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	5/6/2026-5/15/2026*
	FEI NUMBER 3014595023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Deepak Gondaliya, President-Technical Operations

FIRM NAME	STREET ADDRESS
Emcure Pharmaceuticals Limited	Plot No. Sm-14, 15 & 16/1, Gidc, Sanand - Ii, Charal, Tal-Sanand
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ahmedabad, Gujarat, 382110 India	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

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A) Your firm has not conducted any protocol-driven Performance Qualification (PQ) Studies with pre-approved acceptance criteria for the following equipment that is utilized to produce (b) (4) (b) (4) (b) (4)

B) You failed to conduct equipment performance requalification (RQ) studies per your approved protocol# RQ/MFG/048-01 (approved on August 31, 2021) for the Block (b) Line (b) Vial Filling and Stoppering Machine (Equipment ID# ES/MFG/366) which is used during the production of (b) (4) According to the protocol, requalification was required due to the introduction of the new container closure configuration — a (b) (4) mL (b) (4) vial. Per the protocol, (b) (4) runs at (b) (4) speeds are assessed for, but not limited to, the *Verification of the Performance in Terms of Output and Stoppering Efficiency* testing parameter. However, during the qualification studies of the filling and stopping of the (b) (4) mL (b) (4) vial with the (b) (4) stopper, your firm assessed the equipment at (b) (4) speed (b) (4) and failed to determine and qualify the

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equipment at the worst-case scenario. Your firm has received approximately 225 complaints from health professionals or healthcare establishments related to the displacement of (b) (4) stoppers of (b) (4) (b) (4) within the last 4 years.

OBSERVATION 2

There is a failure to thoroughly review 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) Complaints that identify a product but not a specific batch are not fully investigated. According to the procedure titled "Handling of Market Compliant" CQ-039/09, section 5.2.4.3, the investigation of product complaints that include the product name but are missing information (i.e., batch number, complaint sample) must include assessment of drug product quality defects that include or is not limited to, drug product deviation history, stability data, retain samples, visual inspection records, annual product reviews, and relevant OOS/OOT investigations.

The following drug product failure to meet specifications complaint investigations were listed as "non-compliant" and closed without a full investigation to determine potential root cause and corrective and preventative actions:

Complaint #	Open Date	Summary	QA Action
PR. No 127661	06/23/2023	"(b) (4) mL vials, potency lost over time."	No investigation was performed; closed due to no lot number
PR. No 133238	08/11/2023	"(b) (4) having to give twice as much with this brand (b) (4) than	No investigation was performed; closed due to no lot number

		they were with (b) (4) ”	
PR. No 140226	10/2023	“Not as efficient/they had to use more to (b) (4) ” as the other manufacturer's product (exact name unknown).”	No investigation was performed; closed due to no lot number
PR. No 157446	04/2024	(b) (4) was notified of an event via email stating "(b) (4) ml, Batch No. (b) (4) ”	Full investigation not performed; only COA and batch record assessed. Closed due to no response for supplemental information.

B) Since 2022, you have received approximately 225 complaints related to (b) (4) stoppers and failed to extend the investigations to other batches of (b) (4) that may have been associated with similar complaints.

OBSERVATION 3

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically, the procedure titled “Handling of Market Complaint” CQ-039 indicates that investigations must include the evaluation of sterile drug product’s possible failure to meet its specifications. The following customer complaints were reported for lack of effect; however, the control samples were not tested for multiple release and stability testing metrics (i.e., (b) (4)

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(b) (4) (b) (4) that may reveal the degradation of drug product stability through the (b) (4) rather than chemical degradation (i.e., assay).

Complaint #	Drug Product, Lot #	Summary	Specifications Tested
PR. No 197980	(b) (4)	"(b) (4) received compliant stating that "Drug ineffective, product doesn't work. Not effective" (b) (4)	Assay only
PR. No 200097		"(b) (4) received complaint stating the doses used for the desired effect were significantly higher than usual doses for (b) (4) ."	Assay only
PR. No 204829		"(b) (4) received complaint "they had to use three times the normal amount of (b) (4)	Assay only

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	(b) (4) (b) (4)	
PR. No 224977	"(b) (4) received complaint stating that "(b) (4) are reporting that it is not effective and it's requiring about two times the usual dose in order to (b) (4) "	Assay only
PR. No 212493	(b) (4) received complaint stating that (b) (4) it was ineffective (b) (4) (b) (4)	Assay only

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(b) (4)

OBSERVATION 4

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,

A) Your firm does not test the following raw materials for the limit of (b) (4), on each container individually within each shipment of each lot, prior to the utilization in the production of drug products:

(b) (4)

B) Your firm does not test the raw material (b) (4) for the limit of (b) (4), on each container individually within each shipment of each lot, prior to the utilization in the production of drug products. (b) (4) is used in the production of (b) (4) Injection, USP, (b) (4) mg/mL).

OBSERVATION 5

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

A. Multiple deficiencies were observed during the airflow visualization study conducted in 2023 for Block (b) (4) Line (b) (4) These deficiencies include, but are not limited to:

1. Intervention (SHOOT-010), *Blockage of* (b) (4) *Seals in Bowl and its Clearance:* the simulation shows the (b) (4) directly over exposed vials; however, no vials were removed.
2. Intervention (SHOOT-082), *Adjustment of* (b) (4) *Stopper Chute*: the simulation shows the (b) (4) directly over exposed (b) (4) stoppers; however, no (b) (4) stoppers were removed.

B. Multiple deficiencies were observed during the airflow visualization study conducted in 2023 for Block (b) (4) (b) (4) These deficiencies include, but are not limited to:

1. Intervention (SHOOT-36), *Broken/Jammed Vial Removal:* the simulation shows the (b) (4) (b) (4) directly over exposed vials; however, no vials were removed.
2. Intervention (SHOOT-117), *Removal of Fallen Vial from* (b) (4) the simulation shows the (b) (4) directly over exposed vials; however, no vials were removed.

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, your firm failed to implement and maintain controls to prevent potential contamination of the drug products produced on the Block (b) (4) Line (b) (4) On 05/08/2026, multiple locations within the ISO 5 (b) (4)

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(Equipment ID # FP/17/035) appeared to have (b) (4) residues on the (b) (4) surfaces. According to (b) (6) (Associate Director of Quality) and (b) (6) (Manager of Manufacturing), the residues and uneven surfaces are (b) (4) used to cover gaps seen in the ISO 5 area. This equipment is used to fill approximately (b) (4) sterile drug products intended for the U.S. market.

OBSERVATION 7

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A) The procedure titled "Audit Trail Review" SOP/QAD/032-07 permits Quality Assurance does not require Quality Assurance to review audit trails electronically. Per section (b) (4) an audit trail review is permitted via paper-based documentation (i.e., "hard copy" and "PDF file format.)" Quality Assurance is responsible for performing periodic audit trail reviews of CGMP software (b) (4) and prior to batch release.

B) According to the document titled "Configuration Specification for Computerized System" EM/CS/07/CS/009/21, Sr.No 49, an analyst has permission to "view quantitation peak fields in review." The setting grants an analyst the ability to see area counts and results of a chromatography-based test prior to deciding whether to save the processed chromatogram or enter additional integration parameters.

*DATES OF INSPECTION

5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri)

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