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 CDER-OC-OMQ-International483Response@fda.hhs.gov	05/04/2026-05/15/2026
	FEI NUMBER 3005587313

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Abhijit Deshmukh, Head of Global Non Sterile Operations

FIRM NAME	STREET ADDRESS
Mylan Laboratories Limited	F-4&F-12, Pune Nashik Road, MIDC, Malegoan,
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sinnar, Nashik Dist., Maharashtra 422113, India	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 phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your Quality Unit lack oversight into ensuring the integrity of manufacturing records and product quality. For example,

1. On 11-May-2026, the evaluation of raw data relating to (b) (4) stages of batch manufacturing revealed altering of the batch number and weights or omitting the weight printouts from the Batch Manufacturing Records (BMRs) for (b) (4) Tablets (b) (4) mg, Batch Numbers: (b) (4), (b) (4) Capsules (b) (4) mg, Batch Number: (b) (4), and (b) (4) Tablets (b) (4) mg, Batch Number: (b) (4).

   On 12-May-2026, your firm initiated Incident Investigation PR ID: 4134254 to investigate the issues of *"balance printouts taken from "View Batch History" of Analytical balances not matching with respective BMR Prints"* and suspended batch manufacturing and batch release from your site as an immediate action as a result of our observations. However, there was no Field Alert Report submitted by your firm to USFDA to notify the potential impact on drug product quality and its supply into the US market.

Few examples depicting the potential for data integrity issues noted under this observation are as follows:

SEE REVERSE OF THIS PAGE	Pratik S. Upadhyay, DDC Investigator Unnee Ranjan, DDC Investigator	PRATIK S. UPADHYAY -S UNNEE RANJAN -S	Digitally signed by PRATIK S. UPADHYAY -S Date: 2026.05.15 08:05:37 -04'00' Digitally signed by UNNEE RANJAN -S Date: 2026.05.15 17:55:44 +05'30'	DATE ISSUED 05/15/2026

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a. The audit trail history log i.e. "View Batch History" for analytical balances when compared against the balance printouts for the respective weighing activities in BMRs depicted the exact same date and time stamp along with the same individual weight of (b) (4) tablets for (b) (4) different batches (b) (4) and varying Nominal weights on the balance printouts. For example,

Batch No.:	Balance ID	Start Date & Time	End Date & Time	Total Tablets Weighed	Tablet Nominal Weight	MFG Stage	Data Source
		(b) (4)					

There was no justification provided for altering balance printouts (meta data) depicting the weighing activities that were conducted for (b) (4) different batches at the same date and time along with the reason for changing the Nominal weights.

b. The evaluation of BMRs and balance printouts revealed missing weight printouts either in the audit trail history log or in the respective BMRs. For example,

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Batch No.:	Balance ID	Start Date & Time	End Date & Time	Total Unit (Tablets/Capsules) Weighed	MFG Stage	Data Source
(b) (4)						

c. The balance weight printouts posted in BMRs showed the weight entries in "mg" whereas the same entries were in "g" in the balance audit trail history for individual weight of capsules for products (b) (4) Tablets (b) (4) mg, Batch Number: (b) (4), (b) (4) Capsules (b) (4) ng, Batch Number: (b) (4), and (b) (4) Tablets (b) (4) mg, Batch Number: (b) (4).

2. On 05-May-2026, the evaluation of your Incident Investigation PR ID: 3606933, Date opened: 12-Sep-2024 at (b) (4) revealed that your Production Operator (b) (6) destroyed balance printouts dated 10-Sep-2024 and time (b) (4) (for balance ID: ESD1770, Location: (b) (4) room)

by tearing into pieces and disposed torn pieces into leftover (b) (4) of batch (b) (4) in the attempt of destroying evidence of weighing activities per the incident investigation. Your investigation is deficient for the following reasons:

