**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Drive, Room 2032<br>Rockville, MD 20857 | 2/6/2023-2/17/2023* |
| | FEI NUMBER<br>3008581988 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Ashish Zitshi, Vice President - Site Head

| FIRM NAME | STREET ADDRESS |
|---|---|
| Cipla Limited | Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic Zone |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Pithampur, District Dhar, Madhya Pradesh, 454775 India | Sterile & Non-sterile Drug Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## PRODUCTION SYSTEM

### OBSERVATION 1

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.

On November 20, 2021, you conducted an aseptic process simulation in the (b) (4) filling Line (b) (4) (suspension line (b) (4) mL)); validation Batch No. (b) (4) This media fill process was carried out following the requirements of validation protocol F/VP/APVSM/01 entitled "Aseptic Process Validation Suspension Manufacturing"; approved on September 14, 2021.

On the fourteenth (14th) day of incubation, you observed turbidity in (b) (4) (b) (4) (b) (4) of (b) (4). The microorganism identified from th cted (b) (4) wa stutzeri-Gram positive soil bacterium. The investigation DEV-1025-2021-00147 attributes the root cause to a (b) (4) in the (b) (4) that may have occurred after (b) (4) inspection during handling or movement of the filled samples, storage, or visual inspection, prior to incubation. No unplanned event was reported in the line during the filling or inspection processes, and no evidence of mishandling of the (b) (4) was documented in the batch manufacturing record or any other laboratory form.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Saleem A Akhtar, Investigator<br>Jose E Melendez, Investigator - Dedicated Drug Cadre | X Saleem A Akhtar Investigator Signed By 2001638440 Date Signed 02-17-2023 16 07 18 | 2/17/2023 |

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According to the media fill acceptance criteria in validation protocol F/VP/APVSM/01, (b) (4) (b) (4) (b) (4) Nonetheless, your Quality Unit approved the questionable media fill batch No. (b) (4) despite the fact that no definitive root cause was identified. Approximately, (b) (4) commercial lots of (b) (4) Suspension (b) (4) mg (b) (4) mL, were released from Line (b) (4) uring the period of January 2022 to December 2022.

## OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, manufacturing process simulation procedures designed to prevent microbiological contamination for the drug products purporting to be sterile are deficient to ensure sterile drugs manufactured in (b) (4) are safe and effective. For example:

A. The firm manufactures sterile solutions and suspensions for the US market in (b) (4) filling lines by using (b) (4) machines in (b) (4) The (b) (4) area (b) (4) is maintained as a Grade A area that is (b) (4) a Grade C area. During filling operations some portion of the (b) (4) (about (b) (4) mm) are exposed to the Grade C area when the (b) (4) (b) (4) Since January 2021, during batch manufacturing there were 8 instances when power failure occurred in the Grade C area that surrounds the Grade A area as follows:

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| (b) (4) Line | Product | Batch # | Date | Market | Power Failure in Minutes |
|---|---|---|---|---|---|
| (b) (4) | | | | | |

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X Saleem A Akhtar Investigator Signed By 2001638440 Date Signed 02-17-2023 16 07 18

DATE ISSUED
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(b) (4)

During power failure, the filling machine stops, however, the HVAC system in Grade Area (b) (4) keep running as it (b) (4) However, HVAC system in Grade C area does not work during power failure. As per the firm's Aseptic Process Validation Protocols for Solutions and Suspension (# F/VP/APV/01, Version: 27 and F/VP/APVSM/01, Version: 10 respectively) a power failure is not considered an intervention and is not carried out during aseptic process simulation (media fill) studies despite the fact that power failures during routine manufacturing require (b) (4) cleaning, which is considered the worst case intervention. The firm does not have scientific data established through process simulation studies to fully understand the effect that power failures have on the manufactured batch.

B. During the manufacturing of (b) (4) Suspension (b) (4) mg (b) (4) mL, batch (b) (4) on 9/27/2021, (b) (4) cleaning was performed (b) (4) due to the fact (b) (4) rformed at (b) (4) failed due to (b) (4) The (b) (4) cleaning cycle (b) (4) was aborted at about (b) (4) due to (b) (4) The site documented orming (b) (4) cleaning i.e., done at (b) (4) The site did not raise any deviation or investigate what caused the (b) (4) that resulted in failing (b) (4)

