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	1/29/2024-2/9/2024*
	FEI NUMBER 3005210225

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajesh Kshirsagar, Chief Operating Officer - Regulated Markets

FIRM NAME	STREET ADDRESS
Micro Labs Limited	Plot# S - 155, & N1 Phase Iii & Phase Iv; Verna Ind Estate Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Verna, Goa, 403722 India	OSD Drug Products Manufacturer (Potent and General Products)

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:
QUALITY SYSTEM

OBSERVATION 1

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

Specifically,

A. The following batches of drug products had valid OOS results but were released by QA and distributed into the US market from October-2019 to December-2023. During this inspection, your firm recalled (b) (4) of these batches from the US market.

Table 1

Valid OOS LOG From 10/2019 to 12/2023 for US Product (Commercial)

Sr. No.	Product	Batch No.	Dispatch Date of Finished Product into the US Market	Section	Confirmed OOS Result
1	(b) (4) Tablets USP (b) (4) mg	(b) (4)		IP (PV)	Assay by HPLC
2	(b) (4) Tablets USP (b) (4) mg			IP (PV)	Assay by HPLC
3	(b) (4) Tablets USP			PV (Com)	Assay by HPLC

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	(b) (4) mg			
4	(b) (4) Tablets USP (b) (4) mg	(b) (4)	IP	Assay by HPLC
5	(b) (4) Tablets (b) (4) mg		PV (Com)	Dissolution by HPLC
6	(b) (4) Tablets (b) (4) mg		PV (Com)	Particle size distribution
7	(b) (4) Capsules (b) (4) mg		PV (Com)	Particle size distribution
8	(b) (4) Tablets (b) (4) mg		PV (Com)	Assay by HPLC
9	(b) (4) Tablets USP (b) (4) mg		IP	(b) (4) by HPLC
10	(b) (4) Tablets USP (b) (4) mg		IP	(b) (4) by HPLC
11	(b) (4) tablets (b) (4) mg and (b) (4) mg		PV (Com)	(b) (4) by GC
12	(b) (4) Capsules USP (b) (4) mg.		IP	(b) (4) by HPLC

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13	(b) (4) Tablets USP (b) (4) mg	(b) (4)	P	(b) (4) by HPLC
14	(b) (4) Tablets USP (b) (4) mg		P	(b) (4) by HPLC
15	(b) (4) Tablets (b) (4) mg and (b) (4) mg.		PV (Com)	(b) (4) by GC

Note: IP (PV): In-process Process Validation Stage, PV (Com): Process Validation Commercial

The "CERTIFICATE OF COMPLIANCE" that is issued at the release of the batch requires the batch to meet all in-process tests, release tests as well as have no deviations or changes that have an impact on the Safety, Integrity, Strength, Quality and Purity of the product. However, your Site Quality Unit Head signed and dated the "CERTIFICATE OF COMPLIANCE" and released the above referenced batches into the US market with confirmed failing test results. In addition, your Site Quality Unit Head completed a "Batch release checklist" for each batch relating to QMS events for the OOS investigations by selecting "Yes" for Complies with the specification for OOS investigations instead of selecting "No" despite the associated OOS investigation concluding as "Valid".

Based on the above observed issues, your firm filed Field Alert Reports (FARs) to the agency on 02-Feb-2024 and 05-Feb-2024 and initiated Recalls for inadequacies on your OOS investigations for (b) (4) Tablets USP (b) (4) mg (b) (4) Batch Numbers: (b) (4) and (b) (4) Manufacturing date: June 2022, Expiry date: (b) (4) Batch Size: (b) (4) tablets and (b) (4) Tablets (b) (4) mg (b) (4) Batch Number: (b) (4) Expiry date: (b) (4) Batch Size: (b) (4) tablets.

B. The Quality Unit does not have oversight of equipment cleaning documentation to assure it

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appropriately reflects the required cleaning operations. For example, per step number (b) (4) of the Type A cleaning procedure for the (b) (4) they are to be cleaned by (b) (4) water (b) (4) (b) (4) to rinse (b) (4) surface of (b) (4) Duct, (b) (4) Duct, and its gasket. However, I observed these areas were not cleaned when they were opened during inspectional walkthroughs as multiple (b) (4) (b) (4) Ducts appeared completely encrusted with powdery materials, along with the presence of contaminated water in the immediate vicinity of (b) (4) Duct damper located at the (b) (4) Your production officers completed each "Equipment Cleaning Record of (b) (4) by handwriting the time details for "From" and "To" for this approximately (b) (4) activity without conducting cleaning of the (b) (4) Duct, (b) (4) Duct and its gasket that is required for a Type A cleaning. On 07-Feb-2024, your production employees and leadership team acknowledged that the (b) (4) were only cleaned in the areas of ducts that are visible from the processing area.

