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	11/4/2019-11/13/2019*
	FEI NUMBER 3008461619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Rajesh Shashikant Kulkarni, Vice President - QA/QC

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited - Unit IV	Plot Nos. 4, 34 To 48, EPIP, TSIIC, IDA, Pashamylaram, Patancheru Mandal, Sangareddy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medak District, Hyderabad, Telangana, 502307 India	Sterile Drug Manufacture

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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

A. The "Aseptic Processing Simulation (Media fill)" document number FU4-QA-gen-020, dated 29 Jan 2018 establishes "…a procedure on planning, executing and evaluating aseptic media fill in the manufacturing lines with a view to demonstrate the capability to produce sterile drug products manufactured through aseptic processing."

"Aseptic Process Protocol" document number, FU4-Line-(b) (4) APSP-0005, dated 08 May 2019, establishes an acceptance criteria that includes "All Units shall be free from contamination." The following information concerns the aseptic process simulations for the media fill processes performed for (b) (4) Block (b) (4) and Block (b) (4) Line (b) (4) for example, but are not limited to:

Area	*Batch # MF/*	*Begin media fill date of manufacture*	*Total units filled*	*Total units incubated*	**Unfilled units used to balance* (b) (4)	***Batch record – no assignable cause for*

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(b) (4) [redacted]

The "Cleaning, Operation and Conveyor Change Over of Automatic Loading and Unloading System (ALAUS) (Make (b) (4) [redacted]" document number, FU4-PR-MF-OPI-116, dated 31 Aug 2018, establishes "…a procedure for Cleaning, Operation and Conveyor Changeover of Automatic Loading and Unloading System (ALAUS)". The standard procedure includes (b) (4) [redacted]

(b) (4) [redacted]

1. The Senior Executive Production, Senior Executive Quality Assurance, Deputy Manager Quality Assurance, and the Senior Vice President Operations explained that glass vials are used to balance the (b) (4) [redacted] during routine aseptic processing. However, during the aseptic process simulation (aka media fill), the

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glass vials used to balance the (b) (4) do not include the use of microbial growth media;

2. Not simulating the aseptic process with microbial growth media in the glass vials used to balance the (b) (4) as established in the "Aseptic Processing Simulation (Media fill)" document number, FU4-QA-gen-020, dated 29 Jan 2018, precludes the company from "…planning, executing and evaluating aseptic media fill in the manufacturing lines with a view to demonstrate the capability to produce sterile drug products manufactured through aseptic processing";
3. Regarding the rejected unit without an assignable cause, the Senior Executive Quality Assurance, Senior Executive Production, Deputy Manager Quality Assurance, and General Manager Corporate Quality Assurance explained the media filled vials are rejected due to th (b) (4) process. However, the batch manufactu e cause(s) for the media fill rejections e.g., glass vials broken, no (b) (4) stopper, glass vial fallen over. The absence of providing an assignable cause, as established in the "Aseptic Process Protocol" document number, FU4-Line (b) (4) APSP-0005, dated 08 May 2019, precludes the company from evaluating and ensuring that they have met their aseptic process simulation criteria i.e., "All Units shall be free from contamination";
4. The following is a summary of the reconciliation record regarding media filled vials that were discarded during the aseptic process simulation;

Area	*Batch # MF/*	*Begin media fill date of manufacture*	*Reconciliation Filling Rejects*	
			Vials with no stopper	(b) (4) (b) (4) *vials*
(b) (4)				

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(b) (4)

The Senior Manager of Production, Senior Executive of Production, and Vice President of Operations confirmed there is no record in the media fill batch manufacturing record to document and confirm the number of media filled glass vials discarded.

B. The (b) (4) of Clean Areas (Grade B, C and D) at (b) (4) Block" document number, FU4-PR-GEN-019, dated 03 Mar 2018, establishes "a procedure for (b) (4) of clean areas at (b) (4) block (Grade B, C and D). The process requires a determination of the (b) (4) for (b) (4) and total (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) The following table contains a few for (b) (4) Block (b) (4) (b) (4)

(b) (4) *Block*	*Room No.*	*Area ft²*	(b) (4)	*Quantity (ml)*	(b) (4)
			(b) (4)	(b) (4)	(b) (4)

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(b) (4)

[redacted]

The Senior Executive Quality Assurance and General Manager Corporate Quality Assurance confirmed the (b) (4) process performed for (b) (4) Block (b) (4) have not been validated.

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C. As per the QA Assistant General Manager and the QA Validations Senior Manager, the current (b) (4) (b) (4) procedure was initially (b) (4) (b) (4) (b) (4) efficacy on the evaluation of environmental monitoring results (b) (4) with the use of a simulated worst-case scenario of microbial contamination (e.g. HVAC turned on and off) (b) (4) is typically used for (b) (4) and is currently/has been used in Block (b) (4) (Lines (b) (4) and Block (b) (4) (b) (4) n of respective line construction and air quality (i.e. equipment s of construction, air flows, temperature and % relative humidity).

