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	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal, Telangana, 500090 India	Finished Dosage 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 responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. The list of observations noted below document that the Quality Unit has not performed the necessary assessments/reviews to ensure that the objectionable conditions do not negatively affect the manufacturing process and Quality Control tests in support of the finished drug products.

B. During my walkthrough of your firm's facilities on 05/14/19, I observed uncontrolled, loose handwritten notebooks with what appears to be laboratory test data results, a recent data logger temperature study for a new vendor, and unsigned SOP's with respect to sterile operations (interventions) performed at (b) (4) (sterile operations) in response to a recent USFDA inspection performed from

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre	X Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 05-24-2019 08:07:36	5/24/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY Medchal, Telangana, 500090 India	TYPE ESTABLISHMENT INSPECTED Finished Dosage Manufacturer

OBSERVATION 2

A sample which is representative of each lot in each shipment of each active ingredient is not appropriately identified and retained.

Specifically, on or around 01/22/19, your firm received a notification from USFDA that (b) (4) mg, (b) (4) mg, and (b) (4) mg finished products manufactured at your facility were tested for impurities (b) (4) (b) (4) and (b) (4) with (b) (4) mg and (b) (4) mg testing positive for (b) (4) however below the "interim acceptable limit). As a result, your firm performed the following activities (not in order), but not limited to, with respect to this information from USFDA and communication with EMA: (1) Tested (b) (4) and (b) (4) contents for above batches and API's used in manufacture using GC method; (2) performed risk assessment with respect to presence of (b) (4) content in (b) (4) drug products at current inspection facility with respect (b) (4) finished products (US Market), (b) (4) finished products (Europe, Canada Markets), and all API's used in the manufacture of finished products, supplier by (b) (4) API facility and other suppliers; (3) Validated GC-MS Method for (b) (4) and (b) (4) impurity testing; and (4) Re-tested API's used in manufacture of (b) (4) drugs using GC-MS Method.

During the current inspection, I randomly selected eleven (11) (b) (4) USP API lots out of (b) (4) lots assessed, which were used in the manufacture of (b) (4) drug products shipped to US Market (including 3 API's used in USFDA tested products), and subsequently checked retained sample weights in your LIMS system. In summary, established retained sample weights were observed to be (b) (4) mg for all samples in LIMS software, with (b) (4) mg to (b) (4) mg withdrawals observed electronically for testing samples by R&D and/or your firms QC. However, upon physically walking to your retained sample room, and pulling and weighing these 11 API's, weight balance of samples weighted versus observed in LIMS did not match. Although bottle labels also stated (b) (4) mg of initial samples weighed, actual weighed remaining samples observed during the inspection ranged from 14.33 grams to 36.27 grams. A summary of all samples is provided below.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre	X Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 05-24-2019 08:07:36	5/24/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019* FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal, Telangana, 500090 India	Finished Dosage Manufacturer

S. No	Batch Number	AR Number	Weight (g) from scribbling pad	Gross weight value from weighed prints (g) (A)	(b) (4) bags+ 2 Seals(g) (B)	Net weight(g) (A-B)
1	(b) (4)		27.4	27.42	13.09	14.33
2			49.35	49.36	13.09	36.27
3			31.11	31.12	13.09	18.03
4			37.38	37.40	13.09	24.31
5			31.94	31.96	13.09	18.87
6			39.99	40.00	13.09	26.91
7			44.38	44.39	13.09	31.30
8			29.8	29.82	13.09	16.73
9			33.6	33.61	13.09	20.52
10			43.89	43.90	13.09	30.81
11			37.77	37.77	13.09	24.68

Based on the firm's reconciliation practices for retained sample observed during the current inspection, there is no assurance that every individual API retained sample batches were tested for (b) (4) and (b) (4) risk assessment.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Arsen Karapetyan, Investigator - Dedicated Drug Cadre