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C. During the manufacturing of sterile drug solutions and suspensions in (b)(4) if there is a breakdown such as the (b)(4) or there is a power failure in the Grade C area the firm performs a (b)(4) cleaning (excludes the cleaning of the (b)(4) tank) in the Grade A area. As of 1/1 e site considered (b)(4) cleaning as the worst case intervention that occurs very rarely and it was performed (b)(4) during media fill studies. In contrast, it was observed during the batch recor performed (b)(4) (b)(4) cleaning about (b)(4) times during the batch manufacturing since January 2021 as listed below:

| (b)(4) Line No. | Product Name | Batch No. | Market | Filling Start |
|---|---|---|---|---|
| (b)(4) | | | | |

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(b)(4)

[redacted]

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Since January 2021, the site shipped about (b) (4) batches of sterile drugs manufactured in (b) (4) to the US. Given the frequency that a (b) (4) cleaning is needed during routine batch manufacturing, the firm failed to demonstrate that its decision to perform a (b) (4) cleaning intervention (b) (4) (b) (4) during process simulation is representative of normal operations.

**OBSERVATION 3**

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

**A**. The (b) (4) are located in the (b) (4) (Grade A zone) of the filling line (b) (4) The (b) (4)

Although the smoke studies do not evaluate/demonstrate the laminar flow from the (b) (4) area to prevent microbial contamination, your Report SR/AFP(b) (4) SDC/01 entitled "Air flow Pattern of (b) (4) in Static and Dynamic condition"; approved on October 10, 2022, concluded smoke studies conducted in the solution manufacturing area for filling line (b) (4) were acceptable. The report did not evaluate the air flow pattern (b) (4) that appeared to show turbulence and where the outer surfaces of the (b) (4) is in direct contact with this Grade C Zone.

**B**. The environmental monitoring of the aseptic filling areas in (b) (4) did not ensure that microbial contaminants that could impact critical areas were identified and investigated for (b) (4)

products distributed to the US market.

The filling Lines (b) (4) are used for filling suspension/liquid products. The (b) (4) are located in a room that is classified as (b) (4) area. Within the (b) (4) (b) (4) These activities are in an environment classified as (b) (4) as well. The (b) (4) used for (b) (4) the drug product are located in the (b) (4) of the filling lines that is classified as (b) (4) ar

Between January 6, 2020, and August 30, 2022, your environmental monitoring program did not require collecting surface swab samples from (b) (4) even though during filling, the (b) (4) (b) (4) During this time, a total of (b) (4) commercial lots of drug products (i.e., suspension/solutions) were manufactured/release/distributed in the USA market.

## OBSERVATION 4

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, appropriate controls are not exercised over the computers and related systems used in the manufacturing of commercial drugs to assure original electronic data pertaining to critical process parameters and alarms is backed up, archived, and retained. For example:

A. During the inspection of Sterile Filling Line (b) (4) (equipment ID: (b) (4) ; used to manufacture sterile drugs for the US market) on 2/6/2023, it was observed that the historical data pertaining to

critical process parameters such as (b) (4) etc. and alarms is not available for verification. It was observed the Human Machine Interface (HMI) connected to this machine overwrites the data and does not allow for printing or transferring of the existing data. The operators use a (b) (4) to take photos of the alarms and these alarms are then included with the batch record. However, the (b) (4) on the (b) (4) are subject to deletion. The Site Head stated all other sterile filling lines such as Line (b) (4) (b) (4) lack these controls. Filling Lines (b) (4) are currently used to manufacture sterile drugs for the US market.

B. Similarly, (b) (4) (IDs: (b) (4) used to manufacture non-sterile (b) (4) iquids & suspensions for the US & rest of the world markets in (b) (4) does not allow printing and transfer of electronic data pertaining to critical process parameters (b) (4) (b) (4) etc. and alarms. Manufacturing Head for (b) (4) stated that the alarms pertaining to critical process parameters disappear after being acknowledged by the operators and cannot be retrieved after about (b) (4) As per Manufacturing Head, the firm considers all alarms as non-critical and that's why these alarms are not documented on the batch records and/or equipment use logbooks.

(b) (4) (ID: (b) (4) is routinely used to manufacture (b) (4) Suspension, (b) (4) mg (b) (4) mL for the US market. It takes about (b) (4) to fill a batch of (b) (4) Suspension (batch size: (b) (4) ) on this (b) (4) . Since January 2021, the site shipped about (b) (4) batches of (b) (4) Suspension to the US. The alarms regarding critical process parameters generated during the manufacturing of these batches could not be verified.