Further, the manual equipment cleaning procedure for the (b) (4) is deficient in that there is no mention of the quantity of (b) (4) water to be used for cleaning purpose, along with water (b) (4) and duration for which the cleaning to be performed to achieve cleaning of the equipment consistently each time. In addition, there is no mention about the opening of (b) (4) and (b) (4) dampers for cleaning purpose during Type A cleaning.

C. The Quality Unit does not have appropriate oversight on the review of raw microbiological data. On February 1, 2024, we observed an environmental settle plate identified as (b) (4) with visible colonies collected on 01/25/2024 in the (b) (4) Dispensing area in Room (b) (4) The initial count was 36 colony forming units (cfu) counted by a Microbiologist which was checked by a Senior Executive- Quality Control and then approved by your Manager-QC Microbiology. However, upon our visual observation of the plate, there were several colonies that did not appear to be counted. A re-count conducted by another microbiology analyst resulted in 67 cfu. The Senior Executive- Quality Control admitted that he does not verify counts on the plate rather he verifies the number on the colony counter display and signs off on the document. No verification of initial counts by the microbiologist is performed therefore there

is no assurance that the raw counts are accurate which are used in environmental monitoring of your production areas, [redacted] (b) (4) samples and microbial limit release testing of finished drug products such as [redacted] (b) (4) USP capsules and [redacted] (b) (4) USP capsules.

FACILITY AND EQUIPMENT SYSTEM

OBSERVATION 2

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

Specifically,

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

Table 2

[redacted] (b) (4)

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[redacted] (b) (4)

* Relocated from [redacted] (b) (4) area [redacted] (b) (4) to [redacted] (b) (4) area on 10/09/09.

On 29-Jan-2024, we observed thick build-up of white to off-white, [redacted] (b) (4) and [redacted] (b) (4) [redacted] (b) (4) color powdery materials inside Air Purification Units (APUs) on [redacted] (b) (4) HEPA filter and its chamber and throughout the [redacted] (b) (4) Ducts of your [redacted] (b) (4) IDs: MLG/PR/12.203, and MLG/PR/12.204 [redacted] (b) (4) Facility [redacted] (b) (4) and MLG/PR/12.205 [redacted] (b) (4) [redacted] (b) (4) Facility [redacted] (b) (4)

We also observed [redacted] (b) (4) ID: MLG/PR/ [redacted] (b) (4) Facility [redacted] (b) (4) contained [redacted] (b) (4) coloration along with off-white color powdery residues inside Air Purification Unit (APU) on [redacted] (b) (4) HEPA filter and its chamber.

Similarly, white to off-white to [redacted] (b) (4) and black color powdery materials were observed on [redacted] (b) (4) HEPA filter and its chamber and throughout the [redacted] (b) (4) Duct of [redacted] (b) (4) IDs: MLG/PR/07.015 [redacted] (b) (4) Facility [redacted] (b) (4) and MLG/PR/09.009 [redacted] (b) (4) Facility - [redacted] (b) (4) Along with powdery materials, we also observed continuously dripping water along with a water

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

puddle inside the chamber of the APUs (between (b) (4) and (b) (4) HEPA filters) for MLG/PR/09.009 (b) (4) Facility (b) (4) The areas post (b) (4) HEPA filters were wet on many sections and indicative of potential bacterial, yeast and mold growth due to discoloration of powdery materials and equipment surfaces to (b) (4) and blackish color.

