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	10/19/2023-10/27/2023*
	FEI NUMBER 3002949099

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Ranjana B Pathak, Global Head of Quality

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Ltd.	Surveys 41, 42 Part, 45 Part & 46 Part, Bachupally
CITY, STATE, ZIP CODE, COUNTRY Medchal-Malkajgiri, Telangana, 500090 India	TYPE ESTABLISHMENT INSPECTED 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:

OBSERVATION 1

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, major production equipment used to manufacture (b) (4) dosage drug products is not appropriately cleaned and maintained to prevent contamination. For example:

A. On 19-Oct-2023, we observed (b) (4) materials along with white to off-white color (b) (4) firm's (b) (4) (b) (4) ID: PRE-078. Along with (b) (4) materials inside (b) (4) observed (b) (4) liquid spillage and (b) (4) of (b) (4) and (b) (4) color on the floor underneath (b) (4) ID: PRE-078 while this equipment and the area (b) (4) was in "TO BE CLEANED" status. Production Operators and IPQA employees identified the (b) (4) materials pertaining to the previously manufactured drug products (b) (4) Tablets (b) (4) and (b) (4) Tablets (b) (4) mg and white color (b) (4) material pertaining to the recently manufactured product (b) (4) Tablets USP (b) (4) mg. The sequence of manufacturing these drug products in campaign using (b) (4) ID: PRE-078 included (b) (4) Tablets (b) (4) ((b) (4) usage date (b) (4) , (b) (4) Tablets (b) (4) mg (b) (4) usage date (b) (4) , (b) (4) Tablets (b) (4) mg

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(b) (4) usage date (b) (4) and (b) (4) Tablets USP (b) (4) mg usage date (b) (4)).

On 19-Oct-2023, the firm collected samples (b) (4) (b) (4) (b) (4) materials) from (b) (4) The qualitative analyses of these samples by HPLC revealed the presence of (b) (4) peak in sample injections at the same retention time to that of standard injections indicating potential mix-up and carryover of (b) (4) Tablets USP (b) (4) mg drug product.

B. On 20-Oct-2023, the firm collected additional samples from the (b) (4) surface of (b) (4) (ID: PRE-078) (b) (4) and analyzed those samples by LC-MS/MS method in the firm's QC laboratory. The analyses of samples revealed the similar peak response for (b) (4) actives in the samples and standard injections confirming the presence of these actives in samples collected from the product contact areas of (b) (4) and non-product contact areas of (b) (4) of (b) (4) while this area and equipment was used in the campaign manufacturin (b) (4) Tablets USP (b) (4) mg.

During the inspection, QC Unit of the firm analyzed (b) (4) Tablets USP (b) (4) mg and (b) (4) Tablets (b) (4) mg for Related Substances by HPLC test methods of (b) (4) finished drug products. The analyses revealed the presence of (b) (4) actives in the test samples of (b) (4) Tablets USP (b) (4) mg and presence of (b) (4) active in test sample of (b) (4) Tablets (b) (4) mg. The details of sampling locations, products analyzed, and test results obtained are tabulated below:

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(b) (4)

NA: Not Applicable ND: Not detected

There is a potential that the obtained carryover materials may react with the product components and form unknown impurity which may increase over the period of the product's shelf life. There is no mechanism established by the firm to identify those impurities for all the batches manufactured using (b) (4) across the firm and that the firm has limited number of batches

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(b) (4) on stability (b) (4) depending on pack sizes.

As a result of finding (b) (4) materials of (b) (4) actives in (b) (4) (b) (4) Tablets USP (b) (4) mg drug product, the firm reported Field Alert for (b) (4) (b) (4) Tablets USP (b) (4) mg, Batch Number: (b) (4) Expiry date: 09/2025.

C. The (b) (4) non-dedicated (b) (4) used in the manufacturing of finished drug products at the firm have not been cleaned and verified for cleanliness underneath the mounted platform areas since their installation several years ago. There is a potential for deposition of (b) (4) materials and microbial growth in these areas in all (b) (4) across the facility.

(b) (4)

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(b) (4)

On 20-Oct-2023, we observed (b) (4) deposition and layers of (b) (4) (b) (4) materials underneath the mounted platform of (b) (4) ID: PRE-078. This (b) (4) mounted platform has about (b) (4) through which (b) (4) residues of drug products manufactured in this room (b) (4) may have deposited throughout the machine components of this (b) (4) over the period of several years due to positive air pressure inside the room. Along with the (b) (4) materials, we observed the surface underneath (b) (4) platform had (b) (4) liquid and wet surface across many areas which is indicative of potential microbial growth in those areas of (b) (4) The swab samples were collected from these areas which revealed the presence of fungal growth on mounted platform surface underneath (b) (4) ID: PRE-078.

