricant from the compression machine punches. A blurry photo with crushed tablets on a (b) (4) background paper was used as documentary evidence to conclude the lack of foreign material as part of the complaint investigation report. The initial (b) (4) tablet was split in half to reveal the embedded dark material and photographed on (b) (4) paper. The same tablet, when subsequently crushed and photographed on (b) (4) background paper, appeared (b) (4) instead of (b) (4) There is a lack of adequate quality oversight for the complaint investigation outsourced to your U.S site.

C. According to the General Manager of Global Quality, quality complaint investigations require a minimum of (b) (4) follow-up attempts prior to closure as per SOP APL-GP-GEN-0059 Management of Product Complaints in the Automated Quality Management System Software,

Version 1.0, Effective Date: October 23, 2025. However, there is no documented explanation for the lack of adequate follow-up for the following complaints involving lack of effect (LOE).

1. Complaint Number APL-FU7-2026- USA-PCM-00009 was received on January 5th, 2026, for (b) (4) Tablets (b) (4) mg Batch Number: Not Available, Complaint: Lack of Effect. There were only (b) (4) out of the (b) (4) required follow-up attempts and the complaint investigation was closed approximately 17 days later without any documented explanation.

2. Complaint Number APL-FU7-2025-USA-PCM-00503 was received on September 9th, 2025, for (b) (4) Tablets USP (b) (4) mg. Batch Number: Not Available. Complaint: Lack of Effect. There were only (b) (4) out of the (b) (4) required follow-up attempts and the complaint investigation was closed without any documented explanation.

3. Complaint Number APL-FU7-2025-USA-PCM-0207 was received on June 03, 2025, for (b) (4) Tablet (b) (4) mg, Batch Number: Not Available. Complaint: Lack of Effect. There were only (b) (4) out of the (b) (4) required follow-up attempts and the complaint investigation was closed on July 21, 2025, without any documented explanation.

4. Complaint Number APL-FU7-2025-USA-PCM-00431 was received on August 06, 2025, for (b) (4) Tablet 1.5 mg, Batch Number: Not Available. Complaint: Lack of Effect. There were only (b) (4) out of the (b) (4) required follow-up attempts and the complaint investigation was closed on October 04, 2025, without any documented explanation.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

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	FEI NUMBER 3007373532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Mettu (M.) Madan Mohan Reddy, Director	
FIRM NAME Aurobindo Pharma Limited, Unit VII	STREET ADDRESS Unit-VII, Sy No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot S1 Part SEZ, TSIIC, Green Ind. Park
CITY, STATE, ZIP CODE, COUNTRY Polepally Jedcherla Mandal, Mahabubnagar Telangana 509302 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer

A. Your Quality Unit lacks adequate oversight in ensuring the drug products quality and purity. For example,

Your firm reported (b) (4) Field Alerts and voluntarily recalled (b) (4) batches of (b) (4) Tablets (b) (4) mg, (b) (4) mg, and (b) (4) mg due to (b) (4) impurity content detected above the Acceptable Intake (AI) limit of (b) (4) µg/g. However, three (3) additional batches (b) (4) were found at the higher side of the Acceptable Intake (AI) limit when initially analyzed in (b) (4) and two (2) out of three (3) batches continued to show upward trend of higher results (borderline results) when analyzed at 12-month long term stability time point in (b) (4) which suggests they will become Out of Specification (OOS) before their (b) (4) (b) (4) expiration, but your Quality Unit continued to keep these batches in the US market without additional analyses.

Table 10

Product Name/Strength	Batch Number	Stability Condition	(b) (4) content (by LCMS/MS) (Results in (b) (4) (5 month)	(b) (4) content (by LCMS/MS) (Results in (b) (4) (12 month)
Acceptable Intake (AI) Limit			NMT (b) (4) µg/g	
(b) (4) Tablets (b) (4) mg	(b) (4)	25°C/60%RH	(b) (4) µg/g	(b) (4) µg/g
Tablets (4) mg			µg/g	µg/g
Tablets mg			µg/g	µg/g

The above batches (**Table 10**) were (b) (4) on stability with a delay of three (3) months (i.e. (b) (4) and the firm was planning to conduct (b) (4) stability study in (b) (4) (which is (b) (4) after the batch expiry in (b) (4) There was no scientific justification provided about delayed

(b) (4) of these batches by three (3) months on stability which may potentially lead to increased degradants level and subpotent drug products being sold to the US customers.

