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 ORAPHARMInternational483responses@fda.hhs.gov	02/09/2026-02/13/2026 FEI NUMBER 3030509366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajesh Chandrakant Gandhi, Chairman

FIRM NAME	STREET ADDRESS
Almon Healthcare Private Limited	Plot No 4, Sankalp Industrial Estate, Behind Keral, GIDC, Bavala
CITY, STATE, ZIP CODE, COUNTRY Ahmedabad, Gujarat, 382240, India	TYPE ESTABLISHMENT INSPECTED API 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

Failure of your quality unit to exercise its responsibility to ensure the active pharmaceutical ingredient (API) and intermediates manufactured at your facility are in compliance with CGMP.

a. Your Quality unit lacked adequate control over the shredder used in the QA document control room. On February 9, 2026, a shredder was found three-fourths full of shredded quality related documents. One partially recognizable fragment contained a batch manufacturing record number ("No (b) (4) "). Furthermore, your QA unit completely deviated from SOP "Document destruction procedure SOP/QA/043" by failing to maintain a logbook documenting when and what quality documentation was destroyed and the name and signature of the person who destroyed the GMP documents.

b. There is no QA oversight on batch issuance record to document who requested, received, returned and accepted the batch record. For example, QA issued a batch manufacturing record (BMR) for (b) (4) on January 22, 2026, with no documentation for requested, received and returned by sign and date. However, QA has the completed BMR that was signed and released by QC and QA signature to proceed to the next stage.

c. Your QA does not review microbial specification results as part of batch manufacturing release. Your firm manufactured (b) (4) (batch (b) (4) (b) (4) and tested finished products for analytical and microbiological testing; however, batch release was based only on analytical results, treating microbiology testing as additional testing not required for product release. (b) (4) batches (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	S. Paranthaman	Paranthaman Senthamarai Kannan, Investigator	02/13/2026

(b) (4) were reviewed and released to the US customer with analytical specifications only. When the customer requested microbiology testing data, your QC/QA revised the COA to include microbiology specification results, which were not reviewed and approved by QA at the time of release. In the batch release check list QC and QA marked N/A for microbial analysis approved/complies as per specification.

d. Your QA did not initiate deviation investigations for production and facility maintenance departments failing to complete work activities inside the cleanrooms (b) (4) for installing (b) (4) -001. This resulted in approximately gaps (b) (4) gap between the (b) (4) bottom and the floor, (b) (4) gap on the top right-hand corner between the (b) (4) and wall, and (b) (4) gap at the topside middle of the (b) (4) towards the ceiling) around the (b) (4) that facilitates free air flow from outside the facility, creating potential for contamination. Your QA and production allowed manufacturing operations for the past six months inside these rooms, including (b) (4) batches (b) (4) to the US market.

e. Your firm's finished product sampling SOP "Sampling procedure of intermediate and finished good, SOP/QC/015) was inadequately written to provide instructions for sampling. While the procedure specifies withdrawing sample quantities per analysis method from each container in equal amounts, it fails to specify sampling locations for different container sizes.

f. Your firm's SOP "Packing material and standard test procedure, STP No. STP/PM0013" was not adequately written to provide instruction for conducting drop impact test on the (b) (4) packing container. The procedure says fill containers to its nominal capacity with (b) (4) and drop the container but fails to clarify whether the nominal amount equals the finished product fill weight to ensure proper impact resistance evaluation.

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g. Your QA failed to control GMP documents for non-GMP use. Your QA issued a control document "Sample distribution, reconciliation & destruction sheet, Annexure Number: SOP/QC/067-01, issue copy No. 20, date, January 6, 2026", however, this controlled document was used as scribbling paper in the QA document control room.

OBSERVATION 2
Your firm failed to use validated and stability-indicating test procedures.

Your firm failed to use stability indicating methods to test active pharmaceutical ingredients (b) (4) batches shipped to the US market when assigning retest dates of (b) (4) The stability indicating aspects of in-house methods used for (b) (4) and the compendial method for (b) (4) USP were not evaluated through method validation and forced degradation studies to ensure no chromatographic co-elution of impurity peaks with the active peak. The following batches were on stability studies:

Batch No. (b) (4)	Manufacturing date	Stability study start date
[redacted]		

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(b) (4)

[redacted]

OBSERVATION 3

Failure to ensure that all specifications are scientifically sound and appropriate to ensure that your raw materials and API conform to established standards of quality and purity.

a. Your firm failed to conduct method validation for the in-house method and verification for compendial methods for the following KSM and APIs.