X Arsen Karapetyan
Investigator - Dedicated Drug Cadre
Signed By: Arsen Karapetyan -S
Date Signed: 05-24-2019 08:07:36

DATE ISSUED
5/24/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY Medchal, Telangana, 500090 India	TYPE ESTABLISHMENT INSPECTED Finished Dosage Manufacturer

OBSERVATION 3

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

On 05/22/19, I observed "Type C" (product changeover) equipment cleaning operations for (b) (4) (b) (4) (and room), Equipment ID (b) (4) 0227 located at Production Block (b) (4) floor, (b) (4) area. Products manufactured on this equipment include, but are not limited to, (b) (4) Tablets, (b) (4) Tablets, (b) (4) Tablets, (b) (4) Tablets, (b) (4) Tablets, (b) (4) Tablets, (b) (4) Tablets, (b) (4) Capsules for the International Markets, including US Market.

Cleaning activities described in the SOP FU3-PR-MF-CLN-072, titled Cleaning of (b) (4) effective date 07/11/16, are not representative of activities observed performed during the inspection:

A. Cleaning operations started on 05/22/19, approximately 15:40 (3:40 pm) and concluded at (b) (4) (b) (4) lasting more than (b) (4) hours. After cleaning concluded (per your firm and operators), I requested the (b) (4) equipment logbook, and observed the following selected handwritten entries from January 2019 to current inspection:

- "05/22/19, Type C Cleaning, 15:40 to (b) (4) " = (b) (4) hours and (b) (4) minutes (current inspection).
- "05/20/19, Type C Cleaning, (b) (4) – (b) (4) = 1 hour 10 minutes.
- "05/13/19, Type C Cleaning, 16:45 (4:45 pm) – (b) (4) = around (b) (4) hour (b) (4) minutes.
- "05/10/19, Type C Cleaning, 15:32 (3:32 pm) – 16:03 (4:02 pm) =30 minutes.
- "05/08/19, Type C Cleaning, (b) (4) – (b) (4) = 1 hour, 20 minutes.
- "04/25/19, Type C Cleaning, (b) (4) – (b) (4) = 1 hour, 25 minutes.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre	X Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 05-24-2019 08:07:36	5/24/2019

- 04/20/19, Type C Cleaning, (b) (4) – (b) (4) = 1 hour 20 minutes.

From January 2019 to current inspection, there are approximately 85 entries of "Type C" cleaning with similar clean times as stated above. After cleaning, I asked your firm's Assistant General Manager why it took more than (b) (4) hours to clean the room and (b) (4) while I was present versus 30 minutes to 1.5 hours on other days. The first two attempts to ask this question resulted in no answer.

Based on this finding, I reviewed the Cleaning Validation Report for (b) (4) and (b) (4) Production Block (b) (4) Solid Dosage By Using (b) (4) Document Number FU3-PB (b) (4) SD-CVR-005, dated 08/24/2015. In addition, I reviewed verification report, Cleaning Verification Report For (b) (4) and (b) (4) Production Block (b) (4) Solid Dosage, Document Number FU3-PB (b) (4) SD-CVR-0173, dated 09/29/18. In both cases, the studies were based on SOP FU3-PR-MF-CLN-072, titled Cleaning of (b) (4) using (b) (4) Cleaning times for both studies were as follows (3 batches for initial 2015, and one batch for verification in 2018).

08/05/15, Type C, from 13:15 (1:15 pm) – 15:13 (3:13 pm) = approximate 2 hours.
08/07/15, Type C, from (b) (4) – (b) (4) = 2 hours, 10 minutes.
08/08/15, Type C, from 13:33 (1:33 pm) – 15:49 (3:49 pm) = 2 hours, 16 minutes.
09/14/18, Type C, from (b) (4) – (b) (4) = 1 hours, 15 minutes.

There is no assurance that that complete and adequate cleaning activities were performed during both validation and verification activities, per firm's procedure.