a. The "Product Impact/Conclusions" section indicated no impact was found upon review of Trackwise history for the period of preceding 12 months from the incident open date for Production Operator. However, the evaluation of Batch Manufacturing Record for (b) (4) stages revealed that your Production Operators (b) (6) potentially changed balance printout on a later date. The assessment of balance printouts for legibility of ink color and fonts revealed notable differences in balance printouts dated 10-Sep-2024. The printout time stamped (b) (4) (relating to the weight of (b) (4) tablets") appeared to have **dark blue color ink** whereas the printouts time stamped (b) (4) (relating to the weight of (b) (4) tablets"), (b) (4) (relating to the weight of (b) (4) "(b) (4) tablets"), (b) (4) (relating to the weight of (b) (4) Tablets"), and (b) (4) (relating to the weight of (b) (4) Tablets") appeared to have printouts in light blue color ink. The evaluation of (b) (4) verification record of analytical balance logbook revealed the legibility of balance printout for ink color and font remained consistent i.e. dark blue color ink on 09-Sep-2024 to 11-Sep-2024 indicating the balance printer remained unchanged. This ruled out the possibility of using a different printer which may have caused notable difference in print color on 10-Sep-2024.

b. On 07-May-2026, your Site Operation Head (b) (6) indicated that the Operator may have changed ribbon of balance printout causing differences in the legibility of ink colors on printouts. However, there is no indication of the printer ribbon being changed since the color of fonts on balance printout remained consistent between print dated 10-Sep-2024 timed (b) (4) (relating to the weight of (b) (4) tablets") to printout taken on 11-Sep-2024 using the subject balance ID: ESD1770.

c. Per your Production Supervisor (b) (6) balance ID: ESD1770 and its printer among other equipment of the room cannot be taken out of the respective manufacturing room and other similar equipment cannot be brought inside the room during manufacturing to avoid cross-contamination. Therefore, there is no possibility of changing the printer for balance ID: ESD1770.

d. Your firm has no balance usage logbook for analytical balances that are used in weighing drug products (tablets/capsules) at different stages of manufacturing activities.

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As a result of these notable deficiencies, your firm reopened this incident investigation on 8-May-2026 (i.e. after about 1.5 years) to determine the integrity of data for variability between balance printouts taken on 10-Sep-2024 and evaluate the impact of your employees practices on other products manufactured at the site.

B. Your Quality Unit has no raw data or meta data to support Quality Control testing integrity. For example,

1. On 04-May-2026, we observed that your firm has no documented record of testing relating to material weighed (balance printout), (b) (4) preparation, lot number and manufacturer details for chemical and reagents used along with record of (b) (4) preparation as per the stepwise instructions mentioned in your test procedures relating to finished products, swab samples, raw materials (API + Excipients) and packaging materials.

Your firm found (b) (4) raw data worksheets relating to Finished Products such as (b) (4) (b) (4) (b) (4) Tablets (b) (4) mg that lacked provision for documenting testing details in accordance with the respective STPs. Moreover, (b) (4) worksheets relating to active residue (swab and rinse) analyses were also found deficient. These deficiencies were also observed for worksheets relating to (b) (4) APIs, (b) (4) worksheets covering different excipients, and (b) (4) worksheets relating to packaging materials testing. Your firm simply revised worksheets (through Change Control 3615818) to align it with testing requirements per your STPs. However, there was no Risk Assessment performed to evaluate the impact of your previous practices on the integrity of testing to ensure product quality and patient safety.

2. On 05-May-2026, we observed that your firm identified additional (b) (4) worksheets relating to APIs and (b) (4) worksheets relating to excipients testing which lacked information relating to individual samples testing. For example, your worksheets had provision to record testing information for only (b) (4) sample out of (b) (4) samples. Hence, the sample testing details for the remaining (b) (4) samples were found missing.

Your firm revised (b) (4) out of (b) (4) worksheets relating to APIs testing, and (b) (4) out of (b) (4) worksheets relating to excipients through CAPA 4052216, dated opened: 03-Feb-2026. However, there is no Risk Assessment performed to evaluate the impact of your previous practices on the integrity of testing to

ensure product quality and patient safety. Additionally, your firm has not evaluated the risk relating to testing integrity in the absence of raw data and meta data for the worksheets that are not yet revised, and the QC Analysts are continuing to use it routinely to conduct analyses.

