

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov		DATE(S) OF INSPECTION 11/10-21/2025*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Ranjana Pathak, President, Chief Quality Officer - CQA		FBI NUMBER 3004819820
FIRM NAME Lupin Limited	STREET ADDRESS 15-B, Phase IA, Verna Industrial Area,	
CITY, STATE, ZIP CODE, COUNTRY Verna, Salcette, Goa - 403 722, India	TYPE ESTABLISHMENT INSPECTED 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.

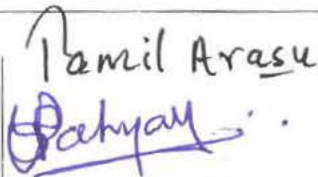
Specifically, your quality unit did not take appropriate market action for batches of the US drug product that failed to meet the regulatory Acceptable Intake (AI) limit for (b)(4) Impurities (b)(4)

For example:

(b)(4) out of (b)(4) commercial batches of (b)(4) Capsules USP (b)(4) mg, (b)(4) mg, (b)(4) mg, (b)(4) mg, (b)(4) mg, (b)(4) mg failed to meet the AI limit of NMT (b)(4) ppm for (b)(4) impurity when analyzed as a part of (b)(4) risk assessment in (b)(4) Details are as follows:

**Table 1**

Sr. No.	Strength	Batch No.	Mfg. Date	Expiry	Date of Testing	Age of sample during testing	Results
(b)(4)							

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(b) (4)

In your subsequent evaluation of additional (b) (4) commercial batches, (b) (4) patches failed to meet the AI limit of NMT (b) (4) ppm for (b) (4) impurity when analyzed in (b) (4).  
Details are as follows:

**Table 2**

Sr. No.	Strength	Batch No.	Mfg. Date	Expiry Date	Date of Testing	Age of sample during testing (b) (4)	Results (NMT (b) (4) ppm)
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(b) (4)

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Sr. No.	Strength	Batch No.	Mfg. Date	Expiry Date	Date of Testing	Age of sample during testing	Results (NMT (b)(4) ppm)
(b)(4)							

Further evaluation of additional (b)(4) commercial batches revealed (b)(4) batches failed to meet the AI limit of NMT (b)(4) ppm for (b)(4) impurity when analyzed during (b)(4) (b)(4) Details are as follows:

**Table 3**

Sr. No.	Strength	Batch No.	Mfg. Date	Expiry Date	Date of Testing	Age of sample during testing	Results (NMT (b)(4) ppm)
(b)(4)							

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Sr. No.	Strength	Batch No.	Mfg. Date	Expiry Date	Date of Testing	Age of sample during testing	Results (NMT (b)(4) ppm)
(b)(4)							

The following was observed relating to (b)(4) testing failures:

**A.** Your firm continued to manufacture and release batches into the US market even if over (b)(4)% of your batches failed to meet AI limit of NMT (b)(4) ppm (refer to Table 3). There were no investigations conducted for the (b)(4) batches (refer to Tables 1 to 3) that failed to meet the AI limit of NMT (b)(4) ppm for (b)(4) (b)(4) content in (b)(4) Capsules USP. This is in deviation of your following procedures:

- SOP\_MUM\_CQA\_007356, Titled: "Handling of Investigation", Version: 10.0, Effective date: 15-Apr-2025,
- SOP\_MUM\_CQA\_033778, Titled: "Assessment for presence of (b)(4) Impurities in Drug Products", Version: 4.0, Effective date: 10-Mar-2025, and
- SOP\_MUM\_CQA\_008193, Titled: "Responsibilities of Quality Unit", Version: 2.0, Effective date: 01-Jul-2025.