B. Your operators did not perform the following activities described in your SOP and Cleaning Process Record of (b) (4) (checklist), which consists of (b) (4) steps:

- "Finally wipe the inner and outer surfaces of (b) (4) lid and gasket, (b) (4) (b) (4) valve and (b) (4) with dry lint free cloth dipped in (b) (4) solution" (Step (b) (4).

I observed the operator dip a lint free cloth inside (b) (4) solution and subsequently stand under the (b) (4) using their hand to clean the inside of the (b) (4) which is within reach. Out of (b) (4) square centimeters inner surface area, I observed approximately 20%-25% of the inner surface area of the (b) (4) cleaned with (b) (4) solution. Per your firm's QA Manger and Cleaning Validation Report, the (b) (4) is used eliminate water spots and used for disinfectant for microorganisms.

- "Remove any adhered material from the outer surface of the (b) (4) using vacuum cleaner" (Step (b) (4)

This step is towards the (b) (4) of the cleaning process. Before this task, I visited the (b) (4) (b) (4) room for approximately 4 minutes. Upon return I observed the operators on Step (b) (4) ("Dismantle the (b) (4) lid by (b) (4) and remove the gasket"). I asked several personnel, including one production personnel, if Step (b) (4) had already been performed, to which they answered "Yes". I asked approximately two more time to confirm, which resulted in "Yes". Upon noticing that the vacuum was in the corner and not plugged in, I requested the checklist from inside the room for confirmation. Upon observing the checklist, Step (b) (4) was not checked. After, the operators who answered "Yes" stated that Step (b) (4) had in fact not been performed.

- "Assemble the dismantled parts in (b) (4) and close all the open parts using the (b) (4) (Step (b) (4).

This step is performed at the (b) (4) of the cleaning process, (b) (4) the (b) (4) instruction "Update the status label as CLEANED" (Step (b) (4). I observed the operator created

and affix a "CLEANED" status label at the end of cleaning without performing this task per cleaning procedure/checklist.

- "Remove the (b) (4) covers to the electrical points, control panel and wipe with dry lint free cloth" (Step (b) (4)).

This item was not performed in sequence, after step (b) (4). Instead, it was performed after Step (b) (4).

C. Activities performed are not detailed in your Procedure:

- "Wipe the inner and outer surfaces of (b) (4) lid and gasket, (b) (4) (b) (4) valve and (b) (4) with dry lint free cloth" (Step (b) (4)).

During this activity, I observed the operator take a ladder and step up inside the (b) (4) with only lower 25% of body appearing. The operator spent approximately 30 minutes inside the (b) (4) wiping it dry. This activity is not detailed in SOP FU3-PR-MF-CLN-072.

OBSERVATION 4

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

There is no adequate data integrity program in place to include an adequate review of all electronic raw data by the Quality Unit to ensure completeness, consistency, and accuracy of all chromatographic raw data generated by the Quality Control (QC) laboratory. Per your firm's procedures, SOP FU3-QA-GEN-0090, titled Review of Analytical Data and SOP FU-3-QC-GEN-075, titled Review of Empower Chromatographic Data By Quality

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal, Telangana, 500090 India	Finished Dosage Manufacturer

Control Reviewers and Lab Compliance Reviewers, both QC and QA are responsible for reviewing electronic raw data.

During my review of laboratory data, I observed multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as "Incomplete Data". During my review of electronic data in Empower 3 software, it was observed that the system administrator and the QA administrator have the user privilege to "Verify Incomplete Data in Raw Data Files". Per your firm's QC Manger, the firm has been aware of this user privilege and function since 2014, however there is no procedure which describes this function and process of verifying incomplete data. There is no justification why your firm did not verify incomplete data in order to perform and adequate assessment of all data available during testing operations. In fact, during review of analytical batch records I observed the following statement printed by your QC reviewers, which appears to contradict actual review practices performed by reviewers:

"I sign this data to attest that I have reviewed this data as per SOP No: FU3-QC-GEN-075. This includes review of all manual entry of meta data (Sample name, Batch Numbers, A.R number etc.). Sample Audit Trail, Method Audit Trail (Instrument Method, Method Set, Sample set Method, Processing Method) and Results Audit trail."