3. There are no documented records of testing for (b) (4) Test to include Chemical Analysis, FTIR, (b) (4) test. Your firm identified these deficiencies among many others through the FDA inspection of your sister facilities conducted between 06/14-26/2024. Your Quality Unit initiated Change Control (PR ID: 3541324, on 29-Jun-2024) to revise worksheets. However, there is no risk assessment performed to evaluate impact of your previous practices of not documenting testing activities on the integrity of data. Your firm reported "Complies" for the testing of (b) (4) of batches analyzed without having raw data and meta data to support the test result.

OBSERVATION 2

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,

We observed that your analytical balances in production blocks lack adequate control to ensure integrity of manufacturing records. for example,

A. Your analytical balance Make: OHAUS, Model: EX224 (Total (b) (4) balances) and EX225AD (total (b) (4) balances) that are used in weighing drug products at the in-process stages of manufacturing including b not limited to (b) (4) etc. has user level access privileges to turn **"On and Off"** – "Date and Time", "Balance ID", "Balance Name", "User Name", "Sample Name", "Sample ID", "Project Name", "Header", "Batch ID", "Result", "Gross", "Net", "Tare", "Information", "Application Name", etc. functionalities in SQC Mode assigned to your Production Operators and Supervisors.

On 06-May-2026, your Production Supervisor demonstrated "On and Off" functionalities stating that Operators and Supervisors are assigned SQC access privileges through which they can turn "On and Off" different functionalities and they can verify weight of tablets without generating printout at different (b) (4) stages by turning off "Result" function. He indicated that it is normal to turn "On and Off"

different functionalities to see tablet weights without generating printout and the printout could be reprinted at a later time. There are no controls established for reprinted balance printout to ensure the weight information remains unchanged and there is no misuse of reprinted balance printout which may affect integrity of manufacturing data.

B. On 07-May-2026, we observed that your procedure SOP-000485434, Titled: "Operation and Cleaning of Balances", Version: 20.0 has stepwise instructions for deleting data and controlling results generation. For example,

- **a.** Sections (b) (4) of your procedure SOP-000485434 indicating stepwise instructions for "Delete All Records" by turning this option "On" in SQC Mode.
- **b.** Sections (b) (4) of your procedure SOP-000485434 indicating stepwise instructions for controlling the generation of results by pressing "On or Off" in SQC Mode.

There is no oversight of your Quality Unit in controlling and monitoring the Operators and Supervisors practices of deleting records and results from analytical balances with Make: OHAUS Model: EX224 (Total (b) (4) balances) and EX225AD (total (b) (4) balances). During the inspection, your IT Administrator stated that the balances can save last ten (10) eighing entries in the internal memory under audit trail history log i.e. "View Batch History". However, the evaluation of "View Batch History" revealed weighing activities were deleted from (b) (4) out of (b) (4) OHAUS model analytical balances that are used in your Production Blocks. The evaluation of "View Batch History" log for (b) (4) balances on 11-May-2026 revealed missing weighing entries in between multiple weights along with the weights and batch numbers were altered (refer to **OBSERVATION 1 A (1)**).

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 investigations of out-of-specification (OOS) results were inadequate because they lacked scientific rationale for root cause determinations. For example,

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A. Laboratory Investigations PR ID: 3717477, Date Investigation Opened: 20-Jan-2025, and PR ID: 3802187, Date Investigation Opened: 15-Apr-2025 for product (b) (4) Tablets USP (b) (4) mg are deficient the annual stability batches with (b) (4) shelf life for the issues of OOS result observed for Organic Impurity by HPLC test.

PR ID: 3717477, Batch Number: (b) (4), Stability timepoint: Long Term (LT) (25°C/60%RH) at 18 months, and

PR ID: 3802187, Batch Number: (b) (4), Stability timepoint: Long Term (LT) (25°C/60%RH) at 24 months,

The content of (b) (4) Impurity was found (b) (4) **% (OOS)**
Specification (%w/w): NMT (b) (4)

Final classification: Invalid OOS.

These investigations were extended to your Global Quality Investigation (GQI) Team.