Additionally, white to off-white color powdery materials were also observed inside (b) (4) HEPA filter and its chamber and throughout the (b) (4) Duct of (b) (4) IDs: MLG/PR/07.014 (b) (4) (b) (4) Facility (b) (4) This non-dedicated (b) (4) is used in the manufacturing of potent drug product (b) (4) Tablets (b) (4) mcg and (b) (4) mcg (b) (4)

The area and equipment status of these (b) (4) on 29-Jan-2024 are as follows:

Table 3

Sr. No.	Area	Equipment ID	Area status on date of inspection
1	(b) (4) (b) (4) facility	MLG/PR/09.009	Type B cleaned and under campaign manufacturing of (b) (4) mg Batch no. (b) (4)
2	(b) (4) (b) (4) facility	MLG/PR/07.014	Type A Cleaned
3	(b) (4) (b) (4) facility	MLG/PR/07.015	Type B cleaned and under campaign manufacturing of (b) (4) mg Batch no. (b) (4)
4	(b) (4) (b) (4) facility	MLG/PR/12.203	Under Type A cleaning
5	(b) (4) (b) (4) facility	MLG/PR/12.204	Type A Cleaned

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6	(b) (4) (b) (4) facility	MLG/PR/12.205	Type B cleaned and under campaign manufacturing of (b) (4) mg Batch no. (b) (4)
7	(b) (4) (b) (4) facility	MLG/PR/12.206	Type B cleaned and under campaign manufacturing of (b) (4) mg Batch no. (b) (4)

These five (5) non-dedicated (b) (4) (MLG/PR/09.009, MLG/PR/07.014, MLG/PR/07.015, MLG/PR/12.203, and MLG/PR/12.204) among the total (b) (4) are used in the manufacturing of (b) (4) drug products of which the following drug products at varying strengths are sold into the US market:

(b) (4)

On Jan-29, 30 and Feb-05-2024, your firm collected multiple swab samples from different locations of (b) (4) HEPA filter chambers and (b) (4) Ducts of non-dedicated (b) (4) (MLG/PR/07.014, MLG/PR/07.015, MLG/PR/12.203, and MLG/PR/12.204) and analyzed swab samples for chemical analysis by HPLC to identify the presence of drug substances of the previously manufactured drug

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products. Test data revealed the presence of different drug substances present as high as up to about (b) (4) times the acceptance limit indicating a potential risk for drug products cross-contamination with other drug products active materials (drug substances) that were manufactured using these (b) (4) Swab samples test results for chemical analysis by HPLC are tabulated as follows:

Table 4

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	DATE ISSUED 2/9/2024

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(b) (4)

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(b) (4)

Note: The swab locations with the highest test results are only listed in the above table.

Furthermore, swab samples testing of (b) (4) (Table 4) showed numerous unknown peaks, many of which had an area response several times higher than the known active peak, 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 table. There is a potential that the unknown peaks could be due to active and degradant materials of drug products manufactured using these (b) (4) Your firm did not attempt to identify any of these unknown peaks during the inspection.

On Jan-29 and 30-2024, the swab and (b) (4) samples were collected by your firm from the areas of APU at (b) (4) The testing of these samples revealed TNTC (Too Numerous To Count) microbial, fungal, yeast and mold colonies. There is a potential for microorganisms, fungal, yeast and mold grown inside these areas of APUs and (b) (4) to get carried with the high velocity air through the (b) (4) (b) (4) Duct in to these (b) (4) and potentially contaminate the product while it is used for the

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manufacturing of drug products.

Table 5

(b) (4)

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(b) (4)

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Following the swab sample and (b) (4) sample results, your firm reported Field Alerts for the eleven (11) drug products (b) (4) (b) (4) to the FDA during the current inspection indicating the risk for cross-contamination.

Your firm has deviated from (b) (4) cleaning procedures: ML06/SOP/PRCL/0067-005, effective date: 04/08/2022 and ML06/SOP/PRCL/0014-010, effective date: 23/08/2022. Per the Type A (product changeover) cleaning sections, production employees are required to clean the (b) (4) surfaces of (b) (4) (b) (4) and (b) (4) Ducts each time.

B. Your firm has not established a cleaning procedure and periodically cleaned the following non-dedicated tablets (b) (4) machine's APU along with (b) (4) and (b) (4) Ducts:

Table 6

(b) (4)

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[redacted] (b) (4)

These non-dedicated [redacted] (b) (4) machines are used in the [redacted] (b) (4) process of drug products sold into the US market along with the domestic, ROW, and other regulated markets. There is a potential for carryover of powdery materials deposited inside the areas of APUs and [redacted] (b) (4) Duct to get carried with the high velocity air through the [redacted] (b) (4) Duct into these [redacted] (b) (4) machines and potentially contaminate the product while it is used for the manufacturing of drug products.