B. Your stability sample management and testing program is deficient. For example,

Your global procedure APL-GP-F-QC-GEN-0001, Titled: "Stability Studies of Drug Products", Version: 3.0.0.0, Effective date: 09-Oct-2025 does not have a requirement for (b) (4) of the finished product batches within stipulated timeline in your procedure. Therefore, your Quality Unit delayed in (b) (4) batches on long term and accelerated stability conditions by multiple months. The delayed (b) (4) of finished product batches on stability led to continued stability studies post expiry of the batches for the final stability timepoint of either (b) (4) as applicable based on the product shelf life. There were multiple products and batches that failed at the final stability timepoint which may trigger additional investigations and appropriate regulatory notification and market action.

On 09-Feb-2026, it was observed that about (b) (4) batches were (b) (4) on stability beyond 30 days of the batch manufacturing date. There is potential for batch failure at the last stability time point may not get identified causing subpotent drug products to remain in distribution in the US market. Your firm received (b) (4) Lack of Efficacy (LOE) and (b) (4) Adverse Events (AE) for the products distributed in the US market.

C. On January 30th, 2026, it was observed that the Senior Executive of In-Process Quality Assurance (IPQA) had signed off on completing Batch Record verification checkpoints without actually completing all the required review line items, including Step No. (b) (4) Check to ensure results recorded on CoA comply with specification; Step No. (b) (4) Data entry in Process pad is completed; Step No (b) (4) Process pad data approved; and Step No. (b) (4) All the investigations/PNC are closed related to manufacturing, for the following batch records:

1. (b) (4) Tablets USP (b) (4) mg, Batch No. (b) (4)
2. (b) (4) (b) (4) Tablets, USP (b) (4) mg, Batch No. (b) (4)
3. (b) (4) Tablets, USP (b) (4) mg, Batch No. (b) (4)

4. (b) (4) Tablets, USP (b) (4) mg, Batch No. (b) (4)

D. Released and Approved Batch Production Record (BPR) for (b) (4) mcg, Batch No. (b) (4) Mfg. Date: February 2025, Expiration Date: (b) (4) was observed to have multiple blank and unused checklist copies attached. There is no documented reasoning for the additional page requests that remains blank in the approved BPR. This includes:

1. Two (2) open blank copies for Type C Cleaning Work Sheet for (b) (4) Reference SOP: FU7-PR-MF-CLN-009.
2. Four (4) open blank copies for Checklist for Movement and Usage of (b) (4) Equipment, Reference SOP: FU7-PR-GEN-005.

E. According to the Document Requisition Form Logbook (APL-GP-GEN-0001), one (1) copy of the Area Line Clearance Checklist (b) (4) Document No: FU7B-QA FORM-001) was requested as part of a product development batch from the Document Storage and Retrieval System (DSRS). However, two (2) copies of the same form were instead present in the In-Process Quality Assurance (IPQA) office of the (b) (4) Block (b) (4) According to the AVP of Quality Assurance, the QA department had overlooked the required number of copies written in the logbook and issued two copies instead of the one (1) required copy.

OBSERVATION 6

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

Specifically,

Your Quality Unit lack an adequate oversight in ensuring the integrity of testing data. For example,