Your Phase 1 (laboratory), Phase 2A (manufacturing), and Phase 2B (extended laboratory) investigations identified no root cause. Your firm extended the OOS investigation to R&D and determined composition of HPLC column (b) (4) containing (b) (4) content at (b) (4) (b) (4) is the root cause for obtaining failing test result. This OOS investigation is deficient for the following reasons:

1. Your firm switched chromatographic systems from HPLC ID: IQC305 (original analyses) to HPLC IDs: IQC264 (Analyst 1) and IQC98 (Analyst 2) during the retest analyses. The column used during the original analyses contained (b) (4) content whereas the retest analyses were performed using column containing (b) (4) content. There was no scientific justification provided for changing HPLC systems along with columns that potentially may have an impact on the accuracy of test results.

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2. Your firm did not perform analytical method reverification to ensure accuracy, precision, LOD, LOQ, and linearity parameters upon changing HPLC column (b) (4) (b) (4) containing (b) (4) content instead of (b) (4)

3. Your firm closed the OOS investigations with significant delays and took up to 8 months to conclude the OOS Investigation PR ID: 3717477 and about 4 months to close OOS Investigation PR ID: 3802187. There are about (b) (4) batches analyzed by your firm since the implementation of CAPA PR ID: 3717477 (date closed: 23-Aug-2025). However, your firm has not closed the corresponding Change Control PR ID: 4036996 that was opened with delays on 22-Jan-2026 relating to changes in column and typical chromatography in the test method.

4. You started using HPLC column with (b) (4) content instead of (b) (4) content column to overcome the issue of higher (b) (4) Impurity formation based on the recommendation from Analytical R&D department through the series of experiments conducted using HPLC columns containing (b) (4) (Document Number: MLLRDAVL/BHC/INS/069R/25-00, Approval date: 10-Jun-2025). However, your firm did not report the change in column composition which could give significantly lower test results for (b) (4) Impurity to the USFDA.

B. Laboratory Investigation PR ID: 3624563, Date of Original Analysis: 29-Sep-2024, Date Investigation Opened: 01-Oct-2024, Product: (b) (4) Tablets (b) (4) mg, Batch Number: (b) (4) Stability timepoint: Long Term (LT) (25°C/60%RH) at 3 months (annual stability batch), Issue: OOS result observed for Assay by HPLC test. This investigation was extended to the Global Quality Investigation (GQI) Team.

Result (%w/w): Injection 1: (b) (4) % and Injection 2: (b) (4) **% (OOS)**, Average: (b) (4) **% (OOS)**
Specification (%w/w): (b) (4) % to (b) (4) %

Final classification: Invalid OOS

1. Your hypothesis investigation found no obvious cause for failing results from the review of sample preparation along with its storage and handling. The evaluation of HPLC ID: IQC300 performance during the original analysis showed no pressure fluctuation, and no shift in Retention Time (RT)

of main peak. The %RSD of standard and bracketing standard injections was within the limit i.e. (b) (4)% RSD, Limit (b) (4)% during the original analysis. The test results of (b) (4) concurrent batches analyzed in the same sample set sequence met the specification limit for Assay test except for the subject batch (b) (4)

However, your firm invalidated the original test results based on instrument malfunction as the suspected root cause. This was followed by conducting retest analysis using different HPLC IDs: IQC176 and IQC149 by two (2) different Analysts which gave favorable test result for batch (b) (4) on 18-Oct-2024.

2. Your OOS investigation referred to precision test failure for (b) (4) µl (Result: (b) (4)%, Limit: (b) (4)%) during HPLC ID: IQC300 (b) (4) calibration. Per your OOS investigation and the associated Quality Impact Assessment (QIA) Report PR ID: 3638723, date opened 17-Oct-2024, the root cause for calibration precision failure and batch (b) (4) was due to V3 valve malfunctioning. Moreover, your HPLC calibration expert determined that *"V3 valve might have closed partially and because of that less injection volume drawn by syringe during intermittent injection that led to failure in precision test"* during calibration.

   However, your firm did not evaluate the impact of "less injection volume" on the accuracy and reliability of test results for drug products that were analyzed between the period of (b) (4) to (b) (4) (i.e. the previous calibration period) using HPLC ID: IQC300.

