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	04/20/2026-05/01/2026
	FEI NUMBER 3006370524

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Shirish Ambulgekar, President & Global Quality Head

FIRM NAME	STREET ADDRESS
Alkem Laboratories Limited	Plot No 164, 165/1/2/3 168/215/216/234, Srv No 167; Village Dabhel, Mahatma Gandhi Udyog Nagar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Daman and Diu, 396210, 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

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 relating to Out of Specification (OOS) and Out of Trend (OOT) investigations are not thoroughly investigated and the CAPA taken is inadequate to determine the risk to the drug products sold into the US market. For example,

A. Your OOS and OOT investigations for (b) (4) USP (b) (4) ml, and (b) (4) ml (b) (4) are not thoroughly investigated. For example,

OOS Investigation Number: 157370, Date of Initiation: (b) (4), Product: (b) (4) USP (b) (4) ml (b) (4) Batch Number: (b) (4), Mfg. date: (b) (4), Expiry date: (b) (4) Stability Timepoint: 6-month long term stability condition (25°C/60%RH), Shelf life of product: (b) (4) Issue: Related Substances by HPLC test found OOS test result for individual unidentified impurity (due to an unknown peak at RRT about (b) (4) Result: (b) (4) %, Limit: NMT (b) (4) %, Investigation conclusion: Valid/Confirmed OOS.

Your Quality Unit reported Field Alert (FAR/A/24/010) on (b) (4) to the agency but this annual stability batch (b) (4) was not recalled from the US market upon confirming OOS at 6-month stability timepoint. This batch failed again at 12-month stability time for the same individual unidentified impurity at RRT about (b) (4) (Result: (b) (4) %) on (b) (4). Your firm initiated OOS investigation number 178824 for the 12-month

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failure and confirmed the test results as valid. Subsequently, your Quality Unit analyzed retention samples of (b) (4) USP (b) (4) ml, and (b) (4) ml (4) (b) through protocol (A/PCR/0506-000) and found OOT test results for (b) (4) out of (b) (4) batches. The details are as follows:

Table 1

Sr. No.	(b) (4)	Batch number	Expiry date	Age of the batch when tested in Month (M)	Highest Individual unidentified impurity (Limit: NMT (b) (4) %)
(b) (4)					

On (b) (4), your firm recalled the above (b) (4) batches including the OOS batch (b) (4) with a delay of about (b) (4) from the date (b) (4) of becoming aware of the failing test results for (b) (4) USP (b) (4) ml. The delayed recall led to multiple batches either expiring in (b) (4) or nearing to its expiry (b) (4) (refer to **Table 1**).

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Furthermore, on (b) (4) your firm had conducted OOS investigation number: 6715 for individual unidentified impurity of annual stability batch failure at 3-month long term stability condition (25°C/60%RH), unidentified impurity (Result: (b) (4) %) for batch number (b) (4) . Product: (b) (4) USP (b) (4) ml, (b) (4) The OOS investigation concluded as valid OOS. However, the failing batch remained in distribution in the US market. This batch failed again at 9-month long term stability timepoint for individual unidentified impurity (Result: (b) (4) %) on (b) (4) (OOS Investigation: 18622). However, your firm did not recall the batch until (b) (4) from the US market. This was with a delay of about (b) (4) (b) (4) USP (b) (4) ml from the date of becoming aware of the failing test results for (b) (4)

Moreover, your firm obtained valid OOS (OOS Investigation: 26190) test result at 3-month long term stability (25°C/60%RH) condition for individual unidentified impurity (Result: (b) (4) %) on (b) (4) for batch number (b) (4) USP (b) (4) ml, (b) (4) However, the failing batch remained in distribution in the US market. This batch failed again at 6-month long term stability timepoint due to individual unidentified impurity found at RRT (b) (4) (Result: (b) (4) %) (OOS Investigation: 33681). However, your firm did not recall the batch until (b) (4) from the US market.