C. On 01-Feb-2024, your Deputy General Manager of Production, Assistant Production Manager, Deputy Manager of QA, Senior Executive of QA, along with Senior Officer and Executives of Engineering departments stated during interviews that they had raised concerns and informed site leadership about the presence of large quantity of powdery materials found inside each of the [redacted] (b) (4) and [redacted] (b) (4) machine's [redacted] (b) (4) and [redacted] (b) (4) Ducts while cleaning activities were underway from June 2022 to July 2023. Per their instructions, the powdery materials were removed and disposed through Hazardous Waste Practices making an entry into the logbook for the quantity of powdery materials disposed. The verification of an entry in the Hazardous Waste Management logbook revealed between [redacted] (b) (4) kg to [redacted] (b) (4) kg of powdery materials being disposed into the waste. This [redacted] (b) (4) and [redacted] (b) (4) Ducts cleaning activity was performed for all [redacted] (b) (4) and Tablets [redacted] (b) (4) machines by your third-party contract cleaning services provider. The evaluation of the third-party cleaning revealed the following observations:

1. The cleaning was restricted to [redacted] (b) (4) and [redacted] (b) (4) Ducts only and there was no cleaning performed on APU's [redacted] (b) (4) HPEA filters and its assembly connecting to the [redacted] (b) (4) Duct leading the filtered air

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	DATE ISSUED 2/9/2024

to the [redacted] (b) (4)

2. No swab samples were collected from the [redacted] (b) (4) and [redacted] (b) (4) Ducts post completion of cleaning activities to evaluate the effectiveness of cleaning.

3. There was no risk assessment and no impact assessment performed by your firm in regard to the [redacted] (b) (4) kg to [redacted] (b) (4) kgs quantity of powdery material found inside the [redacted] (b) (4) and [redacted] (b) (4) Ducts.

D. Your Preventative Maintenance (PM) of [redacted] (b) (4) is deficient for the following reasons:

1. Your firm simply focused on replacing the [redacted] (b) (4) HEPA filters of APUs without understanding the purpose of these filters. For example,

On 28-Jan-2024 (one (1) day prior to the start of this inspection), your Engineering Unit in coordination with Production and Quality Units replaced the [redacted] (b) (4) HEPA filters of [redacted] (b) (4) IDs: MLG/PR/12.203 and MLG/PR/12.204 [redacted] (b) (4) Areas [redacted] (b) (4) However, the APU chamber of these [redacted] (b) (4) HEPA filter and [redacted] (b) (4) [redacted] (b) (4) Duct surrounding these HEPA filters in the direction of air toward [redacted] (b) (4) were observed completely encrusted with white to off-white powdery materials on 29-Jan-2024. Your Engineering, and Quality focused on following the timeline [redacted] (b) (4) for the replacement of these filters without understanding the purpose of these [redacted] (b) (4) HEPA filters was to block particles larger than [redacted] (b) (4) and that there should not be any powdery materials present inside the [redacted] (b) (4) Duct and the surrounding areas of [redacted] (b) (4) HEPA filter inside APU. As a result, there were no investigation logged to determine the impact and risk of potential products cross-contamination.

2. Your [redacted] (b) (4) and [redacted] (b) (4) PM and an [redacted] (b) (4) HEPA filter integrity test of [redacted] (b) (4) is deficient as there is no evaluation of the condition of [redacted] (b) (4) HEPA filter and its assembly for the cleanliness.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/29/2024-2/9/2024*
	FEI NUMBER 3005210225

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajesh Kshirsagar, Chief Operating Officer - Regulated Markets

FIRM NAME	STREET ADDRESS
Micro Labs Limited	Plot# S - 155, & N1 Phase Iii & Phase Iv; Verna Ind Estate Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Verna, Goa, 403722 India	OSD Drug Products Manufacturer (Potent and General Products)

3. Your Quality and Product Units has no oversight on the cleaning, PM and [redacted] (b) (4) HEPA filter integrity test of [redacted] (b) (4) Per your procedures ML06/SOP/ENPM/0036-011, ML06/SOP/ENPM/0035-009, and ML06/SOP/ENCL/0004-012 pertaining to cleaning of HVAC filters, and PM of [redacted] (b) (4) Engineering Unit is solely responsible for all these activities.