(b) (4)

KSM	Test Description	USP/Inhouse	STP number
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	S. Paranthaman	Paranthaman Senthamarai Kannan, Investigator	02/13/2026

(b) (4)

[redacted]

b. Analytical method verification carried out by your firm for (b) (4) related substances by HPLC using outside laboratory's validated method failed to identify all the unknown impurities. Your firm is using this analytical method (STP(b) (4)/005) for testing related substances in the finished (b) (4) API and stability samples.

OBSERVATION 4

Your firm failed to exercise sufficient controls over computerized systems to prevent unauthorized access or changes to data and failure to have adequate controls to prevent omission of data.

a. HPLC and GC data from instruments GC HS QC/001, HPLC QC/002, QC/024 and QC/0025 covering January 2024 to June 2025 saved on standalone computer were backed up only once in June 2025 to an external hard drive without assurance of correct data was saved and backed up. Additionally, the firm has not established a process to retrieve and verify the reliability of the backed-up HPLC and IR data saved from June 2025 till February 2026 in the server.

b. On February 10, 2026, an analyst was observed using another analyst's username and password to log into OpenLabs HPLC software from computer in room (b) (4) (Instrument Lab (b) (4) during data audit review for (b) (4) data in the presence of the Executive QA and QC Manager.

c. Your firm's Executive QA is the administrator for HPLC and IR software and data backup due to staff shortage.

d. Your firm failed to restrict privileges to employees for accessing Raw material specification word document (b) (4) Specification No. SPC/RM066, Revision No.: 01) used by QA. This document is not locked to prevent any changes. Further your firm provided cut, copy, rename and delete provisions to this document.

OBSERVATION 5

Failure to properly maintain buildings and facilities used in the manufacture of intermediates and API.

a. Your firm failed to maintain cleanroom conditions that prevent contamination from the outside environment (b) (4) processing room (b) (4) contains (b) (4) 001 and (b) (4) 001 for processing all APIs including (b) (4) for the US market. During the walkthrough of the facility on February 10, 2026, the following gaps were observed around the (b) (4) 001: approximately (b) (4) gap between the (b) (4) bottom and the floor, (b) (4) gap on the top right-hand corner between the (b) (4) and wall, and (b) (4) (b) (4) gap at the topside middle of the (b) (4) towards the ceiling. These gaps create free airflow from outside the facility into the clean room with potential for contaminants and dust particles to enter. According to the Executive QA, (b) (4) -001 was installed in August 2025 and the facility manufactured and shipped (b) (4) batches of (b) (4) to the US market. Your firm-initiated change control CC/PR/25/008 to install the (b) (4) in the

production area; however, no evaluation and/or impact assessment was performed for products manufactured inside this room for the past six months.

b. Room (b) (4) adjacent to (b) (4) had a makeshift wall (approximately (b) (4)) constructed in the left side corner to install (b) (4) -001. This created a gap of approximately (b) (4) between the makeshift wall and the room wall, facilitating free air flow from outside the facility into the cleanroom with potential for contaminants and dust particles to enter. This makeshift wall has been in place since August 2025. Additionally, it was also noted that your firm turned the air handling unit (AHU) on and off based on production activities. According to your Executive QA, a minimum of (b) (4) is required to recover the ISO 8 (Class D) condition. However, the recovery time was not mentioned in the test report. APIs, including (b) (4) shipped to the US market were (b) (4) inside this room.

c. The following areas in the cleanroom facility for processing and packing API were maintained in unsanitary condition:

i. (b) (4) area (clean room): Walls, floors and ceiling showed apparent (b) (4) (b) (4) stains. The (b) (4) was unclean with blocked (b) (4) (b) (4) showed apparent rust and (b) (4) stains. The door to the intermediate processing area was not properly closed. Cleaning logs showed (b) (4) cleaning on February 10, 2026.

ii. (b) (4) clean room: apparent (b) (4) stains were visible on walls and ceiling. An incomplete construction area in the corner next to (b) (4) -001 (b) (4) contained apparent dirt like material.

iii. (b) (4) clean room: apparent (b) (4) stains were present on walls. An incomplete construction area containing apparent dirt-like material.