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The firm's SOP (1035-B0035, Version: 2.0, Effective Date: 4/30/2021), "Retention and Destruction of Electronic Data" (b) (4) [redacted]

## QUALITY SYSTEM

### OBSERVATION 5

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, procedures related to investigation of written and oral complaints for (b) (4) [redacted] (b) (4) [redacted] mcg are deficiently written or followed. For example:

A. Since 2020 the site distributed (b) (4) [redacted] batches of (b) (4) [redacted] in the US and the number of patient complaints received each year is as follows:

| Year | No. of US batches distributed | No. of US Complaints Received | Batch Size (b) (4) [redacted] Units) |
|---|---|---|---|
| 2020 | (b) (4) [redacted] | 324 | (b) (4) [redacted] |
| 2021 | | 1065 | |
| 2022 | | 1619 | |
| **Total** | | **3008** | |

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The breakdown of complaints specifically for (b) (4) is as follow:

| Year | (b) (4) |
|---|---|
| 2020 | |
| 2021 | |
| 2022 | |

In addition to 3006 complaints, as of 2/4/2023 the firm received about 266 complaints in 2023 that are under investigation. The site did not perform any Health Hazzard Evaluation about these complaints to evaluate if any market action is warranted.

In 01/2021, the firm performed a risk assessment for the complaints received in year 2020 as the patients complained about many issues including but not limited to (b) (4) (b) (4) and stopped working, medication was not (b) (4) (b) (4) is not working etc. On 1/18/2021, the site concluded that adequate measures are available and there is no risk to the product quality and patient safety.

As per your Executive Summary (effective date: 1/31/2023) of complaints for (b) (4) about 2653 (out of 3008 complaints) were related to (b) (4) and about 94 complaints were regarding (b) (4) Together, over 91% (2747/3008) of the complaints are related to the performance of the product. Even with the increasing number of complaints received in subsequent years (2021 and 2022), the QA Site Head stated on 2/16/2023that the firm has adequate controls in place, there is no risk to product quality & patient safety, and the firm's

risk assessment performed on 1/2021 is still valid. The firm's Quality Unit failed to implement effective corrective actions to reduce the number of complaints related to the performance of the product.

B. The firm received two confirmed complaints # COM-1035-2021-01785 (for batch [(b) (4)] manufacturing date: [(b) (4)] expiration date: 9/30/2022) and COM-1035-2021-02088 (for batch [(b) (4)] manufacturing date: [(b) (4)] expiration date: 9/30/2022) on 6/29/2021 and 7/30/2021 respectively. In both complaints the patients reported that the medication was not [(b) (4)]

During the investigation of both complaints, the firm confirmed that a [(b) (4)] [(b) (4)] piece was dislodged somewhere within the [(b) (4)] and got [(b) (4)] The vendor that supplies [(b) (4)] to Cipla examined the impacted samples and confirmed that the observed particle report Cipla has been potentially generated by the damaged [(b) (4)] The vendor reported maintenance work was done on [(b) (4)] when [(b) (4)] batches (vendor lot # [(b) (4)] were manufactured. [(b) (4)] with vendor lot # [(b) (4)] were used in [(b) (4)] batches [(b) (4)] [(b) (4)] The vendor identified [(b) (4)] other [(b) (4)] batches [(b) (4)] supplied almost same time) whe e maintenance work w [(b) (4)] and/or [(b) (4)] during manufacturing. These potentially compromised [(b) (4)] batches of [(b) (4)] vendor were used to manufacture about [(b) (4)] batches of [(b) (4)] batches as below:

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| Vendor Batch no. for (b) (4) | (b) (4) Batch No. | Manufacturing date* | Expiry date* | Shipping date* |
|---|---|---|---|---|
| (b) (4) | | | | |

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(b) (4)

Review of complaint records indicated the customer reported similar complaints pertaining to all aforementioned (b) (4) batches comprising of (b) (4) For example, about 14 similar nature complaints were received for batch (b) (4) manufactured on (b) (4)

C. The firm's complaint SOP (# 1035-G-011, Version: 14), "Handling of Product Complaints" requires all complaints be investigated, reviewed, and closed in (b) (4) In addition, the complaint SOP does not require any formal request for extension and approval in case the complaint investigation is overdue. Some complaints pertaining to (b) (4) were kept open for extended period of time such as 314 day, 278 days, and 210 days without a written justification. It was observed that about 94 complaints pertaining to the performance of (b) (4) drug were kept open for an extended period of time including but not limited to 314 days, 278 days, 210 days. Examples of few complaints is as follows:

| S. # | Complaint | Brief complaint summary | Days |
|---|---|---|---|

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| (b) (4) | Number | (b) (4) | delayed |
|---|---|---|---|
| | COM-1035-2021-01785 | | 314 |
| | COM-1035-2021-02088 | | 278 |
| | COM-1035-2022-01569 | | 210 |
| | COM-1035-2021-00177 | | 189 |
| | COM-1035-2021-00195 | | 183 |
| | COM-1035-2021-02380 | | 183 |
| | COM-1035-2022-01674 | | 183 |
| | COM-1035-2022-01187 | | 170 |
| | COM-1035-2021-01453 | | 155 |
| | COM-1035-2021-02693 | | 154 |
| | COM-1035- | | 149 |