D. As per the Assistant Manager of Microbiology, the most recent (b) (4) (2011) (b) (4) (August 2018) and (b) (4) (January 2018) disinfectant efficacy studies fail to evaluate all materials of construction within Block (b) (4) (Lines (b) (4) and Block (b) (4) (b) (4) such as, but not limited to: (b) (4)

E. (b) (4) are used in the Grade A (ISO 5) areas e.g., (b) (4) in the (b) (4) loading and unloading area (b) (4) (b) (4) in the vial filling area (b) (4) (b) (4) in the vial sealing area (b) (4) (b) (4) loading and unloading area (b) (4) in the (b) (4) nd unloading area Block (b) (4) Line (b) (4) The Vice President Quality Assurance / Quality Control and Senior Vice President of Operations confirmed that the (b) (4) are not cleaned and sanitized on a periodic basis.

F. The (b) (4) are not cleaned and sanitized on a periodic basis. The (b) (4) remained covered during the (b) (4) process. The Vice President Quality Assurance / Quality Control and Senior Vice President of Senior confirmed that the (b) (4) is not cleaned and sanitized prior or post the aseptic filling operations

G. During our review of your firm's Quality and Manufacturing unit by observing Close Circuit Video (CCTV)

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Medak District, Hyderabad, Telangana, 502307 India	Sterile Drug Manufacture

Tapes located at Block (b) (4) and Block (b) (4) Line (b) (4) which are used in the manufacturing of Aseptic (b) (4) products, the following were observed:

1. On August 3, 2019, time stamp (b) (4) employees were observed not moving in a slow and deliberate manner during line (b) (4) set up. In the video, the employees were observed cleaning the (b) (4) putting in the Petri dish for environmental sampling, and other activities.

2. On August 6, 2019, time stamp (b) (4) employees were observed not moving in a slow and deliberate manner during what appears to be the manufacturing of glass vials. The employee was opening the glass (b) (4) and fixing sampling plates.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Your firm's sampling plan does not represent the worst-case activities and conditions that proved a challenge to aseptic operations. For example, but are not limited to:

The active air sample location of your firm's Grade A mobile Laminar Air Flow, Equipment ID, LAF PN/MTLAF-005 (b) (4) located on Line (b) (4) where (b) (4) (b) (4) are manufactured for the US Market, is not located in the most challenging condition.

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According to your firm's Vice President of QA/QC, this mobile LAF is utilized during the (b) (4) (b) (4) for each batch manufactured on Line (b) (4) These sterilized items include, but not limited to: (b) (4)

From January 2018 – November 2019, your firm has recovered (b) (4) CFU for location (b) (4) According to your firm's SOP, FU4-QC-MIC-GEN-017: "*Microbiological Monitoring Program (MMP) in Manufacturing Areas*", the mobile LAFs are monitored (b) (4) . According to your firm's November 2018 – November 2019 distribution log, your firm has distributed (b) (4) batches to the US:

(b) (4)

OBSERVATION 3

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Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. A corrective and preventative action (CAPA) number APL-FU4-CAPA-19005 was initiated as a commitment in a response to an FDA 483 observation noted in December 2018. The CAPA describes a (b) (4) (b) (4) (b) (4) Based on outcome, frequency of NVPC monitoring and needed recovery period will be defined in respective NVPC SOPs." The "General Study Protocol" and "Report For Evaluation of Recovery Period Under LAF for (b) (4) Intervention" document FU4-MISC-MSVP-0823 dated 09 Jan 2019 and FU4-MISC-MSVR-820 dated 26 Feb 2019, respectively, objective "…is to evaluate the recovery period for any particles that may be generated during the (b) (4) and personnel passage through the (b) (4) (b) (4) The corrective measure is to perform NPM within the (b) (4) area by placing a mobile NVP monitoring equipment within the Grade A area (b) (4) Grade-A (b) (4) The NVP monitoring of the Grade A (b) (4) area begins when the (b) (4) . The following table below is a summary of the number of interventions with respect to opening the (b) (4) i.e.,

1. For (b) (4) Block (b) (4) there is no NVP monitor nd obtained when the (b) (4) (b) (4) are (b) (4) or when personnel access (b) (4) and/or during the routine pro activities e.g., when personnel (b) (4) the EM microbial sampling and/or the mobile NVP monitoring equipment from the (b) (4) (b) (4) via the use of a (b) (4) there is no NVP monitoring performed for the (b) (4) k (b) (4)
2. There is no data regarding the NVP levels during the aforementioned personnel activity and (b) (4) (b) (4) the NVP levels within the Grade A (b) (4) during the aforementioned dynamic manual operations remains to be unknown. Please note the aforementioned NVP monitoring

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considerations for the (b) (4) areas also apply for the aseptic fill lines (b) (4) in Block (b) (4)

3. The aseptic process simulations (aka media fill) and batch manufacturing records document the number of times when personnel access the (b) (4) Grade A area. A summary is provided in the table below. There is no NVP monitoring performed during the period of time when personnel enter (b) (4) (b) (4) Grade A area. The NVP levels for (b) (4) A area during the aforementioned dynamic manual operations remains to be unknown:

Area	*Batch # MF/LS*	*Date of Manufacture*	(b) (4) *i*	***NVP level during interventions*	****NVP monitoring per batch*
(b) (4)				*	-
				unknown	(b) (4)
				unknown	
				unknown	
				unknown	
				unknown	
				unknown	
				*	
				unknown	
				unknown	

Note: *monitoring for NVP counts at (b) (4) implemented March 2019;
** NVP counts at the (b) (4) per aseptically filled batch;
***number of times monitoring for NVP during (b) (4) nterventions.

