DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER CDER-OC-OMQ-International483Response@fda.hhs.gov	DATE(S) OF INSPECTION 03/10/2025-03/14/2025 FEI NUMBER 3010868532
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Abhay Kumar B Mohite, Head of Operations	
FIRM NAME Oxalis Labs	STREET ADDRESS Tehsil- Baddi, Theda
CITY, STATE, ZIP CODE, COUNTRY Himachal Pradesh, 174101, India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product 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 email address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

(b) (4)

OBSERVATION 1

All records of production and testing associated with (b) (4) exhibit drug product batches are not maintained nor available for review.

Specifically,

A) According to the Head of Operations and Vice President Corporate of QA, all room equipment and cleaning logbooks used during the production of (b) (4) out of the total (b) (4) exhibit batches for (b) (4) (b) (4) manufactured in July 2019 and September 2019 were destroyed in January 2025 and not available for review during the current U.S FDA inspection. This includes the destruction of: (b) (4)

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This also includes the lack of logbook data available for review during the inspection of (b) (4)

1. Logbook entries for production start/end date and time, product name, batch number, specific activity details, and production activities done by signatures and checked by signatures.
2. Logbook entries for preventive maintenance (PM) start date and time, specific preventive maintenance activities, and PM done by signatures and checked by signatures.
3. Logbook entries for breakdown of equipment, including date, time and checked by signatures.
4. Logbook entries for cleaning dates and time, specific cleaning activities details, performance of Type A or Type B cleaning, and cleaning activities done by signatures and checked by signatures.

B) According to the Head of Operations and Vice President Corporate QA, all QC instrument user logbooks pertaining to the (b) (4) out of the total (b) (4) exhibit batches for (b) (4) (b) (4) tested in July 2019 and September 2019 were destroyed in January 2025 and not available for review during the current U.S FDA inspection. This includes the destruction of:

(b) (4)

This includes the lack of QC logbook entries and data available for review during the inspection of (b) (4) for: instrument usage date and time, test performed, Analyzed By signatures, Checked By signatures, and transcribed Remarks.

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OBSERVATION 2

Control procedures are not established which monitor the output, validate the performance, of those manufacturing processes that may be responsible for causing variability in the characterization of the in-process material and of the drug product.

Specifically,

Multiple equipment and/or process related changes have been implemented and/or is in progress since the execution of the (b) (4) exhibit batches for (b) (4) Exhibit Batch No. (b) (4) and (b) (4) (b) (4) Batch No. (b) (4) This includes the following changes:

1. Change Control # PR265211, Date Opened: January 03, 2025, (b) (4) line is to be installed to the (b) (4) manufacturing and filling system, Status: Change Control In-Progress. This was a result of corrective and preventive actions for a laboratory investigation opened on August 04, 2023, for atypical results observed in (b) (4) Assay test results for R&D (b) (4) USP, Batch No. (b) (4). The observed results were near to the defined lower specification limit. PR #187356 investigation attributed the probable causes of losses in the assay result during filling operation due to adherence of API inside the filling line. The CAPA details and decision included: more (b) (4) to filling line (manufacturing to filling and (b) (4) line) to be provided, which will be applicable to all products.

2. Change Control PR #270865, Date Opened: February 06, 2025, for the length of the (b) (4) (b) (4) line to be reduced, Status: Change Control In-progress. Reason for Change: to reduce the bulk loss in the process pipeline due to long distance; length of pipeline in between the (b) (4) vessel and (b) (4) filling machine shall be reduced. According to the Executive Vice President (EVP) Head of R&D and VP of R&D, a Comparison Study for Actual Residual (b) (4) (Before and After Reduction Filling Pipe Line) for a non-U.S marketed (b) (4) product batches demonstrated that approximately (b) (4) of (b) (4) loss is reduced as a residual (b) (4) after reduction of filling pipe length.