**B.** There was no justification provided for not testing (b)(4) batches of (b)(4) (b)(4) Capsules USP which are within the product shelf life in the US market and many of the batches has a potential to fail for (b)(4) content based on the above trend of failing results. On (b)(4) your firm suspended manufacturing and distribution of (b)(4) (b)(4) Capsules USP (b)(4) due to continued risk associated with the formation of (b)(4) (b)(4) in your product. Further, your Quality Unit initiated a deviation investigation DEV-GO-288-25-0010 and analyzed (b)(4) batches of which (b)(4) batches failed to meet the AI limit of NMT (b)(4) ppm for (b)(4) Details are as follows:

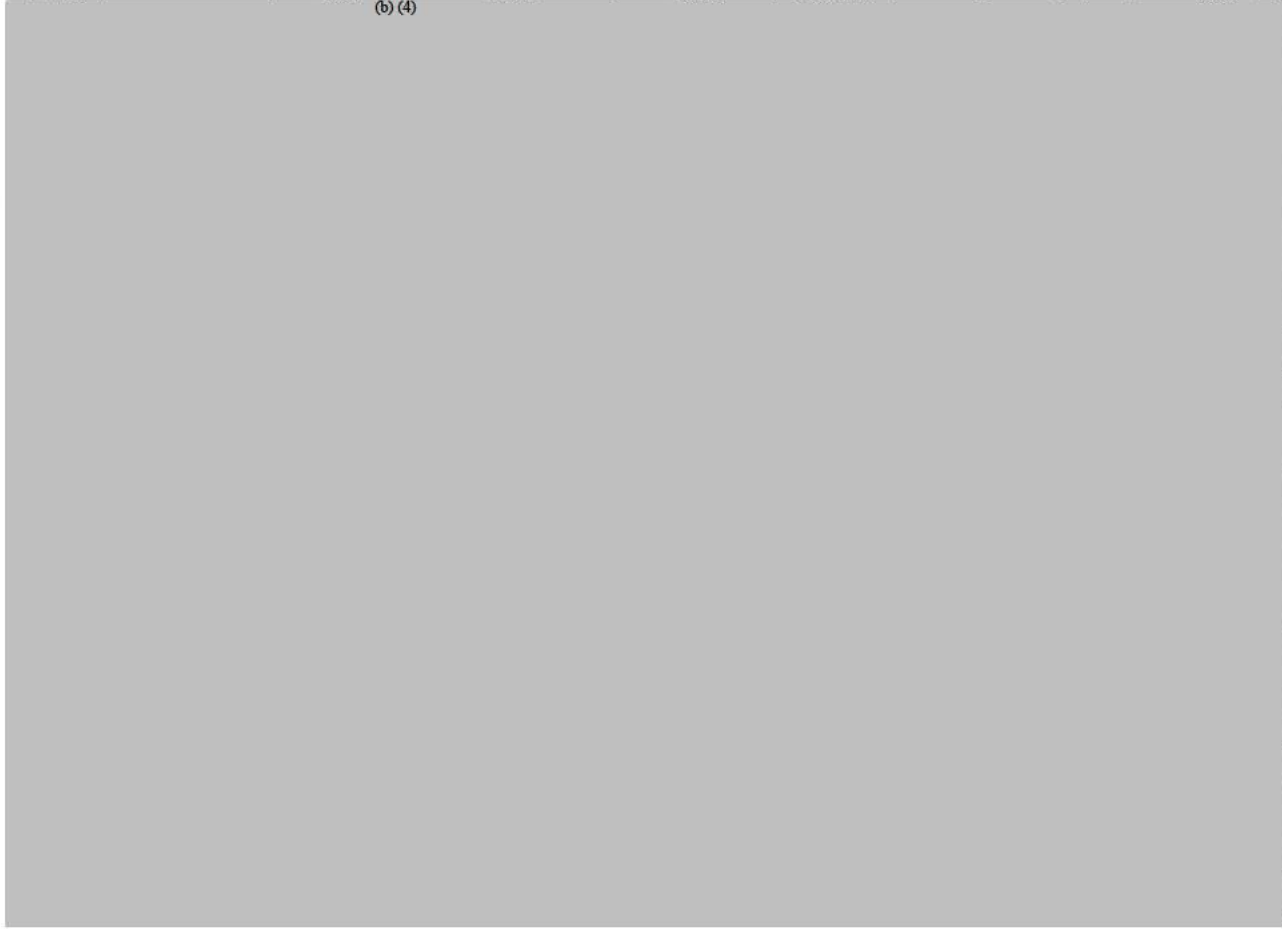
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**Table 4**