B. The "Non-Viable Particle Monitoring (NPM) Programme In Production Area at (b) (4) Block" document number FU4-PR-MF-OPI-155, dated 04 Mar 2019, objective is "To lay down a edure for routine Monitoring of non-viable particle monitoring (NPM) programme in production area at (b) (4) block." The

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standard procedure specifically establishes the following for 'Other Grade "B" Areas like (b) (4) (b) (4)

Please note the Grade B areas include the (b) (4) that are designated as ISO 5 manufacturing areas. The standard procedure is silent with respect to performing NPM during routine in-operation/dynamic aseptic manufacturing processing. In addition;

1. Production personnel (b) (4) sterilized fill equipment parts and utensils from the (b) (4) (b) (4) into the Grade A (ISO 5) fill line. During the (b) (4) process, the sterile fill and utensils are exposed to the Grade B environment. The Assistance General Manager Quality Assurance and the Senior Vice President of Operations confirmed that there is no NVP monitoring performed during the dynamic operations to ensure that the Grade B environment is maintained (the NVP levels within this area remains to be unknown);
2. The aseptic filling process is performed within an (b) (4) estricted Access Barrier (RAB) System, a Grade A (ISO 5) classified environment. The manufacturing area surrounding the Grade A aseptic filling zone is classified as a Grade B environment. The Grade B area is monitored for the presence of NVP at the (b) (4) The Grade B area is monitored via the use of a (b) (4) NVP monitoring equipment. I observed NVP monitoring performed at the (b) (4) and in one location, that is, near an air return vent (b) (4) There was no dynamic manufacturing operation being performed during the NVP monitoring process; at that time, there was no other Grade B area monitored for the presence of NVP;
3. Aseptic filling processing of finished drug products i.e., from aseptic filling to the glass vial sealing processing steps, are performed within a Grade A (ISO-5) environment. The following is a summary regarding the noted locations that are not monitored for non-viable particles (NVP);

Area	*Aseptic fill lines*	*Brief description - distance between (b) (4) loc*	*Distance meters*	*NVP between locations*
(b) (4)				

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(b) (4)

C. A (b) (4) is used to transfer sterile fill equipment parts and utensils from the (b) (4) (b) (4) The (b) (4) provides HEPA filtered (b) (4) is classified as a Grade A environment. The Deputy Manager Quality Assurance confirmed a NVP measurement is obtained prior to loading sterile fill equipment parts and utensils into the (b) (4). However, the NVP measurements are not

taken of the Grade A interior during the dynamic operations;

1. There is a (b) (4) positioned in the (b) (4) system [G (b) (4) at is used to (b) (4) The (b) (4) s positioned approxim (b) (4) (b) (4) respectively. Excluding the immediate area near the (b) (4) (b) (4) (b) (4)
2. The (b) (4) finished drug product glass vials are sealed with a (b) (4) within a Grade A environment. The (b) (4) in the Grade A (b) (4) pproximately (b) (4) below the (b) (4) Monitoring for the NVP levels of the Grade A HEPA filtered air is mately (b) (4) of the stoppered glass vials and not near the work surface. The NVP levels near or at the work surface are unknown.
3. The company has prepared a protocol to document the "Rationale for the Selection of On-line Non-viable Particle Counter Locations (b) (4) Block" document number FU4-MISC-Rationale-002 dated 04 Mar 2019. A similar protocol and report have been initiated for (b) (4) Block (b) (4) as well. The protocol and report concludes for example "Based on the review…" "…it is concluded that that the existing installed online non-viable particle counters locations are adequate enough to capture the particles from the working /activity height in critical zones of (b) (4) to generate and monitor the online on-viable particle count data." The Vice President Quality Assurance / Quality Control confirmed they have not performed a "formal" evaluation for the non-online NVP monitoring locations for the Grade B areas, for example, the Grade B areas that surround the Grade A (b) (4) and (b) (4) production areas;
4. For (b) (4) Block (b) (4) NVP measurements are taken of the Grade B environment that surrounds the (b) (4) RABs Grade A r. Regarding (b) (4) Block (b) (4) the NVP monitoring includes obtaining an NVP measurement at t (b) (4) locations at (b) (4) in (b) (4) (b) (4) and (b) (4) in (b) (4) The Vice President Quality Assurance / Quality Control confirmed that there are no production operations or personnel activity performed near the NVP monitoring locations.