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| (b) (4) | (b) (4) | |
|---|---|---|
| 2022-02314 | | |
| COM-1035-2022-00869 | | 146 |
| COM-1035-2021-02056 | | 139 |
| COM-1035-2021-01757 | | 137 |
| COM-1035-2022-00260 | | 131 |
| COM-1035-2022-00272 | | 127 |
| COM-1035-2021-02998 | | 125 |
| COM-1035-2021-00813 | | 124 |
| COM-1035-2022-02396 | | 121 |
| COM-1035-2021-00735 | | 120 |
| COM-1035-2021-03710 | | 118 |
| COM-1035- | | 118 |

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| | | |
|---|---|---|
| (b) (4) | 2021-00099 | (b) (4) |
| | COM-1035-2022-00417 | 115 |
| | COM-1035-2022-02801 | 115 |
| | COM-1035-2022-00531 | 114 |

## OBSERVATION 6

An (b) (4) Field Alert Report was not submitted within (b) (4) of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically, your Quality Unit failed to submit a Field Alert Report (FAR) as required under SOP (1035-G-0014, Version: 7.0), "Field Alert Report" for complaints received for (b) (4) Complaint reports COM-1035-2021-01785; Lot (b) (4) and COM-1035-2021-02088; Lot (b) (4) received on 06/29/2021 and 07/30/2021, respectively, were related to "drug product (b) (4) During the investigation of both complaints, the firm confirmed that a (b) (4) piece was (b) (4) within the (b) (4) (b) (4) defect was also confirmed by your supplier of the (b) (4) In May 2022, your Quality Unit closed the complaint investigations COM-1035-2021-01785 COM-1035-2021-02088; and dispositioned both as "Confirmed". You used these potentially defective

(b) (4) to manufacture (b) (4) batches of (b) (4) (about (b) (4) units).

The site Quality Head confirmed the firm received similar complaints for all (b) (4) batches. For example, about 14 similar nature complaints were received for batch (b) (4) manufactured on (b) (4) (b) (4) From 2020 to 2022, your firm received approximately 3008 complaints for (b) (4) (b) (4) associated to the performance of the drug product.

## OBSERVATION 7

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

Specifically, your Quality Unit failed to retain numerous original GMP records including records pertaining to (b) (4) ((b) (4) mg/(b) (4) mL) (b) (4) Ampoules, batch (b) (4) and (b) (4) (b) (4) Spray, batch (b) (4) Packaging for these batches were ongoing in (b) (4) respectively at the start of the inspection on 2/6/2023.

A. During inspectional walkthrough of the facility premises at about 9:45 am on 2/6/2023, I observed a truck (License plate: (b) (4) loaded with bags of scrap from (b) (4) The following documents were observ nspection of scrap bags loaded on this truck as well as the bags stored at central scrapyard intended for shredding:

   a. Numerous torn pieces of printer weigh slips pertaining to packaging of (b) (4) (b) (4) Ampoules, batch (b) (4) (intended for (b) (4) market).

   b. Micro lab sample label (b) (4) sample; originating from (b) (4) dated: 2/5/2023) with

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Drive, Room 2032<br>Rockville, MD 20857 | 2/6/2023-2/17/2023* |
| | FEI NUMBER<br>3008581988 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Mr. Ashish Zitshi, Vice President - Site Head | |
| FIRM NAME<br>Cipla Limited | STREET ADDRESS<br>Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic Zone |
| CITY, STATE, ZIP CODE, COUNTRY<br>Pithampur, District Dhar, Madhya Pradesh, 454775 India | TYPE ESTABLISHMENT INSPECTED<br>Sterile & Non-sterile Drug Manufacturer |

QA wet signatures pertaining to (b) (4) batch (b) (4) This batch is intended for the (b) (4) market.

c. An uncontrolled page with handwritten notes specifically for Line (b) (4) and Line (b) (4) (pertaining to (b) (4) indicating specific time period as follow:

d. (b) (4)

e.

Review of records indicated the site packaged (b) (4) Suspension (b) (4) mg (b) (4) mL batch # (b) (4) intended for the US mar (b) (4) perator (b) (6) performed in-process checks for this batch at (b) (4)

f. Many torn pieces of a printed sheet that appeared to have the names of various employees working in the manufacturing areas.