C. Laboratory Investigation PR ID: 3525929, Date of Original Analysis: 12-Jun-2024, Date Investigation Opened: 13-Jun-2024, Product: (b) (4) Tablets (b) (4) mg, Batch Number: (b) (4) Stability timepoint: Long Term (LT) (25°C/60%RH) at 24 months (annual stability batch), Issue: OOS result observed for Assay by HPLC test. This investigation was extended to the Global Quality Investigation (GQI) Team.

Result (%w/w): Injection 1: (b) (4) % and Injection 2: (b) (4) %, Average: (b) (4) **% (OOS)**
Specification (%w/w): (b) (4) % to (b) (4) %

Final classification: Invalid OOS

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Your hypothesis investigation found no obvious cause for failing results from the review of sample preparation along with storage and handling recorded in LIMS worksheet. The evaluation of HPLC system and column performance during the original analysis showed no pressure fluctuation, and no shift in Retention Time (RT) of main peak. The system suitability and %RSD of standard and bracketing standard injections was within the limit. The test result of concurrent batch (b) (4) analyzed along with subject batch (b) (4) in the same sample set sequence met the specification limit for Assay test. The following issues were observed:

1. Your firm concluded the investigation by invalidating the original test results based on suspecting extraction errors even though there was no obvious error identified.

2. The LIMS worksheet (raw test data) and test procedure (STP No.: FPPACP096R-06) for Assay by HPLC analysis showed series of stepwise instructions for the test sample solution preparation by stirring (for (b) (4) and sonication (for (b) (4) to ensure (b) (4) tablets get dissolved in the diluent. Your firm provided no justification for inadequacy of the test method in extracting active while the concurrent batch (b) (4) for which the test solution was prepared side by side along with the subject batch (b) (4) showed passing test result for Assay by HPLC test method.

D. (b) (4) operators adjust equipment parameters after samples are collected but prior to in-process testing. In some instances, the samples are not tested for approximately (b) (4) after being pulled and in other instances they are tested in under (b) (4) The reasons for altering machine settings are neither documented nor investigated.

Manufacturing operators stated that average weights are checked, and if variation is observed, machine parameters are then adjusted. However, documentation of reason for these changes and records of the weight checks are not available and no explanation was provided for why the parameters are adjusted before the sample results were obtained.

We observed such adjustments to machine settings for products such as but not limited to (b) (4) Tablets, (b) (4) mg, (b) (4) Tablet USP (b) (4) mg, (b) (4) Tablets (b) (4) mg, (b) (4) (b) (4) Tablets (b) (4) mg and (b) (4) Tablets USP (b) (4) mg.

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There is no assurance that the data collected during in-process testing represents the actual condition of the products manufactured.

For example,

1. During the (b) (4) operation of (b) (4) Tablets, (b) (4) mg, batch (b) (4) (U.S. batch), approximately (b) (4) samples were collected by Manufacturing and Quality for in-process testing. For (b) (4) of these samples, (b) (4) parameters were adjusted prior to the execution of testing.

Date	Responsible department for test	Type of test	Sample collection time documented by	Machine adjustment	Purpose of adjustment	Samples testing time based on the	Results
		(b) (4)					

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Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
		(b) (4)					

2. During the (b) (4) operation of (b) (4) Tablets, (b) (4) mg, batch (b) (4) (U.S. batch), approximately (b) (4) samples were collected by Manufacturing and Quality for in-process testing. For (b) (4) of these samples, (b) (4) parameters were adjusted prior to the execution of testing.

Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
		(b) (4)					

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Dr. Abhijit Deshmukh, Head of Global Non Sterile Operations

FIRM NAME	STREET ADDRESS
Mylan Laboratories Limited	F-4&F-12, Pune Nashik Road, MIDC, Malegoan,
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sinnar, Nashik Dist., Maharashtra 422113, India	Finished Drug Product Manufacturer

Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
		(b) (4)					

The firm has distributed approximately (b) (4) batches of (b) (4) Tablets, (b) (4) mg, for the U.S. market.