The protocol (A/Protocol/0069-000 and A/Protocol/0071-000) assessment revealed (b) (4) out of (b) (4) batches were OOS. The details are as follows:

Table 2

Sr. No.	Product Name	(b) (4)	Batch number	Expiry date	Age of the batch when tested in Month (M)	Highest Individual Unidentified Impurity (Limit: NMT (b) (4) %)
(b) (4)						

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(b) (4)

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(b) (4)

[redacted]

Your firm recalled the above (b) (4) batches from the US market between (b) (4) to (b) (4) with a delay of about (b) (4) since becoming aware of the failing test results.

Your firm reported the root cause for obtaining failing test results for individual unidentified impurity at RRT about (b) (4) was due to the formation of (b) (4) which according to R&D study report (Study Report No.: SR/AD/922/-00, Approval date (b) (4) is formed if (b) (4) (b) (4) However, the verification of Batch Manufacturing Records (BMRs) for (b) (4) USP (b) (4) ml and (b) (4) ml indicated the (b) (4) does not exceed beyond (b) (4) throughout the manufacturing and the entire manufacturing is completed within

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(b) (4) Additionally, the evaluation of your long term (25°C/60%RH) and accelerated (40°C/75%RH) stability condition data for Process Validation and Exhibit batches along with the forced degradation studies performed at (b) (4) did not show the formation of unknown impurities at RRT about (b) (4)

Moreover, the unknown impurity at RRT (b) (4) was observed in (b) (4) out of (b) (4) batches i.e. only about (b) (4) % of the total number of batches manufactured of this product. This ruled out the possibility about the formation of unknown impurity was due to (b) (4). Your investigation lacked scientific justification to support the root cause for the presence of unknown impurity at RRT (b) (4) There is a potential for other unknown impurities either co-eluting or are present at RRT about (b) (4) and are observed sporadically in few but not all batches of (b) (4) USP (b) (4) ml, and (b) (4) ml.

B. Your Quality Unit deviated from Out of Trend (OOT) investigation procedure CQA/0172-009, Effective date: 20-Jan-2026 by not conducting OOT investigations for the finished products at release and annual stability batches. Some of the OOT test results later confirmed as valid OOS. Due to these deficiencies in your procedure and practices, some of your failing products remained in distribution in the US market potentially impacting patient health and safety. For example,

a) On 23-Apr-2026, we observed that your Quality Unit did not conduct OOT investigations upon finding borderline test results at release for the following finished drug products sold in the US market. As a result, there is potential that your drug products may lack safety and efficacy throughout the claimed product shelf life.

1. Product: (b) (4) Tablet USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC

   Result: (Complies at USP (b) (4) stage)

   - Minimum (b) (4), Maximum (b) (4), Average (b) (4)

   Limit: NLT (b) (4) and NMT (b) (4)

   This batch was not charged on stability or monitored throughout its shelf life.

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2. Product: (b) (4) mcg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4)
   Test: Dissolution by HPLC

   Result: (Complies at USP (b) (4) stage)

   - Minimum (b) (4), Maximum (b) (4), Average (b) (4)
     Limit: NLT (b) (4).

   This batch is charged on long term (25°C/60%RH) stability and the stability trend showed sporadic increase in test results at 3 month and subsequent timepoint to Minimum (b) (4) Maximum (b) (4) Average (b) (4) There was no OOT investigation conducted to determine the reliability of test results that increased between (b) (4) in the subsequent stability timepoint.

3. Product: (b) (4) Tablet USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC

   Result: (Complies at USP (b) (4) stage)

   - Minimum (b) (4), Maximum (b) (4), Average (b) (4)

   Limit: NLT (b) (4) and NMT (b) (4)

   This batch was not charged on stability or monitored throughout its shelf life.

4. Product: (b) (4) Tablets USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) (b) (4) Test: Dissolution by HPLC

   Result: (Complies at USP (b) (4) stage)

   - Minimum (b) (4), Maximum (b) (4), Average (b) (4)

   Limit: NLT (b) (4)

   This batch was not charged on stability or monitored throughout its shelf life.