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D. The "Dynamic Air Flow Visualization Protocol (b) (4) Block" document #FU4-QA-GEN-033, dated 18 Feb 2019 for (b) (4) (b) (4) Block Unit – (b) (4) objective is to ensure that the Laminarity of air flow during man and material movements and activities of personnel during critical aseptic operations do not adversely affect the airflow pattern within the critical working zone (b) (4) " The air flow pattern verifications include for example;

- "Ensure that the smoke shall move along with the operator during the activity / intervention(s) performed.
- Verify the (b) (4) for unidirectional airflow during execution.
- Verify the operator activity is not causing any turbulence / distortion in (b) (4) "

and, examples of the established acceptance criteria include;

- There should not be any turbulence / limited distortion of unidirectional air flow during manned conditions such as;
- Air should flow from the supply point to working zone and should leave the working zone without bouncing back to supply stream;
- The air flow should always be from the high critical (b) (4)
- There should not be any reverse flow of air from (b) (4)
- Operator's intervention should not cause any turbulence / distortion / eddy effect in air flow."

The following table lists numerous instances where the unidirectional air flow patterns could not be determined and/or observed, which precludes the company from verifying the unidirectional air flow patterns and to assure they meet their established acceptance criteria. Note: The summary provided in the table is not intended to be an all-inclusive and/or exhaustive list of concerns; the summary list does not include similar unidirectional air flow concerns in (b) (4) Block (b) (4) and Block (b) (4) Line (b) (4). The concerns are as follows, for example;

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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	FEI NUMBER 3008461619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Rajesh Shashikant Kulkarni, Vice President - QA/QC

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited - Unit IV	Plot Nos. 4, 34 To 48, EPIP, TSIIC, IDA, Pashamylaram, Patancheru Mandal, Sangareddy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medak District, Hyderabad, Telangana, 502307 India	Sterile Drug Manufacture

Approximate time stamp	(b) (4) Block (b) (4) – Brief description of manual activities
(b) (4)	(b) (4)
	Observe air flow movement downward within the mobile LAF
	Observe faint smoke on top center of video; unable to observe air flow movement after the smoke contacts the individual (if at all); it appears that the smoke may be in between individual and the mobile LAF; it is not clear what the intend of the air flow evaluation is meant to demonstrate;
	Note: No smoke can be observed on th (b) (4) within the mobile LAF Grade A areas; unable to o towards the (b) (4) of the LAF Grade A area
	Observe personnel opening (b) (4) into (b) (4) air flow can be observed at upper and cente ideo; unable to observe air flow as personnel back into the aseptic fill room
	Observe air flow movement on right hand side of video that appears to be moving inward towards the aseptic fill room (b) (4) (b) (4)
	There is no visible smoke and unable to observe unidirectional air flow at the time that the (b) (4) enters into the aseptic fill room
(b) (4)	(b) (4)
(b) (4)	Smoke at top of (b) (4) eading into (b) (4) aseptic fill room from the (b) (4) there is no air flow pattern eva hing the (b) (4) (b) (4) (i.e., routine dynamic conditions) into the aseptic fill room;
(b) (4)	(b) (4) the (b) (4)) (4) flow of air

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(b) (4)	within the LAF unit should be moving in a downward direction within the LAF; air is moving from Grade A (b) (4) of LAF to Grade B environment of the aseptic fill room
	Unable to observe impact of the manual operation on the air flow due to no smoke over the individual who is performing the manual operations
	During the cleaning of the LAF access (b) (4) there is no smoke over the individual and the manual ope in order to determine the impact upon the air flow
	Observe horizontal air eddies over personnel's right shoulder; turbulence and air eddy effect on air flow are not consistent with the acceptance criteria;
	Personnel in Grade B area adjacent to (b) (4) RABs near filling (b) (4)
	Personnel positioning (b) (4) container into the Grade A area inside the (b) (4) RABs; unable to observe the manual activities perfo within the Grade A area and the impact upon the unidirectional air flow;
	Unable to observe the manual activities performed within the Grade A area and the impact of the personnel activities upon the unidirectional air flow;
	There is no smoke above the area of the personnel activity i.e., as individual wipes down the access (b) (4) o the (b) (4) RABs; unable to determine the manual activity's t upon the unidirectional air flow
(b) (4)	(b) (4)
(b) (4)	Cannot observe unidirectional airflow from Grade A into Grade B area
	Cannot observe unidirectional airflow from Grade A into Grade B