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(b) (4)

There are (b) (4) drug products manufactured in (b) (4) area of which about (b) (4) are sold into the US market.

D. On 10/19/2023, during the inspection of module manufacturing area/Unit (b) (4) (b) (4) attached to (b) (4) (equipment ID: TEA-01) was observed with two cracks on the (b) (4) Both cracks impacted the (b) (4) surface from (b) (4) This (b) (4) is a

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product contact surface. There is a reasonable chance that the tiny pieces from the cracked (b) (4) (b) (4) can potentially be introduced into the product. Equipment use logbook indicated the firm performed product changeover cleaning on this equipment on 10/18/2023 after manufacturing a US batch of (b) (4) Tablets (b) (4) for (b) (4) mg Tablets, batch # (b) (4)

OBSERVATION 2

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

Specifically, There is a lack of adequate evaluation of equipment conditions upon preventative maintenance, equipment cleaning, and line clearance. For example:

A. On 19-Oct-2023, we observed the firm's production operators and IPQA officers conducted inadequate visual inspection of (b) (4) ID: PRE-078 upon major cleaning (Type (b) (4) . This (b) (4) contained (b) (4) residues of previously manufactured (b) (4) products on (b) (4) and (b) (4) (product contact areas). As a result of this, (b) (4) residues of previously manufactured drug products were observed inside (b) (4) while the firm manufactured (b) (4) (b) (4) Tablets USP (b) (4) mg. In addition to equipment clearance, we observe pertaining to area clearance. There were (b) (4) residues of previously manufactured drug product underneath product (b) (4) and mounted platform of (b) (4) ID: PRE-078 (Refer to OBSERVATION 1A to C).

B. The firm performed (b) (4) preventative maintenance (PM) of (b) (4) ID: PRE-078 on 06-Oct-2023. On 19-Oct-2023, we observed broken (b) (4) sealant along with missing pieces of sealant on many areas of (b) (4) ID: PRE-078. The firm's PM is deficient in that there is no evaluation of uneven, and dent marks on equipment surfaces along with the presence of (b) (4) residues and

potential leakage leading to wet surfaces underneath equipment in the surrounding areas of (b) (4) (b) (4) (Refer to OBSERVATIONS 1A to C and 9B).

OBSERVATION 3

Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products.

Specifically, determination of conformance to written specifications are deficient for TAMC (Total Aerobic Microbial Count) test and TYMC (Total Yeast and Mold Count) test conducted for purified water and drug products.

On 10/19/2023, the colony counter (equipment ID: QCE 739) in micro lab was observed missing the colony counts when the analyst was reading the plates and reviewer was verifying the counted colonies for (b) (4) samples collected on 10/14/2023. For example:

A. The colony counter did not count every colony for multiple samples including LIMS sample # (b) (4) (location: (b) (4) when micro lab analyst (b) (6) pressed the media plate placed on the colony counter (QCE 739) with (b) (6) pen.

B. The colony counter did not count every colony for multiple samples including LIMS sample # (b) (4) (location: (b) (4)) when micro lab reviewer (b) (6) performed the verification of the colonies counted by analyst (b) (6) During the verification pressed the media plate placed on the colony counter (QCE 739) with (b) (6) pen. For this sample, the colony counter failed to count the colony even when the reviewer pressed the plate with such a force that the tip of (b) (6) pen broke.

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This colony counter (QCE 739) has been in use since it was qualified on 7/22/2015. In addition to routine environmental monitoring samples, this equipment has been used for the last six months to test (b) (4) batches ((b) (4) commercial release and (b) (4) stability batches) of drug products for the US market.

C. Discrepancies were observed in number total colony counted by the analyst and the reviewer pertaining to many media plates that were read on 10/19/2023. Following are few examples:

Sample LIMS #	Colony Counts by Analyst	Colony Counts by Reviewer
(b) (4)		

The analyst and reviewer are working in the micro lab for about (b) (4) respectively.