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5. Product: (b) (4) Tablets USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) (b) (4) Test: Dissolution by HPLC

   Result: (Complies at USP (b) (4) stage)

   - Minimum (b) (4) Maximum (b) (4) Average (b) (4)

   Limit: NLT (b) (4)

   This batch was not charged on stability or monitored throughout its shelf life.

b) On 23-Apr-2026, we observed that your Quality Unit did not conduct OOT investigations upon finding borderline test results for the following (but not limited to) drug products at long term stability timepoint. These products continued to remain in distribution and available to US customers when these products continued to show increasing trends and potential for failure.

1. Product: (b) (4) Tablet USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC, Stability condition and timepoint: 25°C/60%RH at **9 months**, Product shelf life: (b) (4)

   Result: (Complies at USP (b) (4) stage)

   - Minimum (b) (4) Maximum (b) (4), Average (b) (4)
     Limit: NLT (b) (4) and NMT (b) (4)
   - Minimum (b) (4) Maximum (b) (4) Average (b) (4)
     Limit: NLT (b) (4) and NMT (b) (4)

   This batch showed increasing trend during the 3 month and 6 month stability timepoints. However, no OOT investigation was conducted, and no impact assessment was carried out.

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Table 3

(b) (4)

This batch confirmed as valid OOS (Trackwise PR ID: 213326, Date initiation: (b) (4) at 9-month stability timepoint for Dissolution test and the batch was recalled (Trackwise PR ID: 220901, Date of initiation: (b) (4) The lack of OOT investigation led this batch to remain in the US market for additional about (b) (4) since the batch was trending OOT at 6-month stability testing.

2. Product: (b) (4) USP (b) (4) mg Tablets, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC, Stability condition and timepoint: 25°C/60%RH at **3 months**, Product shelf life: (b) (4)

   Result: (Complies at USP (b) (4) stage)

- Minimum (b) (4), Maximum (b) (4) Average (b) (4)
  Limit: NLT (b) (4) and NMT (b) (4)

3. Product: (b) (4) Tablet USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC, Stability condition and timepoint: 25°C/60%RH at **9 months**, Product shelf life: (b) (4)

   Result: (Complies at USP (b) (4) stage)

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- Minimum (b) (4) Maximum (b) (4) Average (b) (4)
  Limit: NLT (b) (4) and NMT (b) (4)

4. Product: (b) (4) USP (b) (4) mg Tablets, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC, Stability condition and timepoint: 25°C/60%RH at **9 months**, Product shelf life: (b) (4)

   Result: (Complies at USP (b) (4) stage)

- Minimum (b) (4) Maximum (b) (4) Average (b) (4)
  Limit: NLT (b) (4) and NMT (b) (4)
- Minimum (b) (4) Maximum (b) (4) Average (b) (4)
  Limit: NLT (b) (4) and NMT (b) (4)
- Minimum (b) (4) Maximum (b) (4) Average (b) (4)
  Limit: NLT (b) (4)

5. Product: (b) (4) Capsules USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Dissolution by HPLC, Stability condition and timepoint: 25°C/60%RH at **3 months**, Product shelf life: (b) (4)

   Result: (Complies at USP (b) (4) stage)

- Minimum (b) (4) Maximum (b) (4), Average (b) (4)
  Limit: NLT (b) (4) and NMT (b) (4)
- Minimum (b) (4) Maximum (b) (4) Average (b) (4)
  Limit: NLT (b) (4) and NMT (b) (4)

C. Your Quality Unit lacked adequate oversight to ensure product quality and safety. For example,

Product: (b) (4) Tablets USP (b) (4) mg, Batch No.: (b) (4) Mfg. date: (b) (4), Exp. Date: (b) (4) Test: Assay by HPLC, Stability condition and timepoint: 25°C/60%RH at **3 months**, Product shelf life: (b) (4) (b) (4)

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This Process Performance Verification (PPV) batch showed an increase in Assay test result from (b) (4) % at initial (T0) stability timepoint to (b) (4) % at 3-month stability timepoint against the specification limit of NLT (b) (4) % to NMT (b) (4) %. The increase in the test result of (b) (4) % between the two stability timepoints was not investigated. This batch later failed at 6-month stability timepoint for Assay by HPLC test. Your firm concluded the failing test result as valid OOS through Investigation Number: A/OOS (b) (4) 0086 (PR ID: 188294), Date of Initiation: (b) (4), Date of Closure: (b) (4), Result: (b) (4) %. The batch was recalled on (b) (4)

Your firm determined the root cause for OOS investigation was due to use of a (b) (4) (b) (4) However, looking through the trend of batches manufactured there was no outlier seen in terms of deviating from the validated (b) (4) Your firm provided no justification for concluding the OOS investigation based on these probable root causes being (b) (4) while the evaluation of batch manufacturing trend data showed batch with (b) (4) have been manufactured.