Sr. No.	Strength	FG Batch No. (b) (4)	Manufacturing Date	Expiry Date	Date of Testing	Age of sample during testing	Results (NMT) (b) (4)
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Sr. No.	Strength	FG Batch No.	Manufacturing Date	Expiry Date	Date of Testing	Age of sample during testing	Results (NMT)(b)(4)
(b)(4)							

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Sr. No.	Strength	FG Batch No.	Manufacturing Date	Expiry Date	Date of Testing	Age of sample during testing	Results (NMT) (b) (4)
(b) (4)							

- C. There was no justification provided for using (b) (4) limit of NMT (b) (4) ppm while (b) (4) indicated you to use regulatory AI limit of NMT (b) (4) NMT (b) (4) ppm).
- D. There was no Health Hazard Assessment (HHA) performed to evaluate the risk due to out of acceptance limit for (b) (4) impurity in your (b) (4) Capsules USP. This was in deviation of your procedure SOP\_MUM\_DERM\_006469, Titled: "Preparation of Health Hazard Assessment Reports", Effective date: 10-Nov-2023, sections 4.1 which requires assessment of the

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likelihood of occurrence of the hazard and section 5.2 relating to initiating HHA when the OOS results and impurities are detected.

Based on the above observed issues, on 14-Nov-2025 your firm provided HHA report dated 14-Nov-2025 indicating "(b) (4) impurity is mutagenic. Considering the mutagenic potential of (b) (4) (b) (4) impurity and longer term use of (b) (4) Capsules USP, a risk of carcinogenicity cannot be ruled out."

**OBSERVATION 2**

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

Specifically,

Your firm's analysis of (b) (4) impurities in the same batch at various time points yielded inconsistent test results. While these results were reported as within specification limits, the significant variability lacks scientific justification and raises concerns about analytical method reliability and product quality control for these impurities. You have not investigated why these impurity tests gave varying but inconsistent results at various time points. You have accepted these results for reporting purposes without any investigations including to evaluate why validated analytical test methods for (b) (4) Impurities (b) (4) do not give consistent test results and/or what are the factors causing such variability.

Your LC-MS/MS analytical test methods were validated with an acceptance criterion of (b) (4) % RSD precision (peak area of impurity) at Limit of Quantitation (LOQ) and reporting %RSD values of (b) (4) % during validation. However, it was observed that sample test results of a single batch were reported with variations up to (b) (4) % (or (b) (4) fold) at different time points. These results were not in any consistent manner and thus lack confidence. Your firm was unable to explain and justify the origin of high level of variation for (b) (4) impurities for the same batch and between batches for selected products. Also, you have not identified whether this is caused by materials, manufacturing process, storage conditions, environmental factors and/or test method precision. This raises concerns about the accuracy of these reported (b) (4) impurity test results, and the precision and robustness of the method used and your ability to control the (b) (4) impurities on these drug products in a scientifically acceptable manner. Examples include, but are not limited to the following:

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- A.** (b) (4) Capsules USP – You have reported (b) (4) impurity result of (b) (4) ppm for batch# (b) (4) when tested at (b) (4) different time points in addition to values ranging in-between at other time points. This variation in impurity levels of approximately (b) (4) % between (b) (4) results of the same batch could not be adequately explained and was not investigated. However, your validated analytical method (b) (4) (0134/00) for the (b) (4) impurity test for this product has an LOQ of (b) (4) ppm with a precision at LOQ of (b) (4) % RSD. You have also reported impurity level variations of approximately (b) (4) % between batches manufactured using the same process. No justifying explanations were provided for the large variation in results leading to lack of confidence in the reported results and suitability of your testing method.
- B.** (b) (4) Capsules USP – You have reported (b) (4) Impurity (b) (4) for same batch (Batch# (b) (4)) was reported as (b) (4) ppm at different time points which is approximately (b) (4) fold (b) (4) % relative difference. Similarly, relative difference of impurity results among different batches was approximately (b) (4) fold (b) (4) % with actual values of (b) (4) ppm (LOQ) (b) (4) (b) (4). However, the analytical method has been validated (b) (4) MVS-R23-056 (01)] with an LOQ of (b) (4) ppm with a precision at LOQ of (b) (4) % RSD. No investigations were carried out and no justifications were provided for the high variation.
- C.** (b) (4) Capsules USP – The results reported for (b) (4) impurity varied between batches to the extent of (b) (4) fold (b) (4) % with actual values ranging from (b) (4) ppm, while the analytical method was validated (b) (4) (25-26/MVR/086) with an LOQ of (b) (4) ppm with a precision at LOQ of (b) (4) % RSD. Same batch variations at different time points for this product are not available as data is not available. No investigations were carried out and no justifications were provided for the high variation.
- D.** (b) (4) Tablets USP - The results reported for (b) (4) impurity varied between batches to the extent of approximately (b) (4) fold with actual values ranging from (b) (4) (b) (4) ppm, while the analytical method was validated (b) (4) (J2-MVR-23-052) with an LOQ of (b) (4) ppm with a precision at LOQ of (b) (4) % RSD. No investigations were carried out, and no justifications were provided for the high variation.

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**OBSERVATION 3**

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,

Your firm has deviated from equipment cleaning validation procedure to ensure validated procedure is established in reducing (b)(4) Impurities (b)(4) on direct and indirect product contact surfaces of shared (non-dedicated) equipment to predetermined Acceptable Intake (AI) limits. For example,

**A.** According to your procedures SOP\_MUM\_CQA\_011679, Titled: "Cleaning Validation for Drug Products", Version: 5.0, Effective date: 25-Sep-2025, Section 5.3.1.3.7 "*The worst-case (b)(4) shall be selected for cleaning validation in respect to (b)(4) impurities, including (b)(4) by considering risk factors\*\*\**" Further this procedure has detailed series of factors to be evaluated including MACO calculation for (b)(4) impurities in subsequent sections of the procedure. However, your firm has deviated from this procedure by not performing cleaning validation for (b)(4) impurities.

On 17-Nov-2025, your QA Manager for Validation (b)(6) stated the reasoning for not conducting cleaning validation for (b)(4) impurities (b)(4) was due to recently including these requirements in their revised procedure (SOP\_MUM\_CQA\_011679) with Version 5.0, dated 25-Sep-2025. According to him, these requirements were never part of the procedure in their previous version (4.0). However, we found similar set of requirements relating to (b)(4) impurities were part of the previous version (4.0) of this procedure which had effective date 14-Nov-2024. Therefore, your firm has deviated from the procedure for over a year by not validating equipment cleaning procedure for detection of (b)(4) impurities on product contact surfaces of non-dedicated equipment.

**B.** On 17-Nov-2025, your QA Manager for Validation (b)(6) stated that in the absence of establishing cleaning validation for (b)(4) Impurities (b)(4) they have conducted risk assessment to evaluate the potential risk of carryover of (b)(4) Impurities across all commercial products. The evaluation of Risk Assessment Number: QRM/25/L008/P/056/00, Approval date: 07-Nov-2025 revealed the following:

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1. In your justification for risk analysis rating, you have mentioned that "Cleaning validation strategy with respect to (b) (4) impurity is specified in SOP No.: SOP\_MUM\_CQA\_011679 titled "Cleaning validation for drug products". As per SOP\_MUM\_CQA\_011679, detailed procedure is in place for establishing worst case (b) (4) for cleaning validation w.r.t. (b) (4) impurities and establishment of MACO. Hence, detectability of risk is rated as 4 based on the available controls". However, there is no cleaning method validation performed for worst case (b) (4) w.r.t. (b) (4) impurities and no MACO is established for (b) (4) impurities.