QUALITY SYSTEM

OBSERVATION 3

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, your laboratory investigations pertaining to Out of Specification (OOS) investigations are not thoroughly investigated and the CAPA taken is incomplete to determine the risk to the drug products sold into the US market. For example,

OOS Investigation No.: OOS:ML06:20061, Date initiated: 25-May-2020, Product: [redacted] (b) (4) [redacted] (b) (4) Tablets USP [redacted] (b) (4) mg, Batch No.: [redacted] (b) (4) Mfg. date: May 2020, Expiry date: [redacted] (b) (4) [redacted] (b) (4) Issue: OOS for Assay by HPLC test (compression tablets). Limit: [redacted] (b) (4) % to [redacted] (b) (4) %, Result: [redacted] (b) (4) %, OOS final classification: Invalid

Your Quality Unit found no assignable root cause during this OOS investigation for the [redacted] (b) (4) sample tested at the compression stage. Despite a valid OOS, your firm concluded this OOS investigation as invalid and released the batch (Batch No.: [redacted] (b) (4)) into the US market based on favorable (passing) test results of Content Uniformity (CU) by HPLC and Assay by HPLC tests.

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Further, your investigation based on interviews of IPQA and Production employees revealed that the IPQA employee [redacted] (b) (6) did not collect in-process sample at the [redacted] (b) (4) interval during the manufacturing. Additionally, another IPQA employee [redacted] (b) (6) falsified the in-process sampling by dividing the [redacted] (b) (4) interval samples into two (2) separate containers and labeled it as the [redacted] (b) (4) interval sample under the name of IPQA employee [redacted] (b) (6) and the [redacted] (b) (4) interval sample under his own name. These samples depicting [redacted] (b) (4) (originally [redacted] (b) (4) sample), and [redacted] (b) (4) intervals were then signed under "Verified by" section by the Production employee. These practices of falsifying samples collection by your IPQA and Production employees were not investigated and there was no impact and risk assessment conducted by Quality Unit for the products sold into the US market. Your firm did not provide any training to employees and the respective departments involved in these practices compromising the integrity of sample collection.

LABORATORY CONTROL SYSTEM

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your Related Substances by HPLC (RS by HPLC) method has not proven to be stability indicating for drug products sold into the US market. For example,

Your Quality Control Unit validated RS by HPLC test methods without obtaining the protocol required [redacted] (b) (4) to [redacted] (b) (4) % degradation for Acid, Alkali (Base), [redacted] (b) (4) Thermal, and Photostability. For example,

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/29/2024-2/9/2024*
	FEI NUMBER 3005210225

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
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1. Product: [redacted] (b) (4) Tablets (b) (4) mg (b) (4) mg, (b) (4) mg (b) (4) mg. (b) (4) mg (b) (4) mg, and (b) (4) mg (b) (4) mg, level of degradation is not evaluated for Acid, Alkali (Base), [redacted] (b) (4) Thermal, and Photostability.

2. Product: [redacted] (b) (4) Capsules (b) (4) mg, [redacted] mg, (b) (4) mg, and (b) (4) mg, Protocol required degradation: (b) (4) to (b) (4) %

Stress condition	%Degradation achieved
Acid	(b) (4) [redacted]
Alkali	
(b) (4) [redacted]	
Photolytic	
Thermal	

3. Product: [redacted] (b) (4) Capsules (b) (4) mg, and (b) (4) mg, Protocol required degradation: (b) (4) to (b) (4) %

Stress condition	%Degradation achieved
Acid	(b) (4) [redacted]
Alkali	
(b) (4) [redacted]	
Photolytic	
Thermal	

4. Product: [redacted] (b) (4) Tablets (b) (4) mg, Protocol required degradation: (b) (4) to (b) (4) %

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	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/29/2024-2/9/2024*
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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Verna, Goa, 403722 India	OSD Drug Products Manufacturer (Potent and General Products)

Stress condition	%Degradation achieved
Acid	(b) (4)
Alkali	
(b) (4)	
Photolytic	
Thermal	

5. Product: (b) (4) Tablets (b) (4) mg, Protocol required degradation: (b) (4) to (b) (4) %

Stress condition	%Degradation achieved
Acid	(b) (4)
(b) (4)	
Photolytic	
Thermal	

B. Standard Test Procedures (STPs) used in the analyses of swab samples analyses are deficient. For example,

1. Your STPs are deficient in that there is no mention of the type of swab stick to be used for collecting swab samples for chemical and microbial analyses. I observed the following issues pertaining to the type of swab stick used by your firm:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/29/2024-2/9/2024*
	FEI NUMBER 3005210225