Furthermore, your firm charged no additional batch on stability while this single PPV batch was confirmed as OOS and discontinued from the stability studies. Moreover, there was no impact and risk assessment done by testing retention samples of commercial batches at periodic frequency to determine product performance. Additionally, your Quality Unit failed to identify the early signs of the batch failure since this batch was found as valid OOT for Uniformity of Dosage Unit test by HPLC at finished product release stage.

The lack of your Quality Unit oversight into monitoring the trend of product performance along with inability to thoroughly investigate the issues allowed batch number (b) (4) to remain in distribution in the US market for additional (b) (4) until its recall from the US market.

D. There is no system in place to assess the quality and safety attributes of products when damage to (b) (4) (b) (4) machine parts used in manufacturing is observed. Damaged parts identified during cleaning after batch manufacturing are removed and destroyed without any assessment of the batches in which these parts were used. The destruction log indicates that approximately (b) (4) machine parts, such as (b) (4)

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(b) (4) associated with (b) (4), were reported as damaged and removed for destruction between January 2024 and April 2026. However, no evaluation of batch quality has been performed.

For example, approximately (b) (4) used for (b) (4) during the (b) (4) of (b) (4) Tablets (b) (4) mg, (b) (4) mg, and (b) (4) mg) were reported as destroyed due to damage between April 2025 and April 2026. A manufacturing operator stated that, in many instances, the damage was not visible during the batch process due to the presence of (b) (4) and therefore (b) (4) integrity was documented as passing. However, after cleaning, the damage became clearly visible. The damaged (b) (4) were then removed and destroyed without conducting a risk assessment of the affected batches. A total of (b) (4) affected batches (b) (4) (b) (4) of this product have been shipped to the U.S. market.

E. On September 9, 2025, your firm identified black particles on (b) (4) Tablets, USP (b) (4) mg, batch (b) (4) during AQL inspection. Based on testing, the black particle had a combination of (b) (4) (b) (4) Based on your investigation, you identified that this was due to a (b) (4) leak (b) (4) (b) (4) from the (b) (4) machine (b) (4) utilized for the subject batch. The affected batch was rejected based on the investigation which was concluded on November 8, 2025.

Your investigation identified that (b) (4) Tablets, (b) (4) mg batch (b) (4) (UK market), manufactured on (b) (4) using the same (b) (4) machine, had similar black spots observed during AQL inspection. The batch was released based on satisfactory AQL results. Your investigation concluded that no other batches manufactured using the same (b) (4) machine were affected and, in addition, that the AQL verification and camera system at (b) (4) packaging would identify similar defects; hence, there was no impact.

However, you received a complaint from a non-US market regarding a dark grey spot on (b) (4) Tablets, USP (b) (4) mg, batch (b) (4) on October 13, 2025. This batch was packaged from the bulk batch (b) (4) in May 2025 using the same (b) (4) machine and the investigation concluded on January 12, 2026, that the extraneous black particle observed in the complaint tablet appeared to be a (b) (4) (b) (4) from (b) (4) and that there was no impact on patient health and safety. This assessment was made without testing the complaint sample. The investigation did not address whether the

(b) (4) leak (b) (4) which was under investigation during this period, may have caused the black spots on the tablets. The same bulk batch (b) (4) was used for packaging batches (b) (4) which were shipped to the U.S market. However, the investigation was not extended to these U.S batches.