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OBSERVATION 6

Failure to clean equipment and utensils to prevent contamination or carry-over of a material that would alter the quality of the intermediates and API.

a. Your firm uses a (b) (4) (b) (4) to (b) (4) No usage or cleaning logbook exists for this (b) (4) This (b) (4) is used in the manufacturing of different APIs including (b) (4) for the US market.

b. On February 9, 2026, a (b) (4) 002) on the (b) (4) floor showed apparent (b) (4) particle deposits along lid, gasket. (b) (4) substance was observed draining and deposited at the bottom despite the status board indicating "empty and cleaned" and the usage logbook showing batch-to-batch cleaned on February 2, 2026.

c. On February 9, 2026, (b) (4) 103 in (b) (4) room (b) (4) showed apparent rust and (b) (4) particle deposits on the exterior of the (b) (4) and (b) (4) particle deposits inside the (b) (4) on the (b) (4) bottom. Usage log showed the last batch to batch cleaning occurred on February 4, 2026.

OBSERVATION 7

Failure to test the identity of each batch of incoming production material and appropriately qualify suppliers to rely upon their Certificate of Analysis.

Your firm failed to perform identity testing on raw materials (b) (4) accepting them based solely on supplier COAs. Your QA Executive confirmed that the supplier for (b) (4) intentionally mislabels and ships (b) (4) containers as (b) (4) because your firm lacks a (b) (4) license. No identity testing has been performed on (b) (4) batches received since 2024. Your firm used this untested

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(b) (4) in manufacture of (b) (4) and shipped to the US market. According to your SOP/QA/002 (Vendor approval/Development), the suppliers for common raw material other than KSM are directly added to the provisional vendor list without qualification. For example, your firm used (b) (4) (Goods receive note, supplier COA and the firm COA show the material name as (b) (4) material code (b) (4) received on October 25) A.R. No. (b) (4) in the manufacture of (b) (4) (b) (4) batches (b) (4) and shipped to the US market.

OBSERVATION 8

Failure to monitor the (b) (4) system to ensure that water is of appropriate quality.

Your firm lacks both preventive maintenance and sanitization programs for the (b) (4) water system, failing to ensure appropriate water quality for API manufacturing and cleaning equipment/utensils that directly come in contact with APIs. Water testing is limited to (b) (4) collection from the (b) (4) water (b) (4) and (b) (4) collection at production point-of-use locations, with testing conducted against in-house specifications including (b) (4) (b) (4)

OBSERVATION 9

Failure to adequately validate written procedures for the cleaning and maintenance of equipment.

Your firm has not performed cleaning validation studies for non-dedicated manufacturing equipment including (b) (4) (b) (4) Your firm manufactures (b) (4) APIs including (b) (4) APIs, (b) (4) for the US market.

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Your Executive QA stated that the cleaning verification was carried out with rinse samples and swab testing of the selected equipment, however cleaning validation was not performed.

OBSERVATION 10

Failure to retain sufficient quantities of reserve sample to conduct analyses.

Your firm failed to collect enough (b) (4) API reserve samples to conduct (b) (4) full specification analyses. Your firm collects only (b) (4) sample, which is adequate for conducting (b) (4) analytical test (b) (4) and microbiological test (b) (4) There is no scientific justification for collecting only (b) (4) sample for each lot of API. Your firm also sent (b) (4) of (b) (4) batches (b) (4) retain samples to contract testing laboratory for (b) (4) analysis.

OBSERVATION 11

Failure to store stability samples in containers that simulate the market container.

Your quality control unit does not perform testing or release of (b) (4) container bags used for stability samples to establish retest dates for APIs including (b) (4) (b) (4) for the US market. Your Executive QA confirmed that the firm uses (b) (4) bags as the (b) (4) container for API stability studies, which do not simulate the (b) (4) bags used for commercial packaging.

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