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	area during personnel activity
(b) (4)	
(b) (4)	During the movement of (b) (4) through Grade A (b) (4) the visible smoke area does not travel downward towards the height of the (b) (4) nable to ascertain the unidirectional flow of air at the wo e; please note on the left side of the video, the end of the (b) (4) is not in a Grade B area
	No visible smoke over the personnel on the left side of the video; unable to observe unidirectional air flow and/or impact of personnel activity on the unidirectional flow of air
	Observe the speed of operator on the left when compared to operator on the right; the operator on the right is engaged in slow and deliberate movements, while the operator on the left is engaged in a higher rate; there is no visible smoke near or over the operator on the left; unable to ascertain personnel movement and impact upon the unidirectional air flow
	There is no visible smoke near or over the operator on the left; unable to ascertain personnel movement and impact upon the unidirectional air flow
	Note: There is no visible smoke on the left side of the video with access (b) (4) there is no visible smoke during the period of time w (b) (4) unable to observe unidirectional flow of air near access (b) (4) on the left side of the video
	Intervention details – CD #APL4/CD/0052/19
(b) (4)	Personnel access (b) (4) LAF Grade A area; unable to observe personnel activity and determine impact upon the unidirectional air flow
	Personnel wiping down access (b) (4) of (b) (4) LAF Grade A area;

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(b) (4)	unable to observe personnel activity and determine impact upon the unidirectional air flow
	(b) (4)
	No visible smoke over personnel hands and where the personnel activities are being performed; unable to observe personnel activity and determine impact upon the unidirectional air flow
	No visible smoke over personnel arms & shoulders, unable to observe and ascertain the personnel activities' impact upon the unidirectional air flow
	No visible smoke over personnel arms & hands, unable to observe and ascertain the personnel activities' impact upon the unidirectional air flow
	Please note, the above recurring sequence of personnel activities document a lack of visible smoke over the personnel activities to verify there is no negative impact upon the unidirectional air flow
Intervention details – CD #APL4/CD/0053/19	
(b) (4)	(b) (4)
(b) (4)	No visible smoke over personnel activities being performed by personnel's e.g., left hand; unable to observe air flow to verify there is no negative impact upon the unidirectional air flow
	Personnel blocking view; unable to observe air flow to determine that personnel activities do not negatively impact the unidirectional air flow

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(b) (4)	
	No visible smoke over left hand where personnel activity is occurring; unable to observe and determine that personnel activity does not negatively impact unidirectional air flow
	Personnel blocking view; unable to observe air flow to determine that personnel activity being performed by individual's right hand do not negatively impact the unidirectional air flow
	No visible smoke over personnel activity to determine manual operation does not negatively impact the unidirectional air flow
	Cannot observe manual activity being performed within Grade A area; no smoke over personnel activity to determine if manual operations do not negatively impact the unidirectional flow of air
CD #APL4/CD/054/19	
(b) (4) (b) (4)	(b) (4) (b) (4) RABs access (b) (4) s opened; air moving in a downward ion within the Grade A area; unable to observe the personnel activity's impact upon the unidirectional air flow; unable to observe if air flow is moving outward from the Grade A interior to the Grade B exterior of the (b) (4) RABs;
(b) (4)	Unable to observe personnel activity's impact upon the unidirectional air flow; the intent of this simulation and air flow pattern evaluation is not clear

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In addition:

1. For Block (b) (4) Fill Line (b) (4) there is a (b) (4) positioned on the (b) (4) (b) (4) system [Grade A (b) (4) The (b) (4) is used to (b) (4) (b) (4) . The air flow patte an assessment to determine whether the configuration and location of the (b) (4) do not assist to generate air turbulence and/or air eddy effects over the (b) (4) vials during the loading of the (b) (4)

E. As previously reported, a (b) (4) is (b) (4) (b) (4) (b) (4) The (b) (4) provides HEPA filtered (b) (4) within the (b) (4) the (b) (4) is classified as a Grade A environment. There is no air flow pattern eva he (b) (4) (b) (4) . There is no record to document that the various equipment parts and utensils are exposed to HEPA filtered air during the (b) (4) process. Please note, Observation #3C documents there is no NVP monito e dynamic operations.

F. The "Operation and Maintenance of (b) (4) Block Building Management System" document number FU4-EN-OPI-066, dated 26 Dec 2018, establishes the standard procedure regarding the operation and maintenance of the (b) (4) Block BMS. The standard procedure defines critical areas as (b) (4) (b) (4) (b) (4) (b) (4) The standard procedure establishes alarm generation time of (b) (4) for critical areas and for less critical areas.

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Your firm logs alarms in all areas are dependent upon set predetermined times. For example, Class "A" Filling Room in Line (b) (4) for Differential Pressure Alarms are logged after (b) (4) However, your firm does not investigate any nonalarm excursions. Your firm has the following number of alarms and excursions for differential pressure for September 2019:

Line (b) (4)
Filling Room Class "A": Excursion: 1,175 Alarms: 13- (b) (4) (b) (4) %
(b) (4) Loading Area Class "A": Excursion: 173 Alarms: 10- (b) (4) (b) (4) % (b) (4)
Filling Room Class "A": Excursion:146 Alarms:0 (b) (4) %
(b) (4) Loading Area Class "A": Excursion: 1,017 Alarms: 3- (b) (4) (b) (4) %
Lin (b) (4)
Filling Room Class "A": Excursion: 596 Alarms: 20 (b) (4) (b) (4) %

Your firm's Senior Vice President Operations and Associate President Operations confirmed that the company is in the process of evaluating the noted excursions and has proposed a revision regarding the alarm generation time delay from (b) (4)

OBSERVATION 4

Established test procedures are not followed.