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a. Your firm has not performed swab suitability and swab recovery studies to scientifically establish that the [redacted] (b) (4) Swab with [redacted] (b) (4) Stick is suitable for its intended use in the collection of residual powdery materials from the equipment surface such as [redacted] (b) (4) and [redacted] (b) (4) Your firm provided no justification about the suitability of this swab stick in collecting residual powdery materials from different surfaces and reliability of swab samples test results for the drug products manufactured using non-dedicated equipment for the US and all other markets.

b. On Jan-29 and 30-2024, the swab samples collected using [redacted] (b) (4) Swab stick" was able to retain very slight residual powdery materials on it indicating if the suitable swab sticks were used for collecting swab samples, then the actual test results could be several times higher than the reported (Table 4).

c. The [redacted] (b) (4) material did not appear to sufficiently retain powdery materials due to the very soft and slippery texture of [redacted] (b) (4) Swab stick". Further, the official labeling of [redacted] (b) (4) Swab stick" indicates "NOT FOR DRUG USE". Your firm provided no justification for the suitability of these swab stick's use in sampling from different equipment surfaces.

2. Your IPQA personnel's swabbing techniques were inadequate in collecting swab samples. For example, On Jan-29-2024, your IPQA personnel swab sample collection technique was observed inconsistent with the expectations described in your procedure number: QAP/ML06/0023-012, Titled: CLEANING VALIDATION, Effective date: 30-Aug-2023. Per section 5.9.3 "For swab sampling, [redacted] (b) (4) However, we observed your IPQA personnel was collecting swab sample by touching only about 30 to 40 % of swab head stick to the equipment surface.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/29/2024-2/9/2024*
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Additionally, per section 5.9.10 swab samples should be collected in the [redacted] (b) (4) motion (which is reflective of [redacted] (b) (4) and [redacted] (b) (4) direction). However, your IPQA personnel was observed collecting swab samples only in one direction which was inconsistent with the expectations defined in your procedure. These practices of inadequately collecting swab test results may lead to unreliable test results.

3. Your STP No.: CVTM [redacted] (b) (4) /R4, effective date: 20-May-2022 for Products: [redacted] (b) (4) Tablets USP [redacted] (b) (4) mg/ [redacted] (b) (4) Tablets [redacted] (b) (4) mg/ [redacted] (b) (4) Tablets [redacted] (b) (4) mg is deficient in that there is no mention of diluent volume to be used for preparing swab sample solution.

4. Your swab solution preparation Standard Test Procedures (STPs) are deficient. For example,

a. On Jan-29-2024, we observed for [redacted] (b) (4) drug substance swab sampling per STP No.: CVTM: [redacted] (b) (4) /R4, only about 30% to 35% of swab head was dipped inside the diluent. As a result of this, there is a potential for only about same percentage of powdery materials may get released into the diluent while preparing swab solution. This will lead to an unreliable and under reporting of the test results as the residual materials present on the remaining about 65% to 70% of swab stick head did not get released into the diluent due to the insufficient volume. This deficiency of insufficient diluent usage for the preparation of swab solution was also observed the following drug products that are manufactured using non-dedicated equipment.

Table 7

Sr. No.	Product Name	STP No.	Diluent
1	[redacted] (b) (4) Tablets (b) (4) mg (b) (4) mg	CVTM: [redacted] (b) (4)	ML
2	[redacted] (b) (4)	CVTM: [redacted]	ML

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	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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	Suspension (b)(4) mg (b)(4) mg (b)(4) mg		
3	(b)(4) Tablets (b)(4) mg (b)(4) mg (b)(4) mg	CVTM (b)(4)	ML
4	(b)(4) Tablets (b)(4) mg (b)(4) mg (b)(4) mg	CVTM	ML
5	(b)(4) Tablets (b)(4) mg, (b)(4) mg, (b)(4) mg, (b)(4) mg, (b)(4) mg & (b)(4) mg	CVTM:	ML
6	(b)(4) Tablets (b)(4) mg, (b)(4) mg, (b)(4) mg, (b)(4) mg & (b)(4) mg	CVTM:	ML
7	(b)(4) Tablets (b)(4) mg (b)(4) mg	CVTM:	ML
8	(b)(4) Tablets (b)(4) mg and (b)(4) mg	CVTM:	ML
9	(b)(4) Tablets (b)(4) mg (b)(4) mg and (b)(4) mg (b)(4) mg & (b)(4) Tablets (b)(4) mg (b)(4) mg and (b)(4) mg (b)(4) mg	CVTM:	ML