2. In your justification for risk analysis rating, you have mentioned that "Based on the nature of the products and regulatory requirements, products are tested for (b) (4) impurities, including (b) (4) prior to release. Therefore, none of the products would be released with (b) (4) levels exceeding the acceptable intake limits". However, as of 18-Nov-2025 your firm has distributed about (b) (4) batches of (b) (4) Capsules USP (b) (4) to the US market of which (b) (4) batches have failed to meet the AI limit of NMT (b) (4) ppm for (b) (4) impurity.

**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,

- A. OOS/Recall: The out-of-specification (OOS) investigation for (b) (4) Tablets USP (b) (4) mg that exhibited failing dissolution results was inadequate, as it failed to extend into manufacturing operations to identify the root cause. Specifically, batch (b) (4) was incorporated into repackaged product batch (b) (4) by your contract partner. During stability testing, this repackaged batch demonstrated OOS dissolution results at the initial time point (T=0) on (b) (4). Subsequently, your repackaging partner, who distributed the product in the United States, initiated a voluntary recall (Recall Number: (b) (4)). Despite the recall action, no Field Alert Report (FAR) was submitted to the FDA as required and no manufacturing investigation was conducted to find the root cause. Your quality assurance

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technical agreement with your repackaging partner is inadequate in establishing the requirement for the repackager to inform the manufacturer when there is a product quality impacting event like OOS.

- B.** Field Alert (b)(4) The active pharmaceutical ingredient (API) supplier reported out-of-specification (OOS) stability results at the (b)(4) time point for an API batch used in the manufacture of (b)(4) Tablets USP. This compromised API batch was incorporated into (b)(4) finished product batches that were distributed in the US market. Although your firm became aware of the API stability failure in (b)(4) no immediate follow-up actions were implemented to verify that the affected finished product batches remained stable throughout their labeled shelf life. Corrective measures were not initiated until (b)(4) (batch expiry), representing a (b)(4) delay in addressing potential product quality concerns. Additionally, your firm failed to conduct full testing of this API batch prior to its use in finished product manufacturing, instead relying on a reduced testing protocol that did not detect the stability issues. This reduced testing approach contributed to the incorporation of potentially compromised API into multiple commercial batches.
- C.** The drug product (b)(4) Tablets at various strengths gave multiple OOS and OOT results since 2023 during finished product release and stability testing. However, attributed root causes were not adequately supported and/or impact assessment were inadequate. Examples include but are not limited to the following:
- OOS-GO-278-23-0016: (b)(4) Tablets, (b)(4) mg, batch number (b)(4) when tested at 9M LT stability resulted in OOS for unspecified degradation products. Result observed: (b)(4) % (Specification: NMT (b)(4) %). The OOS result was invalidated attributing the root cause to an instrument error which was most probably due to particulate matter contamination in HPLC column or check valve or tubings or partial blockage of DIV cartridge at detector. However, other (b)(4) batches (b)(4) (b)(4) tested in the same sequence gave passing results.
  - OOS-GO-278-24-0029: (b)(4) Tablets, (b)(4) mg, batch number (b)(4) when tested at (b)(4) LT stability (at expiry) resulted in OOS for unspecified degradation products. Result observed: (b)(4) %

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(Specification: NMT (b)(4) %). The result was invalidated attributing the root cause to a laboratory error caused by the use of a contaminated stopper in a volumetric flask used for sample preparation.

- OOS-GO-278-24-0032: (b)(4) Tablets, various strengths of (b)(4) batches, when tested for stabilities at various time points, (b)(4) resulted in OOS for unspecified degradation product. Result observed (b)(4) %, respectively (Specification: NMT (b)(4) %). Initial results were invalidated attributing the root cause to a probable laboratory error, caused by the use (b)(4) of specific bottles of a particular lot. However, same lot of the (b)(4) has been used to get passing results on multiple batches prior to and after this event.

Though your firm has discontinued this product there are approximately (b)(4) batches of this product in the US market.