3. During the (b) (4) operation of (b) (4) Tablet USP (b) (4) mg, batch (b) (4) (U.S. batch), approximately (b) (4) samples were collected by Manufacturing and Quality for in-process testing. For (b) (4) of these samples, (b) (4) parameters were adjusted prior to the execution of testing.

Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
		(b) (4)					

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		(b) (4)					

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Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
(b) (4)							

The firm has distributed approximately (b) (4) batches of (b) (4) Tablet USP (b) (4) mg for the U.S. market.

4. During the (b) (4) operation of (b) (4) Tablets (b) (4) mg, batch (b) (4) (U.S. batch), approximately (b) (4) samples were collected by Manufacturing and Quality for in-process testing. For (b) (4) of these samples, (b) (4) parameters were adjusted prior to the execution of testing.

Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
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Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
		(b) (4)					

The firm has distributed approximately (b) (4) batches of (b) (4) Tablets (b) (4) mg for the U.S. market.

5. During the (b) (4) operation of (b) (4) Tablets (b) (4) mg, batch (b) (4) (U.S. batch), approximately (b) (4) samples were collected by Manufacturing and Quality for in-process testing. For (b) (4) of these samples, (b) (4) parameters were adjusted prior to the execution of testing.

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Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
(b) (4)							

The firm has distributed (b) (4) batches of (b) (4) Tablets (b) (4) mg for the U.S. market.

6. During the (b) (4) operation of (b) (4) Tablets USP (b) (4) mg, batch (b) (4) (U.S. batch), approximately (b) (4) samples were collected by Manufacturing and Quality for in-process testing. For (b) (4) of these samples, (b) (4) parameters were adjusted prior to the execution of testing.

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Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
		(b) (4)					

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Pratik S. Upadhyay, DDC Investigator — PRATIK S. UPADHYAY -S — Digitally signed by PRATIK S. UPADHYAY -S Date: 2026.05.15 08:18:06 -04'00'

Unnee Ranjan, DDC Investigator — UNNEE RANJAN -S — Digitally signed by UNNEE RANJAN -S Date: 2026.05.15 18:16:41 +05'30'

DATE ISSUED 05/15/2026

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Date	Responsible department for test	Type of test	Sample collection time documented by operator	Machine adjustment	Purpose of adjustment	Samples testing time based on the instrument	Results
(b) (4)							

The firm has distributed approximately (b) (4) batches of (b) (4) Tablets USP (b) (4) (b) (4) mg for the U.S. market.

E. Equipment breakdowns during batch processing are not adequately investigated to assess their impact on batch quality. A review of work orders initiated during batch manufacturing revealed that appropriate risk assessments are not consistently performed.

For example, for (b) (4) Tablets, during the (b) (4) (b) (4) of approximately (b) (4) batches, equipment malfunctions occurred, resulting in the unloading of (b) (4) The initial assessments for these batches stated that the (b) (4) were discharged into drums and kept covered during maintenance activities. Hence there was no impact on product quality. However, no evaluation was carried out to assess the impact of this unplanned discharge from the (b) (4) equipment on product quality.

Furthermore, (b) (4) out of (b) (4) batches of (b) (4) Tablets that were unloaded as part of unplanned maintenance exhibited atypical dissolution or out-of-specification (OOS) assay results and were rejected. Despite these out-of-specification (OOS) results, no corrective and preventive actions (CAPAs) were initiated to improve the assessment of quality impact when work orders are raised during in-process manufacturing.

For example, the following is a summary of disposition status of finished product batches of (b) (4) (b) (4) Tablets (b) (4) mg:

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Date	(b) (4) batch	Stage	Work order	Problem	Immediate action	Finished Product batch disposition
		(b) (4)				

F. Operators were observed frequently altering machine parameters; however, verification of (b) (4) (b) (4) was not performed following these adjustments. (b) (4) results from previous tests were

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found to be borderline with respect to specification limits, and the impact of the machine adjustments on batch quality was not evaluated. According to SOP-000486284, "In-Process Parameters Monitoring," (b) (4) units) tests are to be performed "(b) (4) ,,

For example, refer to the table below for equipment adjustments during the manufacturing of (b) (4) Tablets, (b) (4) mg, batch (b) (4)