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3. Action Plan for Study of introduction of New (b) (4) to replace the soon-to-be discontinued old (b) (4) and which was used to manufacture (b) (4) exhibit batches. The plan also includes raw material change from (b) (4) to (b) (4) During the inspection, the Executive VP and Head of R&D stated that the firm plans to manufacture additional batches for (b) (4) and perform the following additional studies for the new (b) (4) intended for future commercial use: extractable study, leachable study, final leachables method development and validation for routine monitoring on stability, and additional QC testing activities. The (b) (4) vendor notification letter was received by your firm in October 2020. The (b) (4) vendor Change Control (b) (4) referenced in the notification letter states that their supplier decided to change the (b) (4) due to a regulatory restriction and is under evaluation for another non-U.S market. However, the Head of QA and Head of R&D, was unable to explain the reason for the new (b) (4) material change during the inspection.

4. Change Control (CC) PR #114731, Date Opened: March 21, 2022, for the In-process control (IPC) systems installed for manufacturing equipment in the (b) (4) manufacturing area. This includes IPCs installed for the (b) (4) Vessel- (b) (4) (b) (4) CC closed on: December 28, 2024, Categorization: Major; and Change Control PR #146398, Date Opened: October 27, 2022, for IPC system installed to the (b) (4) Filling Machine available in the (b) (4) filling area, CC closed on: February 23, 2025, Categorization: Major. This included the following installation of computer system controls for major equipment used in (b) (4): Access control and Privileges assessment, Recoding and collection of data, Data generation/meta data, Data control / Record Protection, Data backup, Human Readable Records (Printouts), Audit Trails, Alarms / Notifications or Information messages and Electronic Record / Electronic Signature.

5. Change Control PR #228536, Date Opened: May 09, 2024, for Installation of new (b) (4) and (b) (4) unit for (b) (4) machine, Categorization: Major. Status: Change Control in Progress. The (b) (4) will be installed for stress testing of the filled canisters for (b) (4) (b) (4) batches intended for the U.S market.

However, no holistic quality risk assessment review has been documented by the firm for all the equipment and process related changes that have been implemented and/or are in-progress after manufacturing and filling 2019 and 2020 (b) (4) exhibit batches submitted to the agency.

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OBSERVATION 3

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

Specifically,

A) (b) (4) ration batches for (b) (4) (b) (4) (b) (4) (b) (4) Batch No. (b) (4) However, your firm failed to on with T results for (b) (4) (b) (4) results from the stability study as per SOP/CO/CQA/138-001, Handling of OOS/OOT/Atypical Investigations, Effective Date: December 22, 2023, requirement:

Table 1- (b) (4) (b) (4)

(b) (4)

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(b) (4)

[redacted]

Table 2- (b) (4)

(b) (4)

[redacted]

(b) (4)

(b) (4)

[redacted]

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B) Your firm has submitted (b) (4) bulk hold time study data to the agency for (b) (4) (b) (4) from pre-exhibit batch # (b) (4) as per Hold time study Protocol cum Report # OXUQAD/HTS/FI/001-00 to demonstrate that the product meets its predetermined specifications and quality attributes during holding in manufacturing area. From this batch, your firm has tested the samples for drug product critical quality attributes at the predetermined intervals as per specification at (b) (4) including description, assay, (b) (4) content, (b) (4) Assay, (b) (4) microbial enumeration test. From the reported results of (b) (4) per A.R.NO.- (b) (4) FP/2019/1996, for the sample # (b) (4) for EOU result achieved as (b) (4) % at (b) (4) which is out-of-specification (OOS) as per the current individual specification of: (b) (4) %. However, there was no investigation performed or root cause analysis for the OOS failure.

C) The following deficiencies were observed for equipment breakdown slips for (b) (4) Filling Machine, Equipment ID: EQI/PRM/(b) (4) 001, which is used and intended for future (b) (4) (b) (4) bathes:

1. Breakdown Slip No: 311 Report Date: September 10, 2024, Description: Machine speed high and low alarm observed repeatedly. According to the slip document, the (b) (4) system needs to be checked - (b) (4) of the filling machine. The (b) (4) was greased as a result. However, there was not documented root cause analysis of the machine issue causing multiple alarms. In addition, no holistic assessment was performed to prevent further reoccurrence.