OBSERVATION 4

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, the quality unit failed to investigate deviations and investigations thoroughly that could potentially impact the patient safety and product quality. For example:

A. The firm's Quality Unit did not timely conclude the investigations relating to batch failure and recalled failing batches from the US market. For examples,

The firm's QC unit found failing results for (b) (4) Tablets USP (b) (4) mg, Batch Numbers: (b) (4) Manufacturing date: (b) (4) Expiry date: Jan-2021, Test: Dissolution by HPLC, Stability timepoint: 18 month at 25°C/60%RH. Upon confirming the failing results at (b) (4) on 19-Sep-2020 and 30-Sep-2020. The firm logged-in a single OOT investigation (OOT No.: 420003691, date initiated: 01-Oct-2020) for (b) (4) the lots by underreporting the total number of OOTs. The firm concluded OOT investigation for both the lots as "Valid" i.e. failing to meeting specification limit on 20-Jan-2021. Further, the firm initiated a separate OOS investigation (310019887 and 310019888) on 21-Jan-2021 and filed a Field Alert on 25-Jan-2021 to the agency. The firm concluded the OOS investigation as "Valid" on 11-Mar-2021 which is after crossing (b) (4) shelf life of the product.

There was no justification provided for the delay of over six (6) months in concluding the failing test results investigation for these (b) (4) stability batches. As a result of delayed investigation, (b) (4) Tablets USP (b) (4) mg, Batch Numbers: (b) (4) batches remained available for purchase to the US customers and these batches were not recalled from the US market. On 25-Mar-2021, the firm simply closed FAR without evaluating the impact of

the issues and there was no corrective action taken to avoid the similar events in the future. Additionally, there has been no risk assessment performed for the batches manufactured and sold into the US market in the period of a (b) (4) considering the (b) (4) stability batches failed to meet the specification limits for Dissolution test at 18 month at 25°C/60%RH.

B. The Quality Unit employees' deviated from SOP No.: SOP-GLOB-QC-0011, Titled: Chromatographic Integration Practices, Version: 7.0, Section: 5.3.5 pertaining to "inhibit peak integration procedure". For example,

According to section 5.3.5 - point 2: *"Actual "inhibit integration" timed events should only be utilized to remove the interference of blank / Placebo peaks that are present in the test sample chromatograms as recommended in the respective STP/MoA".*

On 25-Oct-2023, we observed unknown peak in "Test" injection at about (b) (4) in "Typical Chromatograms" of Enantiomeric Purity by HPLC test within Specification & MOA No.: SP-GLOB-000043, Titled: (b) (4) USP, Version 5.0, Effective date: 06-Mar-2023. Subsequent to this, we also observed unknown peak at around (b) (4) in sample test solution of (b) (4) USP API, Batch Number: (b) (4) and standard injections. This unknown peak at around (b) (4) was absent in blank injections and system suitability injection. QC Supervisor of the firm deviated from section 5.3.5 of SOP No.: SOP-GLOB-QC-0011 by applying inhibit peak integration function.

There was no investigation conducted to identify these unknown peaks which were not present historically during the validation of analytical method and qualification of working standards. Further, the firm provided no explanation for the presence of the unknown peak (b) (4) in standard solution injection but not in system suitability injection while the inhouse working

standard used for preparing both standard solutions remained the same.

OBSERVATION 5

The use of instruments, apparatus and recording devices not meeting established specifications was observed.

Specifically, major Laboratory equipment including but not limited to HPLCs, GCs, and UV Spectrophotometers that are actively used in commercial release and stability analysis were observed not meeting the calibration specifications.

In the last three years the firm initiated 40 incident reports when laboratory equipment failed to meet routine calibration specifications. Two of the forty incidents are listed below

Incident No	Date Reported	Equipment name	Equipment ID	Description Of Incident
200374866	7/1/2021	UV spectrophotometer	QCE629	Results not meeting acceptance criteria
200377138	8/4/2021	HPLC	QCE469	%RSD not meeting the acceptance criteria

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Deficiencies were observed in the incident investigation reports (200374866 and 200377138) generated for UV Spectrometer (equipment ID: QCE 629) and HPLC (equipment ID: QCE 469) and the firm's laboratory equipment calibration and preventive maintenance program. For example:

A. Incident report 200374866 was initiated on 7/1/2021 when UV Spectrophotometer (ID: QCE 629) failed to meet the limit of stray light during routine calibration that was being performed on 6/29/2021. The absorbance of stray light at (b) (4) nm was observed as (b) (4) against the specification of not less than (b) (4) This equipment has four mirrors M0, M1, M2, and M3. During the investigation, the firm observed 3 out of 4 mirrors (M1, M2, and M3) appeared to have scratches that caused the OOS results for stary light. The firm replaced all three mirrors, repeated the calibration, and reported the conforming results. It was observed the firm performed preventive maintenance of the equipment on 6/28/2021and replaced the fourth mirror (M0) as well as two lamps (Tungston Halogen Lamp and Deuterium Lamp) during the preventive maintenance that was performed before the calibration.