**OBSERVATION 5**

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Analytical test procedures for swab sample analyses are not reliable to determine the level of active and degradant residual materials on the product contact areas of manufacturing equipment. For example,

There is no evaluation of "(b)(4) swab stick" performed to determine the impact of extreme conditions (b)(4) on swab stick that could potentially cause generation of large number of unknown peaks. Your firm analyzed (b)(4) swab stick as blank during each swab analyses and labeled unknown peaks as "blank peak" without determining the impact of unknown peaks which were coeluting at about the same retention time as to that of active and degradant peaks to ensure reliability on swab sample test results. Due to coelution of unknown peaks with active peak, your firm has never found any failing swab analyses test result since July 2022.

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

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov		11/10-21/2025*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FBI NUMBER
Dr. Ranjana Pathak, President, Chief Quality Officer - CQA		3004819820
FIRM NAME	STREET ADDRESS	
Lupin Limited	15-B, Phase IA, Verna Industrial Area,	
CITY, STATE, ZIP CODE COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Verna, Salcette, Goa - 403 722, India	Drug Product Manufacturer	

On 18-Nov-2025, the overlay chromatograms of standard solution and "blank with (b) (4) swab" solution showed (b) (4) peak was coeluting with a (b) (4) unknown/blank peak at retention time of (b) (4). This unknown/blank peak was absent in blank (diluent) and standard solutions chromatography, but it was present in "blank with (b) (4) swab" and swab sample solution injections. Per your test procedure GA\_MCAP\_006311, Effective date: 18-Aug-2023, retention time for (b) (4) is about (b) (4) (Acceptance limit: (b) (4) (b) (4) (b) (4)).

Further, your deviation investigation: DEV-GO-278-25-0098, product: (b) (4) Capsules (b) (4) mg, date initiated: 19-Jun-2025 for the issue of "out of acceptance limit for retention time of (b) (4) peak in standard solution chromatography" is deficient. There is no evaluation of peak interference due to coelution of (b) (4) peak and unknown peaks due to "blank with (b) (4) swab" solution is performed. Your Quality Unit identified these concerns in December 2024 and initiated evaluation of cleaning samples test procedure for (b) (4) products through non-routine protocol number NRP/25/25-00 on 05-Feb-2025. On 20-Nov-2025, the firm provided interim report dated 19-Nov-2025 (prepared during the inspection based on findings) indicating (b) (4) out of (b) (4) products were evaluated and interference for co-eluting peak against the main analyte peak was identified for (b) (4) products as follows:

(b) (4)

Your R&D Unit developed new analytical test methods for the above (b) (4) products to ensure no peak interference between swab and main analyte peak, but these test methods are not validated. Since initially knowing this issue in December 2024, your firm has continued manufacturing these products using non-dedicated manufacturing equipment irrespective of the risk associated with detection of analyte (API) and degradant peaks using your current test procedures for cleaning sample. Moreover, the verification of cleaning method for peak

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interference is not yet completed for the (b) (4) US drug products that potentially has similar concerns relating to the peak interference with main analyte peak.

**OBSERVATION 6**

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

Specifically,

Your Quality Unit failed to thoroughly investigate adverse drug events (ADE) and market complaints relating to Lack of Effect (LOE), organoleptic defects and medical inquiry related to formulation. For example,

A. On 12-Nov-2025, we observed for majority of your product quality complaints for the period of 01-Jan-2022 to 12-Nov-2025 the batch number remained unknown. For example,

**Table 5**

Nature of defect	No. of complaints reported	No. of complaints without batch numbers	No. of complaints without batch numbers (%)
Organoleptic defect (Odor / Taste)	61	48	78.7
Product Response (ADE / LOE / Batch Quality)	300	243	81.0
Query related to formulation	33	29	87.9
(b) (4)	16	9	56.3

Your Quality Unit failed to identify trend of majority of complaints being reported without the batch numbers which is crucial in investigating the root cause(s) and taking appropriate corrective actions and preventative actions. In the

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absence of batch number, your Complaint Investigation team simply closed investigations by rewriting the similar details in each of your complaint investigations of the same defect. The rewriting of similar details did not lead to the meaningful investigation to determine the root cause while complaints were repeatedly reported for the similar defects.

