DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Email Responses to: CDER-OC-OMQ-International483Response@fda.hhs.gov	02/19/2025-02/25/2025
	FEI NUMBER 3005782879

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Kuber Jagdale, President

FIRM NAME	STREET ADDRESS
Emcure Pharmaceuticals Limited	Plot D-24 Midc, Kurkumbh Industrial Area, Taluka Daund
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pune, Maharashtra, 413802, India	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Facilities and Equipment Systems

Observation 1

Failure to establish and follow adequate written procedures for cleaning and maintenance of equipment to prevent contamination or carryover of materials.

Specifically, during a walkthrough of your facility on 19-20 February 2025, I observed multiple deficiencies related to equipment cleaning, cleaning validation, and maintenance, indicating a lack of adherence to established procedures. For example, but not limited to the following:

A. (b) (4)

- Labeled "clean" per procedure "KMF-601/24, Procedure for Cleaning of Equipment, Accessories, and Auxiliaries, Effective Date: 16 Dec 2024", yet exhibited visible residues ((b) (4) particulates (b) (4) material, and (b) (4) liquid).
- C ng was performed beyond the (b) (4) Dirty Hold Time without corrective action, and swab tests confirmed contamination ((b) (4) .

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There is no supporting data exists for DHT or Clean Hold Time (CHT) limits for Type (b) (4) or Type (b) (4) cleaning.

- An operator performed cleaning without completing required training per procedure "AQA-081/04, Training, Effective Date: 10 Sep 2024".

B. Cleaning Validation Deficiencies:

- Your firm failed to validate the cleaning procedures for (b) (4) vessels, and receiver tanks used in the manufacture of (b) (4) USP, despite documented residues of (b) (4) post-cleaning. Your firm lacks cleaning validation which establishes residue limits for cleaning validation in collection receivers, transfer vessels, and equipment used in all API manufacturing Blocks for Type (b) (4) (b) (4)
- Improper use of gaskets and (b) (4) gaskets wrapped in (b) (4) tape were observed across multiple (b) (4) despite proce EM-020/01, Management of 022" prohibiting such use. (b) (4) tape is not a cleanable surface and can lead to contamination. Your firms Deputy General Manager, Engineer his awareness of the prohibition of (b) (4) tape, but continued to use the (b) (4) tape.
- Cleaning procedures lack objective cleaning criteria and defined cleaning pressure requirements (despite procedure "EOP-032/04, Procedure for Operation and Cleaning of (b) (4) and (b) (4) Effective Date: 29 Jun 2023" specifying (b) (4) kg/cm^2).

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C. Maintenance and Equipment Integrity Issues:

- (b) (4) showed physical deterioration (paint chips, rust, peeling) and e maintenance "KEM-008/06, Preventive Maintenance for (b) (4) Effective Date: 06 Aug 2024" did not require inspection for such damage.
- (b) (4) and (b) (4) #1402 had (b) (4) with numerous dents; cleaning validation did not address potential residue in hard-to-clean areas nor incorporate dent study results.

Quality System

Observation 2
Failure to ensure proper documentation and verification of training records.

Specifically, your firm failed to adequately document and verify training records for personnel involved in manufacturing, equipment, and cGMP training. For example,

- The current training system does not require individual trainees to electronically sign and verify their completion of **ANY** group training.
- Training records for **ALL** group trainings are entered by the trainer for all attendees without individual authentication or verification.
- There is no supporting documentation ensuring that each trainee received and understood the training.

***DATES OF INSPECTION**
02/19/2025 (Wed), 02/20/2025 (Thu), 02/21/2025 (Fri), 02/22/2025 (Sat), 02/24/2025 (Mon), 02/25/2025 (Tue)

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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."