Furthermore, during the inspection, your firm performed an assessment of all your electronic data generated from January 2018 to April 2019. Out of 112 projects, 39 projects were identified to have integrity failures (Data Missing/Incomplete Data), from which 123 channels for chromatograms showed incomplete data, from which 20 samples included elution of principal peak. Subsequently, I requested your QA administrator to verify the incomplete data and process the sample injections for up to four different samples I discovered and samples your firm identified during the inspection and discovered that the injected sampled did in fact run, with all sample injections resulting in elution of principal peak. After processing the incomplete data, your firm performed all related calculations on the unreported processed injections, which appeared to be within specification. However, this discrepancy in your firm's ability to review and investigate all electronic raw data is a significant gap in your Data Integrity procedures and practices reviewed during the current inspection. Per your firm, with respect to

interrupted sequences your firm had documented these instances via analytical process non-conformance reports, however, verification of incomplete data was not always performed for a complete investigation with all test data available for review.

OBSERVATION 5

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically,

Corrective Action/Preventive Action (CAPA's) initiated in response to Out-Of-Specifications (OOS) test results are not always scientifically sound or comprehensive to address all potential root causes. For Example,

-On or around 10/12/2018, OOS FU3OOS180067 was initiated due to OOS for finished product (b) (4) Capsules USP (b) (4) mg, Batch (b) (4) with assay test results as (b) (4) % versus a specification of (b) (4) % - (b) (4) %. Subsequent laboratory and manufacturing investigations by your firm confirmed the OOS and the batch was rejected. Per the OOS investigation and firm personnel explanation during the inspection, no definitive root cause was identified, however, upon further testing of packaged product from (b) (4) of packaging, it was discovered that the (b) (4) packaged product was OOS. Per CAPA APL-FU3-CAPA-18-0234, dated 11/21/18, your firm performed an addendum effectiveness check for finished product assay result for the next (b) (4) batches of (b) (4) Capsules. Per your initial investigation for subject batch in OOS, review of analytical results of (b) (4) and finished product revealed more variation, and (b) (4) average value was not

matching with the (b) (4) assay value. Your addendum effectiveness check did not monitor (b) (4) assay and (b) (4) Furthermore, testing performed under addendum for (b) (4) batches consisted of the same sampling plan used during regular manufacturing operations per SOP FU3-QA-GEN-028, titled Sampling of Semi-Finished and finished product where (b) (4) sampling is performed during (b) (4), from which (b) (4) capsules are randomly selected for testing, of which only (b) (4) capsules are used for both assay preparations (b) (4) capsules per assay). There is no scientific justification for continuing to use regular sampling plan for addendum assessment, when initial capsules were identified to be OOS. Furthermore, your firm did not expand this investigation to other similar immediate release finished product capsule dosage forms for similar discrepancies.