The firm's SOP (1035-G-004, Version: 10.0, Effective Date: 9/19/2022) for "Documentation Control" defines control document as, "a control document is a record having its identification number or footer number associated with the manufacturing, control, and distribution of product". This SOP requires that hard copy of documents/records to be retained for product expiry (b) (4)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Saleem A Akhtar, Investigator<br>Jose E Melendez, Investigator - Dedicated Drug Cadre | X Saleem A Akhtar Investigator Signed By 2001638440 Date Signed 02-17-2023 16 07 18 | 2/17/2023 |

B. You failed to take market action as per your Product Recall Procedure (# 1035-G-0013, Version: 10.0) against (b) (4) batches (# (b) (4) (b) (4) of (b) (4) Suspension that failed to meet stability specifications for viscosity towards the end of the shelf life. These batches were representative for other (b) (4) batches (b) (4) in the market.

Your Site Head stated these batches were manufactured under (b) (4) (b) (4) and were distributed in the Non US market.

## LABORATORY CONTROL SYSTEM

### OBSERVATION 8

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

Specifically, determination of conformance to written specifications of Total Aerobic Microbial Count in (b) (4) used in the manufacturing of sterile and non-sterile dr

(b) (4) are tested in the Micro Lab, (b) (4) as per test method (document # 1035-MM-005-INH, Version: 8.0, Effective Date: 10/7/2022), (b) (4) After incubation, the media plates are inspected for number of colony forming units (CFUs), the photograph of the inspected media plates are taken using (b) (4) oftware)

or (b) (4) and then transferred on the documentation server. Analysis results pertaining to (b) (4) analysis are documented in LIMS and analysis for (b) (4) is documented on paper worksheets.

On 2/6/2022 morning, the micro lab inspected (b) (4) amples/media plates (b) (4) for growth and reported zero CFUs on all these samples. The following significant deficiencies were observed for this analysis:

A. For (b) (4) samples, the results were not entered contemporaneously in LIMS for (b) (4) plate after reading it. The analyst read all (b) (4) samples under the colony counter (that includes verification of sample ID, sample location, date of analysis, and reading the media plate for growth), wrote the number of colonies observed on each plate, made an entry on equipment use logbook indicating start time: (b) (4) end time: (b) (4) and then entered results for all (b) (4) samples in LIMS.

The firm's SOP (# 1035-L-0083), "Microbiological Best Laboratory Practices) requires that the QA reviewer shall verify microbial count on all the plates / test results against reported results. However, there is no evidence that the QA reviewer verified microbial count on all the plates. The only evidence of a QA review for the reported results against the actual test results was available in LIMS. LIMS date/time stamps indicated the review of all (b) (4) samples was completed in about (b) (4) seconds as follows:

| Sr. No. | Sample ID | Observed count (CFU per mL) | Result entered in LIMS at (HH:MM:SS) | Reviewed in LIMS at (HH:MM:SS) |
|---|---|---|---|---|

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| | FEI NUMBER<br>3008581988 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Ashish Zitshi, Vice President - Site Head

| FIRM NAME | STREET ADDRESS |
|---|---|
| Cipla Limited | Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic Zone |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Pithampur, District Dhar, Madhya Pradesh, 454775 India | Sterile & Non-sterile Drug Manufacturer |

(b) (4)

B. The firm's SOP (# UQCP 094, Effective Date: 8/8/2022) requires images/photographs of the media plates be taken after reading the plates either by using (b) (4) software or by a (b) (4) The Micro Lab manager stated (b) (4) software sometimes does not read the media plate barcode. Under these circumstances, the lab uses a (b) (4) to capture the image of the plate. The photographs taken using a (b) (4) are manually uploaded on a

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computer's hard drive. Significant deficiencies observed with the use of a (b) (4) include:

a. The photographs taken by (b) (4) can be deleted any time.

b. The photographs uploaded on the computer hard drive can be deleted any time.

c. The electronic records showing time and date the photograph was taken can be changed on the (b) (4)

The micro lab has been using a (b) (4) to capture images of the media plates since 6/26/2021.

***DATES OF INSPECTION**

2/06/2023(Mon), 2/07/2023(Tue), 2/08/2023(Wed), 2/09/2023(Thu), 2/10/2023(Fri), 2/13/2023(Mon), 2/14/2023(Tue), 2/15/2023(Wed), 2/16/2023(Thu), 2/17/2023(Fri)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Saleem A Akhtar, Investigator<br>Jose E Melendez, Investigator - Dedicated Drug Cadre | X Saleem A Akhtar<br>Investigator<br>Signed By 2001638440<br>Date Signed 02-17-2023<br>16 07 18 | 2/17/2023 |