This UV spectrophotometer is calibrated after (b) (4) and previous successful calibration for this equipment was performed on 1/5/2021.This equipment was initially qualified on 11/26/2012 and since then its mirrors were not changed. The QC Lab Head stated stray light can impact the absorbance of samples and standards. The absorbance value is used to calculate the potency of drug products that are tested by using this equipment. During the impact assessment, the firm did not test any retain samples to assess if the data generated from this equipment is reliable. The firm routinely uses this equipment in quantitative analysis. For example, this equipment was used to test Content Uniformity and Dissolution for about (b) (4)

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batches that were shipped into the US.

B. Incident report 200377138 was initiated on 8/4/2021 when HPLC (ID: QCE 469) failed to meet % RSD specification during reproducibility test when Relative Standard Deviation (RSD) value of (b) (4) % was observed against the specifications of not more than (b) (4) % for the (b) (4) replicate injections. During the investigation, the firm concluded that OOS results were due to the improper (b) (4) The QC Head confirmed that the (b) (4) (b) (4) or any other related part was not replaced during the preventive maintenance that was ed before the equipment calibration.

Review of historical data pertaining to this instrument indicated the site initiated Incident 200374748 when imprope (b) (4) was observed on 6/30/2021 when (b) (4) Tablets batch (b) (4) w olution test as per sample set, (b) (4) The previous successful calibration of this HPLC was conducted on 3/10/2021. During this time, this equipment was used to analyze about (b) (4) batches of commercial drugs that were shipped into the US. However, the site failed to provide scientific justification to show that the historic data generated from this impacted equipment is accurate.

C. The firm's SOP GLOB-QC-019, "Management of Laboratory Equipment and Instrument" requires preventive maintenance be done on the equipment prior to routine calibration. During preventive maintenance (PM), potentially the equipment is opened apart and parts are changed as needed. After PM the equipment calibration is performed. However, by this practice the

equipment is potentially altered just before the calibration and a conclusive assessment cannot be made if the equipment was performing accurately and precisely during the entire calibration cycle.

OBSERVATION 6

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

Specifically, the quality unit failed to investigate consumer complaints thoroughly. For example:

A. The firm's Quality Unit did not adequately investigate issues pertaining to inadequate gowning practices inside the core manufacturing areas of your facility (Refer to OBSERVATION 10B). The firm received the following three (3) market complaints relating hair found inside bottle.

Market Complaint	Date Received	Product	Nature of complaint	Conclusion
200348787	5/16/2020	(b) (4) Tablets (b) (4) mg, ((b) (4) count)	Hair was found embedded on the tablet	Substantiated
200350540	6/16/2020	(b) (4) Capsule USP (b) (4) mg ((b) (4)	Reporter stated about presence of hair in bottle	Substantiated

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		count)		
200378052	8/18/2021	(b) (4) Tablets (b) (4) mg, ((b) (4) ount)	Hair was found embedded on the tablet	Substantiated

For Complaint No.: 200378052, the firm's Production and IPQA employees were retrained and reevaluated for entry and exit procedure along with gowning practices in the production areas as per SOP No.: SOP-FTO-03-PR-0235-02. Out of around (b) (4) employees, about (b) (4) Production employees scored marks in the range of 0% to 60% while the passing criteria is NLT (b) (4) %. There was no retraining and no reevaluation conducted prior to allowing these employees to continue working in the manufacturing areas. These (b) (4) production employees continued to work in the production areas for about eight (8) months prior to their periodic retraining and reevaluation on SOP-FTO-03-PR-0235-02.

For Complaint No.: 200348787, there was no training provided to IPQA employees. The retraining provided to Production Unit employees was with a delay of over 8 months. There was no training evaluation performed through questionnaire-based assessment for the employees that attended the training. Further, one of the training documents was missing training date.

For Complaint No.: 200350540, there was no training provided to IPQA employees. Additionally, the training was provided to only (b) (4) production employees out of over (b) (4) employees. There was no training evaluation performed through questionnaire-based assessment for the employees that attended the training.