-On or around 10/26/17, OOS/091/17 and OOS/092/17 were initiated due to OOS for in process assay and (b) (4) via (b) (4) for product (b) (4) Capsules USP (b) (4) mg (b) (4) with assay average result as (b) (4) for assay versus specification of (b) (4) % - (b) (4) % and (b) (4) average result as (b) (4) % versus specification of (b) (4) % - (b) (4) %. Subsequent investigation in laboratory and manufacturing confirmed the OOS and the batch was rejected. Probable root cause determined to be loss of material during (b) (4) operations, where material was not transferred to the next stage of (b) (4) (b) (4) Per your firm, due to the lower API content of the (b) (4) product, material loss at (b) (4) stage would impact assay and (b) (4) results. After an assessment for the manufacturing process, CAPA APL-FU3-CAPA-18-0027, initiated 02/13/18 to implement a change from calculating % yield after (b) (4) only to calculating % yield at stages for (b) (4) (b) (4) Additionally, your firm performed an evaluation for 24 similar strength type dosage forms, where similar low API content products were identified. These items are not detailed in any investigation or assessment and were provided to me upon request during the inspection. Per your firm, due to no similar failures for the identified strength types, the firm did not extend the % Yield corrective action to these products. Per your firm's risks assessment of (b) (4) Capsules manufacturing process, it was determined that loss of material was the root cause. There is no justification why the % yield calculations at various stages of (b) (4) was not extended to similar product batch records.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY Medchal, Telangana, 500090 India	TYPE ESTABLISHMENT INSPECTED Finished Dosage Manufacturer

OBSERVATION 6

Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

Specifically,

Corrective Action/Preventive Action (CAPA's) initiated in response to complaints are not always sound or comprehensive to address all potential root causes. For Example, during my review of complaints from January 2016 to current inspection for (b) (4) packaged products manufactured for the US Market multiple complaints "EMPTY (b) (4) IN (b) (4) " and "MISSING (b) (4) /EMPTY CARTON" were observed. Finished dosage products with these complaints included, but not limited to, (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg, (b) (4) Tablets (b) (4) mg.

-For approximately 50 complaints for "EMPTY (b) (4) IN (b) (4) ", complaint investigations root cause for most complaints were "(b) (4) struck up at punching tool". As a result, change control APL-FU-CC-17-1442 was initiated on 11/01/17 to add "Cleaning of (b) (4) during type C change over" in your firm's SOP FU3-PR-PK-CLN-059, titled Cleaning of (b) (4) Machine-BQS on or around 11/24/2017. Although this instruction was added to the procedure, the attached checklist for this cleaning procedure, which is used during Type C cleaning for the (b) (4) equipment fails to mention this instruction. As of the current inspection, after implementation of this procedure, your firm continues to receive similar "EMPTY (b) (4) IN (b) (4) " complaints.

-Similarly, for "MISSING (b) (4) /EMPTY CARTON" complaints, root cause for most complaints were due to handling of rejects because of auto-weight checker or camera checker during (b) (4) Per

your firm's procedure, (b) (4) rejects with missing pamphlet or missing (b) (4) can be manually repackaged by personnel, after which they must be sent through the weight check and camera check once more. However, root cause for these complaints was determined to be that operators may have repacked rejects incorrectly and forgot to pass them through the weight check and camera check once more. This practice is described as "very remote possibility" in over 50 complaints from 2016 to current inspection. CAPA's throughout the years have included retraining of operators on procedures, such as SOP No. FU3-PR-PK-GEN-016, titled "Handling of Packing Rejects", however similar complaints with similar root cause have continued to occur. In addition, per your firm's SOP FU3-PR-PK-GEN-001, titled Packing Material Indenting, Staging and Transfer From Stores to Packing, a non-conformance report will be initiated only if additional packing components are issued due to issues on the line (more than (b) (4)% of standard amount issued), however, there is no specified reject limit to raise a non-conformance for trending purposes for number of initial rejects on the (b) (4) line.

OBSERVATION 7

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,

Your firm's manufacturing equipment spread across (b) (4) manufacturing blocks are not 21 CFR part 11 compliant. For example,

A) Your firm's approximate (b) (4) standalone manufacturing equipment are not equipped with HMI/PLC/SCADA system. There is no time stamped audit trail, data management, alarm management, archival and retrieval of records on this standalone manufacturing equipment. The equipment includes but are not limited to (b) (4) (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. M. Madan Mohan Reddy, Director	
FIRM NAME Aurobindo Pharma Ltd	STREET ADDRESS Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY Medchal, Telangana, 500090 India	TYPE ESTABLISHMENT INSPECTED Finished Dosage Manufacturer

B) Your firm's approximate (b) (4) standalone production equipment (b) (4) Packaging, (b) (4) manufacturing) have an inbuilt HMI system but none of the equipment have time stamped audit trail, data management, alarm management, archival and retrieval of records. The equipment includes but are not limited to (b) (4) (b) (4)

OBSERVATION 8

Backup data is not assured as secure from alteration, erasure or loss through keeping hard copy or alternate systems.