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	FEI NUMBER 3007373532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Mettu (M.) Madan Mohan Reddy, Director	
FIRM NAME Aurobindo Pharma Limited, Unit VII	STREET ADDRESS Unit-VII, Sy No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot S1 Part SEZ, TSIIC, Green Ind. Park
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A. Microbiologists responsible for (b) (4) samples collection potentially falsified sample collection data. On 02-Feb-2026, we verified (b) (4) sample collection activities by your Microbiologists (b) (6) from multiple sampling locations of (b) (4) system and manufacturing suites. It was observed that Microbiologists took approximately twice the amount of time while collecting swab samples than what they reported in their previous test data worksheets. It was practically impossible to collect (b) (4) samples from sampling locations in the reported time due to (b) (4) of the manufacturing rooms with (b) (4) Additionally, the microbiologists did not perform primary gowning prior to entering inside the manufacturing suite and they were running in the process of collecting (b) (4) sample. Even after putting all these attempts, the Microbiologists took about twice the amount of time in collecting (b) (4) han the reported time in worksheets as indicated in the table below:

Table 12

(b) (4)

B. According to your (b) (4) collection procedure, (b) (4) is (b) (4) prior to collecting (b) (4) in sampling bottle. On 02-Feb-2026, it was observed that Microbiologists while collecting (b) (4) from the sampling locations of (b) (4) rooms (b) (4) the entire room along with sections of the adjacent (b) (4) and compression rooms and corridor with the (b) (4) During this (b) (4) the tablets compression room (b) (4) was in use for compressing (b) (4) Tablets USP (b) (4) MG. The operators working inside tablets compression room continued to keep working with their (b) (4) shoe cover and gowning.

During the interview, Microbiologists stated that they have (b) (4) the manufacturing rooms each time while collecting (b) (4) samples and they notified the issue to their supervisor. However, there is

no investigation initiated, no risk assessment performed, and no corrective action and preventative action taken.

OBSERVATION 7

GMP training is not conducted on a continuing basis with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically,

Review of your training program revealed significant deficiencies in training completion compliance. Specifically, it was observed that from November 1, 2025, to January 31, 2026, approximately (b) (4) training documents were pending completion among active personnel. According to your written procedure *Document Number APL-GEN-0010: Training of Personnel Using EPIQ Learn IQ, Effective Date: December 18, 2024, Section 2.5.2*, employees are required to complete assigned training within (b) (4) (b) (4) of training issuance.

LABORATORY CONTROL SYSTEM

OBSERVATION 8

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

A. On January 28, 2026, during the walkthrough inspection at your microbiology laboratory in the (b) (4) (b) (4) Block (b) (4) it was observed that your Assistant Manager for Microbiology was signing multiple documents with dates that did not correspond to the actual date of signature. Review of these documents revealed that none of the documents had the date of January 28, 2026, despite being signed on that day. All the documents had dates of January 27, 2026, or earlier. On multiple occasions, your

employee informed me that he did not backdate any documents; however, he later stated that he did perform some backdating of documents. This backdating was observed in the document "*Microbiological Examination of Finished Product:* (b) (4) *Tablet USP* (b) (4) *mg, Lot #*(b) (4) *A.R. No.* (b) (4) "

B. Your standalone Electrolab Trust E Model dissolution apparatuses are capable of generating electronic test reports for each dissolution run. These test reports are electronically stored in each system. Your quality unit neither reviews nor prints these electronic records for review. Additionally, each test run should include the AR Number, Lot Number, Batch Number, and Batch Size according to section 4.25.3 of your written procedure *FU7-QC-CI-OPI-0148: Operation of Dissolution Test Apparatus (Make: Electrolab, Model: Trust -E14), Version: 2.0.0.0. Effective Date: March 01, 2024.* However, this information is not included in the electronic test reports. The following are examples of discrepancies observed while reviewing the analytical package against the electronic test report, but are not limited to:

1. The dissolution data package for (b) (4) Tablets USP (b) (4) mg, Lot No. (b) (4) A.R. No.: (b) (4) recorded the start time as (b) (4) and the end time as (b) (4) However, the electronic test report shows the dissolution start time as (b) (4) and the (b) (4) sample was pulled at (b) (4) The electronic data indicates that the actual dissolution test duration was approximately (b) (4) (from (b) (4) to (b) (4) which exceeds the specified (b) (4) test duration by more than (b) (4)