Specifically,

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5. Two sets of test articles, (b) (4) mL (b) (4) ampules and (b) (4) sterile (b) (4) were observed undergoing sterility testing on 11/4/19 and 11/12/19, respectively.
    3. (b) (4) bottles, each containing (b) (4) (b) (4) mL (b) (4) ampules (A.R. No.: (b) (4) were observed on 11/4/19 incubating in the 22.5˚C (QC (b) (4) -001) and 32.5˚C (QC (b) (4) 002) (b) (4) incubators. Specifically, the (b) (4) mL (b) (4) ampules were observed floating above the sterility test medias (b) (4) and were not (b) (4) as prescribed in procedure GTP037-12 ure Effective 18 Mar 2019. The ampules were used in Line (b) (4) media fill validation MF/L03A/002/19 and are typically used for manufacturing US marketed product, (b) (4) Injection, USP (b) (4)% (b) (4) mg/mL).
    4. (b) (4) bottles, each containing (b) (4) sterile (b) (4) (A.R. No.: (b) (4) respectively) were observed on 11/12/19, incubating in the 22.5˚C (QC (b) (4) -001) and 32.5˚C (QC (b) (4) 002) (b) (4) incubators. Specifically, portions of the (b) (4) were observed floating above the sterility test medias (b) (4) (b) (4) and were not (b) (4) as prescribed in procedure GTP037-12 Sterility Test Procedure Effective 18 Mar 2019. Sterile (b) (4) are typically used in aseptic manufacturing operations and to conduct sterility testing.

OBSERVATION 5

An (b) (4) ield Alert Report was not submitted within three working days of receipt of information concerning bacteriological contamination and significant chemical, physical, or other change or deterioration in a distributed drug product.

Specifically,

Your firm received complaint, APL-FU4-2019-USA-PCM-00107, on 11 July 2019, for (b) (4) Injection (b) (4) ng/vial - (b) (4) mL Vial -USA Market, Batch No. (b) (4) from a health ca (b) (4)

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(b) (4) particles were observed during (b) (4) of (b) (4) Your firm's SOP: CQA-CP-GEN-024, "*Field Alert Reporting*" states a FAR shall be submitted within three (3) National working days for significant chemical, physical, or other deterioration in the distributed drug product, including, but not limited to: foreign contamination and particulates. Your firm's investigation of this complaint did not address the (b) (4) particles observed and your firm did not submit a FAR in accordance with your written procedures.

OBSERVATION 6

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

Specifically,

Your firm received at least ten (10) complaints for lack of effect (LOE) for at least (b) (4) different batches of (b) (4) Injection (b) (4) mg (b) (4) mL for the US Market from November 2018 – November 2019. During our review of this complaint, we observed a trend associated with your (b) (4) USP vendor. For example, all (b) (4) finished batches of (b) (4) associated with complaints for LOE, manufactured at your facility are associated with lots received from your API vendor prior to July 2018. Furthermore, your firm did not receive any LOE complaints for batches manufactured using (b) (4) (b) (4) USP after June 2018 from this same vendor.

On 12 November 2019, your firm's Senior General Manager for Corporate Quality Assurance, contacted your (b) (4) USP vendor, requesting a list of (b) (4) change notifications. Your vendor made a change in the intermediate manufacturer on 12 June 2018. Your firm's Quality Assurance Department who

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initiated these investigations did not include a comprehensive review of your firm's raw materials (e.g. API vendor batch trending).

The following (b) (4) Injection (b) (4) mg/(b) (4) mL batches associated with these complaints were distributed to the US Market from November 2018 – November 2019:

API Vendor Batch Number	Finished Product Batch Number	Mfg. Date	Exp. Date	Quantity Dispatched
(b) (4)				

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(b) (4)

(b) (4)

OBSERVATION 7

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically,

As per the QC Head of Microbiology, Out-of-Limits (OOL) environmental monitoring evaluations specific to the recovery of *Bacillus spp*. in Grade A areas, do not include the assessment of high-risk areas of possible microbial contamination (e.g. change rooms for employees to remove street shoes and clothes and don factory attire).