b. On Jan-29 and 30-2024, we observed the swab solution preparation techniques were inadequate to ensure complete extraction of residual materials from the swab stick into the diluent. We observed your IPQA employees upon collection of swab samples placed it inside individual (b)(4) plastic tube made of (b)(4) material. These plastic tubes containing swab stick attached to the lid of these tubes were then closed and placed inside (b)(4) beakers containing about (b)(4)% water. These beakers were then placed inside sonicator (b)(4) for sonication. As a result of using (b)(4) plastic material of swab tube and placing it inside beaker, there was barely any sonication effect being transferred to the solution inside plastic tube. There is a potential for very less powdery materials release to the diluent from the swab stick. This may lead to an unreliable and under reported test results due to the fact the complete sonication effect was never achieved that is necessary for extraction of active (drug substances) from the swab stick.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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QUALITY SYSTEM

OBSERVATION 5

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

Specifically,

Your firm has delayed by over 1.5 year in reporting Field Alerts and taking necessary market action on the products distributed to the US market upon observing large quantity (between [redacted] (b) (4) kg to [redacted] (b) (4) kg) of powdery materials present inside the Air Purification Unit (at [redacted] (b) (4) HEPA filter), along with [redacted] (b) (4) and [redacted] (b) (4) Ducts of all [redacted] (b) (4) and [redacted] (b) (4) machines during the cleaning activity performed between June 2022 to July 2023. The verification of the cleanliness of randomly selected six (6) out of [redacted] (b) (4) [redacted] (b) (4) revealed layers of powdery materials of previously manufactured drug products along with signs of microbial, yeast and mold growth in the areas of [redacted] (b) (4) HEPA filter, and [redacted] (b) (4) Duct. Upon observing this, your firm reported eleven (11) FARs for the drug products sold into the US market (refer to Observation 2). Your lack of investigation along with no reporting of FARs and no market action has allowed potentially contaminated drug products to remain in the US market.

OBSERVATION 6

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

Specifically,

A. On January 29, 2024, poor pipetting techniques were observed by your Microbiology Analyst performing microbial limit testing on environmental swabs. There were visible air bubbles in the

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	Pratik S Upadhyay, Investigator Patty P Kaewussdangkul, Investigator	X Pratik S Upadhyay Investigator Signed By: Pratik S. Upadhyay -S Date Signed: 02-09-2024 12:53:54	2/9/2024

micropipette tips when the sample aliquot was delivered onto the plate for testing therefore, not delivering the full amount required for testing as stated in your written test procedures. Your firm has an SOP entitled, "OPERATION AND CALIBRATION PROCEDURE OF MICROPIPETTE", No. ML06/SOP/QCMB/0034-005, Effective 13/03/2022 which states to "Release the push button slowly and smoothly to aspirate the liquid". However, your written procedures do not explain that the purpose of slowly and smoothly aspirating the liquid is to prevent air bubbles. The last time any of your Microbiology Analysts received training in proper pipetting techniques was back in 2020. Proper pipetting techniques are critical to ensure that testing is performed adequately to ensure microbial recovery. Your firm routinely performs microbial limit release testing for your finished drug products such as [redacted] (b) (4) USP capsules and [redacted] (b) (4) USP capsules.

B. On Jan-29 and 30-2024, we observed your Microbiology Analyst conduct microbial limit tests and tests for specified microorganisms using the pour plate method and [redacted] (b) (4) distinct streaking techniques. According to your Manager-QC Microbiology, written procedures have not been established to describe in detail how to perform the pour plate method to ensure proper distribution of samples and streaking methods utilized. Your firm has approximately [redacted] (b) (4) microbiology analysts to date which have not received uniform training in microbiological laboratory practices. In the absence of written procedures, it is not possible to ensure that microbiology analysts are performing their tests consistently, accurately, and correctly resulting in reliable data.

***DATES OF INSPECTION**
1/29/2024(Mon), 1/30/2024(Tue), 1/31/2024(Wed), 2/01/2024(Thu), 2/02/2024(Fri), 2/05/2024(Mon), 2/06/2024(Tue), 2/07/2024(Wed), 2/08/2024(Thu), 2/09/2024(Fri)