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B. Your procedure for Handling of Market Complaints (SOP No.: SOP-GLOB-QA-0057, Version: 12.0) is deficient. Per section 5.6.6 *"Identification and evaluation of repeat complaints: Review the last* (b) (4) *data and check if similar complaints are received"*. Your firm provided no justification for conducting historical evaluation for repeat complaints only for the period of (b) (4) while you have drug products sold into the US market with a shelf life of (b) (4) and (b) (4) There is a potential for repeat market complaints for the same drug product and lot outside of the firm's (b) (4) review period of the repeat complaints.

OBSERVATION 7

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, appropriate controls are not exercised over Laboratory Information Management System (LabWare LIMS) that changes in the master production records are instituted only by authorized personnel. Analytical testing in the QC Lab is documented and maintained in LIMS. Deficiencies observed in LIMS include but not limited to:

A. Samples and tests in LIMS are cancelled without adequate controls in place: It was observed that enormous number (as shown below) of tests and samples in the QC Lab are created and cancelled frequently. For example, the QC Lab cancelled following number of tests and/or test replicates in the last three years:

Year	# of Tests and/or replicates cancelled	(b) (4) average
2023	354,923	(b) (4)
2022	378,863	
2021	340,481	

Since 2020, the QC Lab cancelled about (b) (4) samples (on average more than (b) (4) samples (b) (4) (b) (4) in LIMS. The quality unit failed to exercise adequate controls to minimize the number of cancelled tests and samples. The quality unit does not trend the cancelled tests and/or cancelled samples.

B. LIMS sample created without justification and entries are not reviewed: The firm manufactured (b) (4) Tablets USP (b) (4) mg ((b) (4) batch (b) (4), Packing batch numbers: (b) (4) in 5/2021 for the US market. For this (b) (4) batch, SAP inspection Lot # (b) (4) was created on 6/25/2023 and was tested in LIMS as per LIMS sample # (b) (4) On 6/29/2023, the site confirmed out of specification results for impurities test and the batch was rejected later.

However, another SAP inspection Lot # (b) (4) was created on 6/29/2023 for the same (b) (4) batch number (b) (4) to be tested in LIMS under LIMS sample # (b) (4) The site failed to provide reason why this sample was created. It was observed on 7/1/2021, the QC Lab analyst (employee ID: (b) (6) weighed (b) (4) g of (b) (4) to prepare the

dissolution media under LIMS sample # (b) (4) As of 10/25/2023 this analyst entry was not reviewed by the QC Lab. The QC Lab management failed to provide justification as why the analysis was started fo (b) (4) Tablets, USP (b) (4) Batch # (b) (4) under LIMS sample # (b) (4) by the analyst and why it was left in the (b) (4)

OBSERVATION 8

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established.

Specifically, accuracy, sensitivity, specificity, and reproducibility of TAMC (Toral Aerobic Microbial Count) test used to routinely test (b) (4) for the presence of microorganisms has not been established.

(b) (4) samples are collected as per environmental monitoring SOP-GLOB-QC-0110-5.0 and tested for Total Microbial Counts present in the (b) (4) Test method STP # M0A-100001931-03, (b) (4) USP". The QC Head stated the firm has not performed any method validation, method verification, and/or method suitability studies if the method is suitable for intended use.

Additional deficiencies were observed in the Test Method STP # M0A-100001931-03, (b) (4) USP". As per this method sample for TAMC test is prepared by (b) (4) (b) (4) Specification document # R0A-100001931-02 sets the specifications of (b) (4) CFU/mL for Total Aerobic Microbial Count (TAMC) test for (b) (4) analysis. The corresponding specifications for (b) (4) mL of sample are (b) (4) CFUs. The site has not challenged this test to observe and count (b) (4) CFUs on the (b) (4) mm filter. The site QA Head acknowledged that it is not possible to count (b) (4) colonies on (b) (4) mm size filter.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	10/19/2023-10/27/2023*
	FEI NUMBER 3002949099

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Ranjana B Pathak, Global Head of Quality

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Ltd.	Surveys 41, 42 Part, 45 Part & 46 Part, Bachupally
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal-Malkajgiri, Telangana, 500090 India	Drug Manufacturer

OBSERVATION 9

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, core processing areas are not maintained adequately to prevent mix up and or contamination. For example:

A. On 10/19/2023, during the inspection of Room # (b) (4) in module manufacturing area/Unit (b) (4) (that houses (b) (4) equipment ID: TEA-001), we observed cracks on the wall surface, pieces of chi paint. At one location the surface damage was so severe that wall coving got eroded and concrete surface underneath the coving was exposed to the environment. Process area cleaning and clearance procedure, SOP-FTO3-PR-025 requires the walls and coving to be cleaned with (b) (4) mops. However, these cracks and exposed surfaces make the area hard to clean, potentially moisture can stay trapped inside the crevices, cracks & exposed surface, thus enhancing the chances of microbial growth.