The following OOLs were reviewed along with supporting environmental monitoring records, which documented either Nil (zero CFU counts) or CFU's below alert limits in surrounding classified areas:

Date of	OOL	Grade	Organism	Activity	Line	Sampling

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Sampling	ID#				(b) (4)	Location
8/28/18	EM/OOL /125/18	A	*B.amyloliquifaciens*	Filling/Media Fill (MF/LS2/004/18)		
8/30/18	EM/OOL /127/18	A	*B.amyloliquifaciens*	Filling/Media Fill (MF/LS2/004/18)		
8/29/18	EM/OOL /128/18	A	*B.amyloliquifaciens*	Filling/Media Fill (MF/LS2/004/18)		
8/30/18	EM/OOL /129/18	A	*B.amyloliquifaciens*	Filling/Media Fill (MF/LS2/004/18)		
10/20/18	EM/OOL /176/18	A	*B.amyloliquifaciens*	Filling/(b) (4) (b) (4) Injection, Batch (b) (4) (b) (4)		

The following Drug Products are manufactured on Block (b) (4) Lines (b) (4) and (b) (4) Block, (b) (4) or the US Market and Canada:

Drug product name	Dosage form	Line
(b) (4)		

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(b) (4)

OBSERVATION 8

Records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

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	June P Page, Investigator Thomas J Arista, National Expert Marie B Buen-Bigornia, Microbiologist Freddy Ortiz Colon, District Administrative Personnel Dipesh K Shah, Office of International Programs Employee	X June P Page Investigator Signed By 2000405709 Date Signed 11-13-2019 17 49 54	11/13/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/4/2019-11/13/2019* FEI NUMBER 3008461619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Rajesh Shashikant Kulkarni, Vice President - QA/QC

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited - Unit IV	Plot Nos. 4, 34 To 48, EPIP, TSIIC, IDA, Pashamylaram, Patancheru Mandal, Sangareddy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medak District, Hyderabad, Telangana, 502307 India	Sterile Drug Manufacture

The (b) (4) computer-based system captures alarmed events and/or errors that occur during the (b) (4) process. Some of the alarmed events include for example, but are not limited to:

Category	*Alarm*	*Cause for alarm*	*Set value*
(b) (4)	(b) (4) Abnormal alarm	(b) (4)	≤ (b) (4) Mpa pressure ± (b) (4) Mpa
		(b) (4)	≤ (b) (4) °C temperature
		(b) (4) Pressure	≤ (b) (4) Mpa (Difference from (b) (4)
		Over current	≤ (b) (4) AMPS
		(b) (4) too hot / overload	≤ (b) (4) AMPS
(b) (4)	(b) (4)	(b) (4) pressure	≥ (b) (4) Mpa Pressure
(b) (4)	(b) (4) abnormal alarm	(b) (4) (b) (4) mal	≤ (b) (4) C temperature
(b) (4)	Air pressure abnormal	Air pressure abnormal	≥ (b) (4) Mpa
(b) (4)	(b) (4) pressure abnormal alarm	(b) (4) pressure abnormal	≥ (b) (4) Mpa Pressure @ < (b) (4) °C
(b) (4)	(b) (4) pressure abnormal alarm	(b) (4) pressure abnormal	≥ (b) (4) Mpa Pressure
(b) (4)	Power abnormal alarm	(b) (4) power abnormal	≥ (b) (4) V current

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(b) (4)	(b) (4) signal abnormal alarm	(b) (4) power abnormal	≥(b) (4) V current

The Production Executive, the Senior Executive(b) (4) and the Vice President Operations explained th(b) (4) computer system will initiate an audio and visual alarm when the above set points are not within the established limits. However, the computer does not register or has the capacity to register the specific values that caused the alarmed event to occur. Currently, there is no record to documentation the specific values that generated the alarmed events; a lack of data limits the ability for(b) (4) Production personnel and Quality Assurance to adequately evaluate the causality of the alarmed ev o initiate any form of corrective measure.

In addition, the following table is a summary of the most frequent(b) (4) alarmed events that occurred in FY 2019. Please note, this summary is not intended to be an all-inclusive or an exhaustive list of the alarmed events that occur during the routine(b) (4) processing.

FY-2019			
Block	**Alarm**	(b) (4)	**Frequency**
(b) (4)	(b) (4) abnormal alarm	001	174
		002	199
		003	173
(b) (4)	(b) (4) abnormal alarm	001	45
		002	40
		003	41
(b) (4)	Alaus System communication abnormal alarm	001	33
		002	21
		003	36

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Medak District, Hyderabad, Telangana, 502307 India	Sterile Drug Manufacture

(b) (4)	(b) (4) bnormal alarm	001	29
		002	40
		003	44
	(b) (4) signal abnormal	001	27
		002	22
		003	31
	(b) (4) signal alarm	001	27
		002	22
		003	26
	(b) (4) signal abnormal alarm	001	26
		002	19
		003	30
FY 2019			
Bloc (b) (4)	(b) (4)	(b) (4)	40
	(b) (4) abnormal alarm		39
	(b) (4) abnormal alarm		27
	(b) (4) ignal abnormal		25
	(b) (4) abnormal alarm		25
	(b) (4) (b) (4) abnormal alarm		19
	(b) (4) alarm		16
Block (b) (4)	(b) (4) communication failure	(b) (4)	535
	(b) (4) abnormal alarm		206
	(b) (4)		56

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Date Signed 11-13-2019 17 49 54

DATE ISSUED
11/13/2019

	communication failure		
	(b) (4) abnormal		54
	(b) (4) abnormal alarm		33
	(b) (4) abnormal alarm		31
	(b) (4) bnormal alarm		27

The Senior Vice President of Operations confirmed that they do not trend the alarmed events. There is no data to document that the alarmed events have been evaluated, collectively, to ensure that the alarmed events are not drifting away from the validated state of control.