Based on the nature of the complaint regarding batch (b) (4) and the AQL findings on batches (b) (4) (b) (4) there is limited evidence that the (b) (4) machine was in a state of good repair from May 2025 to September 2025. Your firm has shipped approximately (b) (4) batches processed using the same (b) (4) machine between May 2025 to September 2025 to the U.S market.

F. Your firm received a complaint from the US market on July 29, 2022, regarding black spots and metal particle on (b) (4) Tablets (b) (4) mg, batch (b) (4) (manufactured in (b) (4) with an expiry date of (b) (4) (b) (4) Your retention sample inspection identified the presence of black particles, which was concluded as inherent nature of (b) (4). Based on your investigation on August 26, 2022, the metal particle measured (b) (4). External laboratory testing results dated September 13, 2022, confirmed that the particle appeared to be (b) (4) Multiple deficiencies were observed in the investigation performed by your firm.

a) The metal particle was not rejected by the (b) (4) used for manufacturing, (b) (4) (b) (4) (b) (4) Your investigation concluded that the metal particle was smaller than (b) (4) (b) (4) (b) (4). There is no assurance that the (b) (4) (b) (4) in finished products to ensure that the products are safe for human consumption.

b) Your investigation revealed that damage to the (b) (4) of the (b) (4) machine led to the metal contamination. Your investigation did not extend to all batches manufactured using the (b) (4) machine (b) (4) Approximately (b) (4) batches were manufactured using the machine since the previous preventive maintenance and were shipped to the U.S. market.

c) Your investigation stated that the black particles originated from the raw materials (b) (4) However, no characteristic testing was performed to identify the particles.

d) Your investigation into manufacturing equipment also stated that (b) (4), used for the complaint batch, was found destroyed on June 11, 2022, as it was damaged during handling in the storage area. The investigation was not extended to the products manufactured using the (b) (4)

e) Your firm concluded that metal contamination was present in the released product on September 13, 2022. However, a recall decision was only taken on (b) (4). The reason for the delay in market action is not discussed in the investigation.

G. Your firm received two complaints from the US market on December 2, 2023, and January 1, 2024, regarding the presence of a foreign tablet in bottles of (b) (4) mg tablets, Batch# (b) (4) The investigation identified that the foreign tablet was (b) (4) Tablets (b) (4) mg, which was packaged on the same line. The packaging activity for the complaint batch was performed from February 24-25, 2023, and (b) (4) Tablets (b) (4) mg, Batch# (b) (4) was packaged on February 24, 2023, using the same packaging line, Equipment # (b) (4) Although a recall was initiated for the complaint batch, multiple deficiencies were observed in the investigation:

a) During packaging, rejections are collected in rejection bins, and the tablets are recovered for reuse in packaging. Your investigation stated that cleaning of rejection bins was not included in SOP A-PG/0100 titled "Operation and Cleaning of Tablet/Capsule Counter & Filler Machine." Therefore, it is possible that if any tablet became trapped or stuck in the rejection bin from the previous batches due to its small size, there is a chance it could be packed during recovery of rejections. Your CAPA addressed the cleaning of the rejection bins and awareness training for packaging operators during rejection handling. However, no CAPA was initiated to assess the line clearance procedure. The packaging line has (b) (4) rejection bins; however, the line clearance checklist (Document No. HAB/0001-F0003-004) requires only a single signature to verify line clearance.

b) You continue to recover and reuse rejections above a count of (b) (4) bottle. Based on the rejection bin cleaning procedure outlined in SOP# A-PG/0338-010, "Operation and Cleaning of Tablet/Capsule Counter and Filler machine," the rejection bins are wiped with wet, lint-free cloth and subsequently dried. The cleaning procedure for these non-dedicated rejection bins, which are

direct product contact surfaces, has never been evaluated through a validation process to ensure that products are not subjected to contamination.

c) The investigation was not extended to other batches packaged in the facility that also utilize similar cleaning and line clearance procedures.

On June 17, 2025, your firm received another complaint regarding 2 tablets of (b) (4) Tablets USP (b) (4) mg found in the bottle of (b) (4) Tablets USP (b) (4) mg, batch (b) (4) from the U.S market.

