WARNING LETTER

Alchymars ICM SM Private Limited

MARCS-CMS 724429 — MAY 21, 2026

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:

Via Electronic Mail - Return Receipt Requested

Reference #:

320-26-77

Product:

Drugs

Recipient:

Alchymars ICM SM Private Limited

A-14 & 20 Sidco Pharmaceutical Complex
Alathur 603110 Tamil Nadu
India

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

Warning Letter 320-26-77

May 21, 2026

Dear Mr. Kaliyamoorthy:

The United States Food and Drug Administration (FDA) conducted an unannounced inspection of your drug manufacturing facility, Alchymars ICM SM Private Limited, FEI 3005216842, at A-14 & 20 Sidco Pharmaceutical Complex, Alathur, Tamil Nadu, from November 28 to December 4, 2025.

This warning letter summarizes significant deviations from Current Good Manufacturing Practice (CGMP) for active pharmaceutical ingredients (APIs).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your APIs are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your December 26, 2025, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigator observed specific deviations including, but not limited to, the following.

1. Failure to ensure that equipment is maintained.

Your firm failed to adequately maintain the **(b)(4)** used to manufacture **(b)(4)** API for the U.S. market. Our investigator documented **(b)(4)** in the **(b)(4)** manufacturing workshop in various levels of disrepair, including cracked, taped, and deteriorating **(b)(4)** gaskets, rust-like residues on product-contact surfaces such as **(b)(4)**, and cracked **(b)(4)** inside one of the **(b)(4)**. These findings directly contradict your firm's own cleaning and preventive maintenance records, which had documented the condition of all these **(b)(4)** as "ok." Additionally, our investigator observed wet paint on one of your **(b)(4)** while production activities were ongoing.

In your response, you acknowledge the deteriorated condition of your equipment and attributed the deficiencies to inadequacies in your cleaning program and absence of a lifecycle management program for your equipment. You also acknowledge that your inaccurate recordkeeping stemmed from "insufficient inspection rigor." As corrective action, you have initiated physical repair of all equipment and a complete overhaul of procedures for cleaning, maintenance, inspection, and gasket management.

Your response is inadequate because your investigation does not extend to testing residues found in your equipment or retain samples to assess the potential impact on product quality. Furthermore, your response fails to explain the inability of your quality system, despite having numerous checklists and procedures already in place, to identify and proactively address these obvious equipment maintenance issues.

It is your responsibility to ensure your equipment maintenance program is comprehensive and includes appropriate assessment of equipment failures and their impact to product quality.

In response to this letter, provide:

- Your plan to ensure that personnel responsible for maintaining equipment are appropriately trained and capable of performing their assigned duties.
- Your corrective action and preventive action (CAPA) plan to comprehensively address any gaps identified from the assessment of your equipment maintenance program including, but not limited to, inadequate quality unit oversight, inadequate trending of preventive maintenance, and lack of detailed procedures.
- Provide an independent review that determines the effectiveness of your CAPA including, but not limited to:
  o Enhancements to cleaning and maintenance procedures including determination of specific frequencies and locations to be cleaned for all relevant equipment.
  o Adequacy of equipment maintenance and repair history for all **(b)(4)**.

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

You failed to maintain your drug manufacturing facility in a good state of repair. Specifically, our investigator observed the following deficiencies in the **(b)(4)** production building during the inspection:

- Water condensation from **(b)(4)**-216 on the **(b)(4)** floor was actively falling onto the catwalk and subsequently dripping onto the working space for **(b)(4)**-207, resulting in standing water around that **(b)(4)**.
- Water from the bottom of **(b)(4)**-203, **(b)(4)**-204, and **(b)(4)**-209 on the **(b)(4)** floor was dripping onto the production floor and the outer surfaces of **(b)(4)**-204.
- You placed **(b)(4)** drums below the water drips and **(b)(4)** sheeting on the catwalk to shield the **(b)(4)** from overhead dripping water.

In your response, you attribute the condensation to degraded **(b)(4)** and a failure in your preventive maintenance program to monitor **(b)(4)** integrity. You state that you placed batches manufactured during the inspection on hold and conducted microbiological testing on these batches as part of your risk assessment. You commit to repairing and replacing the degraded **(b)(4)**, conducting engineering changes to minimize overhead drips, installing permanent drip barriers, and updating the preventive maintenance program to include routine inspections.

Your response is inadequate because you lack sufficient data to substantiate your conclusion of "no confirmed impact to product quality." Your investigation does not include retain sample testing or assessing the duration of your facility's state of disrepair to determine the scope of potentially affected batches. While you conduct manufacturing operations in **(b)(4)**

systems, your response does not account for the fact that equipment had damaged gaskets and a corroded and damaged **(b)(4)** which can compromise the integrity of **(b)(4)** systems.

It is your responsibility to ensure sustainable corrective actions to maintain your manufacturing facility in a good state of repair.

In response to this letter, provide:

- Your CAPA plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment/facility infrastructure, and improved systems for ongoing management review.
- An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter.
- A summary of all results obtained from testing retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls.
- Documented evidence (for example, photos) of any repairs made to your facilities and equipment.

CGMP Consultant Recommended

Based upon the nature of the deviations we identified at your firm, you should engage a consultant qualified as set forth in 21 CFR 211.34 to evaluate your operations and to assist your firm in meeting CGMP requirements. The qualified consultant should also perform a comprehensive six-system audit[1] of your entire operation for CGMP compliance and evaluate the completion and efficacy of your corrective actions and preventive actions before you pursue resolution of your firm's compliance status with FDA.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Conclusion

The deviations cited in this letter are not intended to be an all-inclusive list of deviations that exist at your facility. You are responsible for investigating and determining the causes of any deviations and for preventing their recurrence or the occurrence of other deviations.

FDA placed all drugs and drug products offered for import into the United States from your firm on Import Alert 66-40 on May 19, 2026.

Correct any deviations promptly. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any deviations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to any deviations.

Failure to address any deviations may also result in the FDA continuing to refuse admission of articles manufactured at Alchymars ICM SM Private Limited, Tamil Nadu, India, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days.[2] Specify what you have done to address any deviations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

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Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3005216842 and ATTN: Marisa Heayn.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

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1 i.e. Quality System, Facilities & Equipment System, Materials System, Production System, Packaging & Labeling System, and Laboratory Control System per FDA's guidance document.

2 Under program enhancements for the Generic Drug User Fee Amendments (GDUFA) reauthorization for fiscal years (FYs) 2023-2027, also known as the GDUFA III Commitment Letter, your facility may be eligible for a Post-Warning Letter Meeting to obtain preliminary feedback from FDA on the adequacy and completeness of your corrective action plans.

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