OBSERVATION 9

The establishment of specifications, standards, sampling plans, test procedures and laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically,

Your lab does not perform enough quality control check test to ensure the analyst is performing the test analysis adequately on a consistent basis. This additional test becomes important since your firm's policy does not require analysts to be qualified on the test that they are performing. This information was corroborated by your firm's Senior General Manager for QC Laboratory Compliance. For example, but are not limited to; the product (b) (4) Injection on assay test analysis performed on Nov. 2nd, 2019 sample set name (b) (4)

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(b) (4) presents a typical sample data set including blank, system suitability (precision), standard agreement and (b) (4). No additional test analysis is included to ensure analyst proficiency.

OBSERVATION 10

Laboratory records are deficient in that they do not include the initials and signature of the person performing the tests and the dates the tests were performed.

Specifically,

Your QC lab worksheets do not document all analyst participation when multiple analysts perform parts of the test analysis as required by lab procedures. The SOP# FU4-QC-GEN-020 establishes "whenever more than one analyst involved in the analysis; respective analyst shall record preparations and signs …". However, there is no areas were additional analysts can sign. Furthermore, your firm's common practice is to assign the sample for test analysis to an analyst; however, one or more analysts can perform several parts during the same test analysis such as standard preparation, sample preparation, instrument setup, processing, calculations and LIMS data entry. In any of these cases, different analysts can be involved; however, on the worksheet only one analyst signs at the end of the document. Your firm's QC Senior General Manager Laboratory Compliance and General Manager QC Laboratory confirmed multiple analysts can perform tasks for the same test analysis.

OBSERVATION 11

Employees are not given training in the particular operations they perform as part of their function.

Specifically,

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Your firm's SOP# FU4-QC-CI-GEN-008 "Qualification Analyst in Quality Control" fails to require experienced analysts (senior executive & assistant managers) to be qualified in any test at the time to be hired. Additionally, the SOP require analysts to be requalified (b) (4) as required by the standard operating procedure. Furthermore, the current policy related to analyst qualification allows the analysts to be assessed in any test analysis regardless of the product or complexity of the test.

For example, but not limited to, for product (b) (4) Injection USP (b) (4) mg in (b) (4) mL ((b) (4) mg/mL) (b) (4) batch (b) (4) (b) (4) analysts conducted mobile phase, standard preparation, and sample preparation. A (b) (4) analyst enter the data into Laboratory Information Management System (LIMS) and the analyst qualification for analyst (b) (4) shows both were qualified for assay and related substances in 2016 but no requalification test has been performed.

OBSERVATION 12

The design history file does not demonstrate that the design was developed following the approved design plan.

Specifically,

Your design history file for (b) (4) Injection USP with (b) (4) number (b) (4) s inadequate because the design and deve ved date of (b) (4) oesn't include major design tasks, product milestones or key decision points. It only contains tasks / activities of the design.

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In addition, your firm doesn't have a design history file for commercialized products: (b) (4) Injection (b) (4) and (b) (4) Injection UPS (b) (4) and filed products: (b) (4) (b) (4) USP (b) (4) (b) (4) Injection (b) (4) and (b) (4) tion (b) (4) A dent of Research and Development confirmed that the above products do not have device history files.

OBSERVATION 13

The design review results, including the date and the individual(s) performing the review, were not documented in the design history file.

Specifically,

Your design review document titled 'Design and Development Plan' for (b) (4) Injection USP with (b) (4) number (b) (4) is not signed and dated by Production, Research and Development and Quality Departments. This document only states that these tasks such as Design Inputs based on user/Patient needs, Design Review, Design Verification, Design Validation Design Transfer and other activities only has been "Completed".

OBSERVATION 14

Design input requirements were not adequately documented.

Specifically,

Your firm did not document Biocompatibility studies, Leachability studies and sterilization during design input for (b) (4) Injection USP with (b) (4) number (b) (4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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*DATES OF INSPECTION

11/04/2019(Mon), 11/05/2019(Tue), 11/06/2019(Wed), 11/07/2019(Thu), 11/08/2019(Fri), 11/11/2019(Mon), 11/12/2019(Tue), 11/13/2019(Wed)

X Thomas J Arista
National Expert
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Date Signed: 11-13-2019 17:50:52

X Marie B Buen-Bigornia
Microbiologist
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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: Not annotated

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Annotations to Observations

Observation 9: Not annotated

Observation 10: Not annotated

Observation 11: Not annotated

Observation 12: Not annotated

Observation 13: Not annotated

Observation 14: Not annotated

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