Specifically,

Your firm's approximate (b) (4) standalone production equipment have an inbuilt SCADA system. The equipment includes but not limited to (b) (4) camera check on packaging lines, and (b) (4) machines. During the inspection, I reviewed batch records for approximately (b) (4) products which included HMI and SCADA equipment. Per your QA, generated production data, such as critical parameters are used for final product release, in the form of In Process QA in production reviewing the raw data after operations. I reviewed the following batch records/equipment:

-(b) (4) mg, Batch No. (b) (4) manufactured on 02/06/19 / Proface IPC/SAWC software, (b) (4) Machine Equipment ID (b) (4) 0784.

-(b) (4) Capsules (b) (4) Batch No. (b) (4) / software Ifix5.1. software, (b) (4) Equipment ID PR(b) (4) /330.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal, Telangana, 500090 India	Finished Dosage Manufacturer

During my review, I requested to see the backup production data for the above batch records. Per your firm, IPC SCADA data is backed up (b) (4), and subsequently deleted from the equipment software. Backup data is saved on one DVD and stored with QA in one building. There is no duplicate backup copy of this data. During my review of the contents for DVD for Proface, I observed that in addition to raw data files, generated PDF documents summarizing critical parameters were also backed up. These PDF documents are not password protected: During the inspection, it was confirmed that the PDF document can be converted to a Microsoft Word document, where data can be change and subsequently saved under the same PDF document name or a different name.

OBSERVATION 9

Drug product expiration dates are not related to the storage conditions stated on the labeling, as determined by stability studies.

Specifically,

During my visit to your firm's stability laboratory on 05/20/19, I performed a walkthrough of stability chamber QC/HC/014, 25 degrees Celsius +/- 2 degrees Celsius /60 % RH, +/- 5%: I observed perforated racks with drug products on stability stacked on top of one another. Your firm's 2009 empty chamber temperature mapping study report/protocol is based on consideration of 75% load occupancy for utilized vertical area (upper) in the chamber. During my walkthrough I observed up to 90% of area utilized due to samples being stacked up on one another. Additionally, your firms recent September/2018 mapping study is based on an as is loaded chamber at the time of the study, however there is no description or pictures regarding chamber being filled at or below 75% load capacity.

OBSERVATION 10

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/13/2019-5/24/2019*
	FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Madan Mohan Reddy, Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit 3, Survey 313 & 314, Bachupally, Medchal-Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal, Telangana, 500090 India	Finished Dosage Manufacturer

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

During my walkthrough of your firm's stability laboratory, stability sample storage room, on 05/20/19, I observed a PVC pipe connected to an air conditioner unit on one end and placed in a blue plastic bucket on the other end with approximate 50% of bucket filled with condensate water. Per your firm, the water in the bucket is empties (b) (4) however there is no documentation of these activities. In addition, there is no procedure for this practice. Per your firm, during the current inspection, there were four other similar setups in the HPLC room and sample preparation room.

***DATES OF INSPECTION**

5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed), 5/16/2019(Thu), 5/17/2019(Fri), 5/20/2019(Mon), 5/21/2019(Tue), 5/22/2019(Wed), 5/23/2019(Thu), 5/24/2019(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Arsen Karapetyan, Investigator - Dedicated Drug Cadre	X Arsen Karapetyan Investigator - Dedicated Drug Cadre Signed By: Arsen Karapetyan -S Date Signed: 05-24-2019 08:07:36	5/24/2019