2. The dissolution data package for (b) (4) Tablets USP (b) (4) mg, Lot No. (b) (4) A.R. No.: (b) (4) recorded the start time as (b) (4) and the end time as (b) (4) However, the electronic test report shows the dissolution start time as (b) (4) and the (b) (4) sample was pulled at (b) (4) The electronic data indicates that the actual dissolution test duration was approximately (b) (4) (from (b) (4) to (b) (4) which exceeds the specified (b) (4) test duration by more than (b) (4)

   Additionally, in both dissolution runs your firm collected samples at (b) (4) Your firm stated that the (b) (4) samples are investigational samples. However, section 4.6.6.13 of your written procedure *FU7-QC-CI-OPI-088: Operation Of Dissolution Test Apparatus With Auto Sampler-*

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Dr. Mettu (M.) Madan Mohan Reddy, Director	
FIRM NAME Aurobindo Pharma Limited, Unit VII	STREET ADDRESS Unit-VII, Sy No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot S1 Part SEZ, TSIIC, Green Ind. Park
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Model-EDT-14lx, Version 6.0.0.0, Effective Date March 01, 2024 specifically requires that (b) (4) mL sample should be withdrawn at final time for investigation purpose.

OBSERVATION 9

Established laboratory control mechanisms are not followed.

Specifically,

During the walkthrough inspection of the (b) (4) Block (b) (4) multiple incidents were observed where employees were not following the written procedures. This includes, but is not limited to:

A. According to section 4.3 of your written procedure *GTP No GTP 151-07: Description/Characteristics, Version 1.0.0.0, Effective Date: December 23, 2021*, appearance testing should be conducted by (b) (4) and observing the details in (b) (4) against (b) (4) backgrounds. However, on January 28, 2026, an analyst from the (b) (4) Block (b) (4) conducted appearance testing by merely observing tablets through blister packaging during stability testing of (b) (4) (b) (4) Tablets USP, (b) (4) mg, (b) (4) mg, (b) (4) mg). Batch Number # (b) (4) Further investigation revealed that your firm has never implemented the required (b) (4) background setup for appearance testing and this procedural non-compliance extends across (b) (4) manufacturing block. Your firm currently manufactures and ships more than (b) (4) products in different strengths to the U.S. market and your complaint history reveals approximately 50 complaints related to appearance issues.

B. On January 28, 2026, it was observed that microbiology plate reading for (b) (4) (A.R. No. (b) (4) was not conducted according to your written procedure *FU7-QC-MB-OPI-007: Operation of Colony Counter, Version 3.0.0.0, Effective Date: March 11, 2024*. The following specific deviations from established procedures were observed:

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Mettu (M.) Madan Mohan Reddy, Director	
FIRM NAME Aurobindo Pharma Limited, Unit VII	STREET ADDRESS Unit-VII, Sy No. 411/P, 425/P, 434/P, 435/P & 458/P, Plot S1 Part SEZ, TSIIC, Green Ind. Park
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1. First, your microbiologist conducted plate reading with condensation present on the lid and failed to visually check for minute colonies as required by the procedure. Condensation on plate lids can obscure colony visualization and lead to inaccurate colony counts, while failure to examine plates for minute colonies may result in underestimation of microbial contamination levels.
2. Second, your reviewer verified the plate by holding it in his left palm, which blocked the light from the colony counter and prevented proper visualization of colonies during the verification process. This improper handling technique compromises the accuracy and reliability of the verification step, which is critical for ensuring data integrity in microbiological testing.

3. Third, colony counter ID: COLB00001 does not have sufficient light for proper colony visualization and enumeration, creating systematic limitations in the equipment's ability to detect all microbial colonies present on testing plates.

***DATES OF INSPECTION**

01/28/2026 (Wed), 01/29/2026 (Thu), 01/30/2026 (Fri), 02/02/2026 (Mon), 02/03/2026 (Tue), 02/04/2026 (Wed), 02/05/2026 (Thu), 02/06/2026 (Fri), 02/09/2026 (Mon), 02/10/2026 (Tue).

SEE REVERSE OF THIS PAGE	Guerlain Ulysse, Investigator Pratik S. Upadhyay, DDC Investigator Nibin Varghese, Investigator	DATE ISSUED 02/10/2026

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."