The firm's procedure SOP-GLOB-EN-0012 requires the personnel working in the production department to raise General Maintenance Notification if they find such impacted surfaces and areas. However, the production department failed to initiate such notification. The engineering team observed the damaged surfaces during facility inspection (done (b) (4) on 10/17/2023 under facility inspection order # (b) (4) Use logbook for Room (b) (4) ndicated that on 10/17/2023, it was being used to manufacture (b) (4) batch (b) (4) for (b) (4) mg Tablets for the US market. After the facility inspection on 10/17/2023, the inspection team documented that the facility is suitable to use. (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saleem A Akhtar, Investigator Pratik S Upadhyay, Investigator - Dedicated Drug Cadre	X Saleem A Akhtar Investigator Signed By: 2001638440 Date Signed: 10-27-2023 18:37:15	10/27/2023

(b) (4) batch (b) (4) ended at (b) (4) on 10/17/2023 and the firm started manufacturing next US batch of (b) (4) batch (b) (4) at (b) (4) on 10/17/2023.

B. On 19-Oct-2023, we observed (b) (4) sealant on (b) (4) ID: PRE-078 (located in room (b) (4)) wore-off and cracked in parts and sealant pieces were missing in many areas surrounding to (b) (4) including at the areas close to (b) (4) There is a potential for (b) (4) penetration through the broken sealant inside the (b) (4) areas of (b) (4) There is no cleaning and microbial monitoring performed underneath the areas of (b) (4) nce the installation of (b) (4) in year 2007. On 20-Oct-2023, swab samples were collected and tested for microbial growth in this area, the test result revealed presence of microbial and fungal growth in this area.

Additionally, electrical panel mounted on the (b) (4) had a broken (b) (4) sealant. There is a potential for dep (b) (4) products and (b) (4) hrough the crack inside this panel potentially lead crobial growth.

OBSERVATION 10

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your firm failed to establish and/or follow adequate written gowning procedures pertaining

to the core manufacturing areas to ensure the drug products have the identity, strength, purity, and quality that they represent to possess. For example:

A. On 10/19/2023, during the inspection of (b) (4) area (Room # (b) (4), Operator (b) (6) was observed with a hole in (b) (6) shoe. This ro ajor production equipment includin (b) (4) (b) (4) (equipment ID: PRE-1615), (b) (4) (equipment ID: 1649), and (b) (4) (equipment ID: 1650). On 10/ being used to manufacture (b) (4) Caplet (b) (4) mg batch (b) (4) for the US market). The firm's SOP-FT03-0005, "Cleaning of Primary and Secondary Footwear" requires the firm provided footwear be inspected for damages before being washed at the (b) (4) This SOP further states, "Damaged shoes shall be sent for disposal". In this case the firm failed to follow its procedure.

B. The firm's employees' have deviated from SOP No.: SOP-FT03-PR00235, Version: 3.0, section 6 - Primary Gowning pertaining to beard mask. On 19-Oct-2023, we observed beard mask were not available for employees entering inside the manufacturing suits. As such, most of the employees working in production areas had exposed beard due to inadequate head cover and not wearing beard covers. Further, the pictorial images for entry and exit posted in the firm's gowning areas does not indicate the need for wearing a beard mask (if necessary). Refer to OBSERVATION 6A.

***DATES OF INSPECTION**
10/19/2023(Thu), 10/20/2023(Fri), 10/24/2023(Tue), 10/25/2023(Wed), 10/26/2023(Thu), 10/27/2023(Fri)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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Medchal-Malkajgiri, Telangana, 500090 India	Drug Manufacturer

X Pratik S Upadhyay
Investigator - Dedicated Drug Cadre
Signed By: Pratik S. Upadhyay -S
Date Signed: 10-27-2023 18:38:08

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Saleem A Akhtar, Investigator
Pratik S Upadhyay, Investigator - Dedicated Drug Cadre

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Investigator
Signed By: 2001638440
Date Signed: 10-27-2023 18:37:15

DATE ISSUED
10/27/2023