OBSERVATION 2

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

Specifically,

Your Quality Unit lacks adequate oversight into the integrity of data pertaining to QC testing on UV Spectrometry. For example,

On 23-Apr-2026, the evaluation of Dissolution by UV test data revealed potential for lack of testing integrity. Your QC Analyst appeared to have analyzed (b) (4) separate test samples on UV Spectrometer in (b) (4) However, when the same analyst demonstrated the analysis for the same product during the inspection on 23-Apr-2026, the analyst appeared to be rushing to complete the analyses and still ended up taking twice the amount of time i.e. about (b) (4) for (b) (4) test sample. Few examples are included as follows:

Table 4

(b) (4)

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	FEI NUMBER 3006370524

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Shirish Ambulgekar, President & Global Quality Head	
FIRM NAME Alkem Laboratories Limited	STREET ADDRESS Plot No 164, 165/1/2/3 168/215/216/234, Srv No 167; Village Dabhel, Mahatma Gandhi Udyog Nagar
CITY, STATE, ZIP CODE, COUNTRY Daman and Diu, 396210, India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer

(b) (4)

There was no justification provided by your QC Analyst about how testing of multiple samples was completed in the shorter time since each sample upon testing underwent rinsing UV-Vis cuvette with test sample solution prior to its analyses. There is potential that your QC Analyst used the same test solution and analyzed it multiple times reflecting multiple samples of either the same lot or different lots were analyzed. This would lead to favoring test results for each sample and it may not show if any unit of tablets fails for Dissolution test which may trigger investigation and marketed action (if applicable). There is a potential for lack of testing integrity related to all testing conducted using UV-Vis Spectrometry including Identification, Assay, and equipment cleaning (swab and rinse) samples analyses.

OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

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Specifically,

a) Your approach to Process Validation is incomplete, as not all process validation batches are subjected to stability studies. Your SOP for Process Validation (CQA/0098-014) does not specify requirements regarding the number of batches to be included in stability studies. You rely on stability data from a single validation batch to assess the quality attributes of products. It was observed that, for (b) (4) products, only one validation batch was subjected to stability studies.

b) You qualified alternate vendors for raw materials used in (b) (4) Tablets USP (b) (4) (b) (4) mg) without establishing critical process parameters; consequently, the (b) (4) rate was significantly slowed. In July 2022, alternate vendors for the excipients (b) (4) (b) (4) were introduced. No assessment of critical material attributes in the finished product or their impact on stability was performed; however, the product was released for commercialization without adequate data to support the assigned shelf life.

Table 5

(b) (4)

On September 3, 2025, the United States Food and Drug Administration (USFDA) tested the drug product (b) (4) Tablets USP, (b) (4) mg (batch # (b) (4) and determined that the batch failed the (b) (4) test. Based on notification from the USFDA, you tested (b) (4) batches of (b) (4) Tablets USP (b) (4) mg, at your site and identified that (b) (4) batches manufactured between September 2024 and April 2025 failed to meet the (b) (4) specification. Your firm decided to recall or destroy (b) (4) batches manufactured from July 2024 to August 2025.

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Your firm has distributed approximately (b) (4) batches to the U.S. market since July 2022 following the introduction of alternate vendor materials. You allowed approximately (b) (4) batches, manufactured using alternate vendor materials, to remain in the U.S. market at risk based on periodic testing protocols conducted at your site.

c) Your firm has received approximately thirty-eight complaints regarding broken/soggy/wet tablets in bottles from several batches of (b) (4) Tablets (b) (4) mg, (b) (4) mg, and (b) (4) mg) distributed to the U.S. market since September 2025. The product is supplied in (b) (4) count and (b) (4) count bottles. Several complaints indicated that at least half of the tablets were found broken within the manufacturer's bottle of (b) (4) ount.