(b) (4)

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SEE REVERSE OF THIS PAGE	Pratik S. Upadhyay, DDC Investigator PRATIK S. UPADHYAY -S Digitally signed by PRATIK S. UPADHYAY -S Date: 2026.05.15 08:20:02 -04'00' Unnee Ranjan, DDC Investigator UNNEE RANJAN -S Digitally signed by UNNEE RANJAN -S Date: 2026.05.15 18:19:52 +05'30'	DATE ISSUED 05/15/2026

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(b) (4)

[redacted]

On April 18, 2025, tablets were observed to have borderline (b) (4) at (b) (4) while the (b) (4) was (b) (4) The operator increased the (b) (4) to (b) (4) at (b) (4) however, a (b) (4) test was not performed following this adjustment.

At (b) (4) the (b) (4) was reduced to (b) (4) IPQA performed (b) (4) testing at (b) (4) which yielded passing results. However, no testing was performed to verify whether (b) (4) met specifications while the (b) (4) remained at (b) (4) during approximately (b) (4) of (b) (4) operation.

OBSERVATION 4

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

On May 4, 2026, we observed the following:

a. The cover of the discharge chute of the (b) (4) (Equipment No. ESD1082) was observed to have (b) (4) residue, and the protective (b) (4) cover was found to be damaged. This

non-dedicated equipment had been cleaned and inspected on April 1, 2026, and was documented as "OK." The equipment was previously used for manufacturing (b) (4) Tablets, batch (b) (4) (non-U.S. market).

b. The cover of the discharge chute of the (b) (4) (Equipment No. ESD1117) was observed to have (b) (4) residue, and the protective (b) (4) cover was found to be damaged. This non-dedicated equipment had been cleaned and inspected on April 13, 2026, and was documented as "OK." The equipment was previously used for manufacturing (b) (4) Tablets, batch (b) (4) (U.S. market).

OBSERVATION 5

The written stability testing program is not followed.

Specifically,

Based on SOP-003041575, "Stability Program," at least (b) (4) batch per year is required to be placed on stability under long-term conditions through the product shelf life. However, no annual stability batches were placed for (b) (4) Tablets, (b) (4) mg, representing batches manufactured in 2024. Your firm shipped (b) (4) mg batches (b) (4) (b) (4) to the U.S. market.

OBSERVATION 6

A (b) (4) -Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established in the application.

Specifically,

Your firm did not submit Field Alert Report (FAR) for the fire incident that caused the entire plant to shut down on (b) (4) 14-Feb-2026. Your Incident investigation PR ID: 4063221 relating to the fire incident

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noted significant impact on the manufacturing and testing of drug products at your site. The testing of drug products and materials that were impacted are as follows:

Sr. No.	Area impacted	Number of analyses impacted	Number of commercial batches	Number of Exhibit/Scale up batches
(b) (4)				

Additionally, the manufacturing of drug products remained paused during this inspection in your manufacturing zone (b) (4) Whereas, Zone (b) (4) was opened for manufacturing about 10 days prior to the start of this inspection. Your firm acknowledg d that the fire incident has impacted testing of stability samples, finished products and distribution of drug products. However, no justification was provided for potential impact on the quality of drug products that are distributed into the US market for which stability testing remained incomplete.

***DATES OF INSPECTION**

05/04/2026 (Mon), 05/05/2026 (Tue), 05/06/2026 (Wed), 05/07/2026 (Thu), 05/08/2026 (Fri), 05/11/2026 (Mon), 05/12/2026 (Tue), 05/13/2026 (Wed), 05/14/2026 (Thu), 05/15/2026 (Fri).

SEE REVERSE OF THIS PAGE		DATE ISSUED
	Pratik S. Upadhyay, DDC Investigator PRATIK S. UPADHYAY -S Digitally signed by PRATIK S. UPADHYAY -S Date: 2026.05.15 08:22:01 -04'00'	05/15/2026
	Unnee Ranjan, DDC Investigator UNNEE RANJAN -S Digitally signed by UNNEE RANJAN -S Date: 2026.05.15 18:23:06 +05'30'	

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."