2. Breakdown Slip: 312, Report Date: September 11, 2024, Description: Filling speed high and filling speed low alarm generated on filling machine. Therefore, the filling machine was not working. According to the slip document, jerking was observed in the (b) (4) The (b) (4) alignment was greased as a result. However, there was not documented root cause analysis of the machine issue causing multiple alarms and no holistic assessment was performed to prevent further reoccurrence. In addition, the slip did not reference the similar incidence that occurred the day prior.

3. Breakdown Slip No: 314, Report Date: September 16, 2024, Description: (b) (4) not running. According to the slip document, the (b) (4) system needed to be checked. As a result, the (b) (4) was changed. However, there was no holistic

investigation or reference to previous incidents concerning the same equipment on September 10th, 2024, and September 11th, 2024.

D) During the inspection walkthrough of the (b) (4) manufacturing area on March 10, 2025, multiple "(b) (4) Level Low" alarms were observed and caused the (b) (4) Filling Machine, Equipment ID: EQI/PRM/(b) (4)/001 to repeatedly stop running for a non-US (b) (4) product batch. According to the Head of Operations, approximately 311 total "(b) (4) Level Low" alarms were displayed between (b) (4) for approximately (b) (4) The production officer had to repeatedly acknowledged each alarm and then opened the (b) (4) of the (b) (4) machine to manually remove the (b) (4) being repeatedly stuck in the (b) (4) transportation line. Similarly, approximately eighteen (18) "(b) (4) Level Low" alarms were reported during the trial batch run for (b) (4) Batch No. (b) (4) on January 09, 2025. However, there has been no investigation, corrective and preventive actions or evaluation of the repeated alarms and production officer interventions until the current inspection.

OBSERVATION 5

Equipment used in the manufacturing and processing of the drug product has not been evaluated for appropriate design, adequate size to facilitate operations of its intended use and cleaning and maintenance.

Specifically,

A) According to the Head of Operations and Head of R&D, the (b) (4) (b) (4) line pipe between the (b) (4) vessels and (b) (4) filling machine EQI/PRM/(b) (4)/001, was purchased from a (b) (4) systems vendor in July 2017 and then modified with bends and refabricated in-house in order to a-fix the pipes on the vessel and machine ports with newly purchased (b) (4) However, a thorough documented review and evaluation was not performed for the newly designed dimensions, design specifications, construction components nor quality risk assessment for design functionality prior to installation, operation and use for manufacturing (b) (4) exhibit batches.

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B) An assessment for introduction of all new products in the non-dedicated (b) (4) manufacturing area has not been completed as per SOP/OL/QAD/047-010 Procedure to Perform Cleaning Validation Study, Effective Date: September 16, 2024, requirement. Section (b) (4) states that a PDE report should be approved from toxicologist and reviewed for site quality for each API input in the new product plan. In addition, Form FRM/SOP/OL/QAD/047/01-006, Review during Introduction of New Product, is required be filled out for review of data and update product matrix, equipment matrix and other annexures as applicable. However, the cleaning validation program and matrix does not include documented assessment of new R&D products introduced on the non-dedicated (b) (4) equipment, including the (b) (4) Filling Machine, (b) (4) Vessel (b) (4) (b) (4) also used for manufacturing (b) (4) batches. This includes the following additional R&D products manufactured on the same equipment since the year 2019:

(b) (4)

C) There are multiple bolts/screws and spaced-out pockets/holes connecting the (b) (4) and shaft of the non-dedicated (b) (4) Vessel - (b) (4) Equipment ID: EQI/PRM (b) (4) /002. The screws/bolts had visibly hard-to-clean threads and uneven surfaces. In addition, there was visible hard-to-clean spaced-out pockets within the assembly of the shaft and (b) (4) However, the screws and assembly pockets were not evaluated as part of the equipment cleaning validation or verification program until the current inspection.

***DATES OF INSPECTION**
03/10/2025 (Mon), 03/11/2025 (Tue), 03/12/2025 (Wed), 03/13/2025 (Thu), 03/14/2025 (Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."