Your investigation determined that the finished product does not withstand vibrations during transportation. Complaints continue to be received despite an increase in the (b) (4) of the tablets. Your impact assessment concluded that the risk to patient health and safety is minimal. However, you continue to manufacture and distribute this substandard product to the U.S. market. Your firm has shipped approximately (b) (4) bottles (b) (4) to the U.S. market. No Field Alert Report (FAR) has been initiated as of April 24, 2026.

d) The ranges for critical process parameters (CPPs) for the manufacturing process are not scientifically justified. We observed approximately (b) (4) products manufactured at the site without scientifically established (b) (4) for (b) (4) operation. Your Quality Control Laboratory has reported approximately thirty-five out of specification results for (b) (4) tests for multiple products since January 2023, where nineteen results were confirmed OOSs. For example,

1. For (b) (4) Tablets, the (b) (4) provided in the current batch manufacturing report was not aligned with the ranges optimized based on feasibility studies. Your Production supervisor stated that the current controls over (b) (4) are taken from historical trend data. We observed several batches failing to meet (b) (4) criteria and several batches failing to meet the specification limits.

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Table 6

Products	Feasibility study (b) (4)	Current specification in batch record	Release test (Number of batches failed (b) (4) criteria)	Stability test (Number of batches failed (b) (4) criteria)	OOS reported since 2021
[redacted]					

For example, (b) (4) failure was reported on (b) (4) Tablets USP (b) (4) mg batch (b) (4) dated February 28, 2024, and the root cause of the failure was attributed to (b) (4) used for (b) (4) of this (b) (4) system formulation, which might have led to (b) (4) which could have caused rise in (b) (4) results. However, the batch report data showed that the product was (b) (4) within the range provided in the batch record and there is no assurance that the range was scientifically optimized. The batch was rejected.

2. For (b) (4) Tablets USP (b) (4) mg), your firm changed the vendors for excipients in July 2022. You continued to use the same (b) (4) for (b) (4) as it was used for the previous excipients, (for example (b) (4) consequently, the (b) (4) rate was significantly slowed. From August 2025, (b) (4) batches of (b) (4) Tablets (b) (4) mg failed to meet (b) (4) and the root cause was attributed to inconsistences on (b) (4) characteristics. Your company recalled approximately (b) (4) batches due to the failure of (b) (4)

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OBSERVATION 4

Your examination and testing of samples did not assure that the drug product and in-process material conformed to specifications.

Specifically,

Your manufacturing operators do not initiate deviation investigations after identifying out-of-specification (OOS) results during in-process testing of tablet formulations during (b) (4) operations. A review of raw data from in-process testing revealed that several batches had failed in-process test results. No manufacturing deviations or documentation in the executed batch records were available for these failures. Your firm follows a similar approach for capsule products as well.

Additionally, the Quality Unit's review performed as part of batch release did not initiate deviations for these OOS in-process results. A review of approximately (b) (4) batches revealed that about (b) (4) batches (b) (4) %) had failed in-process test results for which no deviation investigations were initiated. There is no assurance that products manufactured meet established in-process control requirements. For example, this is not a comprehensive list:

Table 7

(b) (4)

[redacted]

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Mr. Shirish Ambulgekar, President & Global Quality Head

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(b) (4)

[redacted]

SEE REVERSE OF THIS PAGE

Unnee Ranjan, DDC Investigator
Pratik S. Upadhyay, DDC Investigator

UNNEE RANJAN -S
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Date: 2026.05.01 15:00:44 +05'30'

PRATIK S. UPADHYAY -S
Digitally signed by PRATIK S. UPADHYAY -S
Date: 2026.05.01 05:57:14 -04'00'

DATE ISSUED
05/01/2026

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(b) (4)

[redacted]

OBSERVATION 5

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,

a) On April 20, 2026, during inspectional walkthrough of Building (b) (4) which is utilized for the manufacturing of (b) (4) products for the U.S market, the following was observed:

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1. (b) (4) (Equipment ID (b) (4) cleaned and stored on March 27, 2026, was found with brownish rust like discoloration. This (b) (4) was utilized for the manufacturing of (b) (4) Capsules USP (b) (4) mg, batch (b) (4)
2. (b) (4) was observed on the (b) (4) (Equipment ID (b) (4) which was cleaned and stored on April 10, 2026. This (b) (4) was utilized for the manufacturing of (b) (4) (b) (4) USP (b) (4) ml, batch (b) (4)

b) On April 20, 2026, during inspectional walkthrough of Building General block (b) (4) which is utilized for the manufacturing of products for the U.S market, the following was observed:

1. The firm uses (b) (4) for measuring distance from the (b) (4) to the (b) (4) during (b) (4) (b) (4) process. Clean status and traceability of these (b) (4) are not available in the executed batch manufacturing records. The firm currently has about (b) (4), however, no procedural control in place for the usage of these (b) (4)
2. Water droplets were found inside the empty (b) (4) while the Capsule filling machine (Equipment ID (b) (4) was assembling for the batch (b) (4) Capsules, (b) (4) mg, batch # (b) (4) Machine assembling occurs after line clearance by Quality. The manufacturing operators stated that this could be a potential leak from the ceiling, and the reason was unknown.

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 for it in the application.

Specifically,

Your procedures relating to complaint investigation (CQA/0153-008, Effective date: 30-Sep-2024), and Field Alert (CQA/0191-003, Effective date: 31-Jan-2025) are deficient. There is no information relating to impact assessment and market actions that need to be taken in the event of repeated market complaints received for the same product and batch number. For example,

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On 29-Apr-2026, we observed that your PQC team received total 48 complaints for count variability (less count) in the period of 21-Nov-2023 to 17-Oct-2025 for (b) (4) Capsules (b) (4) mg. Out of 48 complaints 37 complaints were substantiated upon retention samples evaluation and packaging line investigation. 13 out of 37 complaints were for batch number (b) (4) and 5 out of remaining 24 complaints were relating to batch number (b) (4) Similarly, your firm received 21 count variability (less count) complaints in the period of 15-Mar-2023 to 30-Oct-2025 for (b) (4) Capsules (b) (4) mg and (b) (4) mg. 17 out of 21 complaints were substantiated upon retention samples evaluation and packaging line investigation.

However, your Quality Unit reported no Field Alert in the event of receiving repeated substantiated market complaints for the same product and batches nor have they established any mechanisms for taking market action based on the nature of complaints to ensure patients receive labelled claims of safe, effective and quality drug product.

OBSERVATION 7

Deviations from written production and process control procedures are not recorded and justified.

Specifically,

a) On April 20, 2026, during the (b) (4) operation of (b) (4) Tablets USP (b) (4) mg, batch (b) (4) the (b) (4) had an in-process limit of (b) (4) The (b) (4) documented in the batch manufacturing record was (b) (4) However, upon verification using the (b) (4) (Equipment # (b) (4) used for the batch, the actual (b) (4) was found to be (b) (4) Based on the manufacturing operator, it was unknown why the (b) (4) was out of the specified in-process limit. He also stated that, during the previous interval, he had recorded a lower value than the actual (b) (4) displayed on the (b) (4)

b) On April 20, 2026, at 12:32 PM, the (b) (4) operation of (b) (4) Tablets USP, batch (b) (4) was placed on hold due to failure to achieve the (b) (4) required by the batch manufacturing record. The production supervisor stated that engineering was notified of the machine issue via phone call. The tablets

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had already been transferred into the (b) (4) at 9:30 AM. However, no documentation regarding this issue was recorded in the executed batch manufacturing record. It is unclear whether contemporaneous documentation was performed during the process steps.

***DATES OF INSPECTION**

04/20/2026 (Mon), 04/21/2026 (Tue), 04/22/2026 (Wed), 04/23/2026 (Thu), 04/24/2026 (Fri), 04/27/2026 (Mon), 04/28/2026 (Tue), 04/29/2026 (Wed), 04/30/2026 (Thu), 05/01/2026 (Fri).

SEE REVERSE OF THIS PAGE	Unnee Ranjan, DDC Investigator Pratik S. Upadhyay, DDC Investigator	UNNEE RANJAN S PRATIK S. UPADHYAY -S Digitally signed by UNNEE RANJAN -S Date: 2026.05.01 15:04:37 +05'30' Digitally signed by PRATIK S. UPADHYAY -S Date: 2026.05.01 06:00:13 -04'00'	DATE ISSUED 05/01/2026

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."