**B. Your ADE investigations relating to Lack of Effect (LOE) are deficient. For example,**

**1. Complaint Number:** DPC-GO-288-24-0252, **Product:** (b) (4) Capsules (b) (4) mg, **date received:** 20-Sep-2024, **Batch Number:** (b) (4) **Classification:** Adverse event and LOE, **Complaint sample received:** Yes, **Complaint sample received date:** 24-Oct-2024, **Photograph received:** No.

Your complaint investigation is misleading since there was no complaint sample received at the site. Per your investigation, complaint sample was received at the pharmacy. However, your site did not attempt to collect complaint sample from the pharmacy. Further, your firm did not attempt to investigate the reported product quality issue through testing of control sample to determine product efficacy for the reported batch number (b) (4)

**2. Complaint Number:** DPC-GO-288-22-0050, **Product:** (b) (4) Tablets USP (b) (4) mg, **Batch Number:** Unknown, **Classification:** Adverse event and LOE, **Complaint sample received:** No, **Photograph of complaint sample received:** Yes.

Your Quality Unit received a picture from complainant showing your product inside pharmacy bottle from the top view. However, the side view of the picture from different angles which would have shown product details was not requested by your firm. Your firm made no attempt in collecting more pictures, physical sample, and batch details which could have helped in determining the root cause and taking appropriate corrective actions and preventative actions.

**3. Complaint Number:** DPC-GO-288-23-0026, **Product:** (b) (4) Tablets USP (b) (4) mg, **Batch Number:** (b) (4) **Classification:** Adverse event and LOE, **Complaint sample received:** No, **Photograph of complaint sample received:** Yes.

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Your firm did not attempt to investigate the reported product quality issue through testing of control sample to determine product efficacy for the reported batch number (b) (4). Additionally, your Quality Unit received a picture from complainant that showed your product inside pharmacy bottle from the top view. However, the side view of the picture from different angles which would have shown product details was not requested by your firm. Your firm made no attempt in collecting more pictures, and physical sample which could have helped in determining the root cause and taking appropriate corrective actions and preventative actions based on scientific justification.

4. Complaint Number: DPC-GO-288-23-0026, Product: (b) (4) Tablets USP (b) (4) mg. Batch Number: Unknown, Classification: Adverse event and LOE, Complaint sample received: No, Photograph of complaint sample received: Yes.

Your Quality Unit received a picture from complainant showing your product inside pharmacy bottle from the top view angle. However, the side view of the picture from different angles which would have shown product details was not requested by your firm. Your firm made no attempt in collecting more pictures, physical sample, and batch details which could have helped in determining the root cause and taking appropriate corrective actions and preventative actions based on scientific justification.

**OBSERVATION 7**

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

Specifically,

We observed the presence of logbooks titled 'Miscellaneous Samples Inward Register' in the QC laboratory and have listed numerous test samples as received with reference to 'Non-routine Protocols'. These non-routine protocols are not found within your Quality Management System. There is no written procedure that describes what is Non-routine Protocol and what is Miscellaneous sample. These logbooks with commercial product batch numbers have multiple entries that do not have information on what type of tests were performed, purpose of these tests and where

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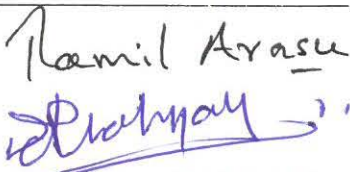

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those tests were carried out. However, most of the samples refer to 'For Information' under Remarks column. Quality unit has not reconciled all the received and tested samples with corresponding test results and reports.

**\*DATES OF INSPECTION**

11/10/2025(Mon), 11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri),  
11/17/2025(Mon), 11/18/2025(Tue), 11/19/2025(Wed), 11/20/2025(Thu), 11/21/2025(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."