DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 Attn: Hyosun Forman ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/21/2026-05/01/2026
	FEI NUMBER 3008405956

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Raja Jeyakumar, COO & Executive Director

FIRM NAME	STREET ADDRESS
Apothecon Pharmaceuticals Pvt. Ltd.	Plot No. 1134-1137, 1138 A&B, 1143 A&B, 1144 A&B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Padra-Jambusar Hwy Tal. Padra, Baroda, Gujarat India 391440	Manufacturer of Drug Substances and Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

QUALITY SYSTEM

OBSERVATION #1

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

Specifically,

A. Your SOP entitled, "SOP on Data Integrity" (SOP No. QA/GEN/074, Version 06, effective February 28, 2026) states that QA is responsible for ensuring data is stored in an adequate electronic format and remains readily available. However, your firm failed to back up data generated by the (b) (4) Leak Tester (Model (b) (4) Serial No. (b) (4) that was purchased on or around June 2018. According to the Assistant General Manager – QA, the original raw data was stored solely on the equipment's hard drive with no automated or manual backup system in place. As a result, (b) (4) integrity data generated prior to February 16, 2023 was overwritten and not retrievable including integrity testing records of the (b) (4) used in the aseptic process validation batches of the sterile drug substance manufactured in August and September 2020.

B. The SOP on Data Integrity (SOP No. QA/GEN/074, Version 06, effective February 28, 2026) also states that "At the time of release of product all the related batch documents are checked for accuracy" by QA for its "integrity & completeness" prior to batch release. However, at time of inspection, the firm failed to ensure that there were no (b) (4) integrity test failures and/or retests performed on the (b) (4) used to (b) (4) during aseptic production of the process validation batches and if there were failures that they were identified, investigated, evaluated and included in the batch records prior to batch release. Additionally, at time of inspection, there was no backup system was in place for data generated by the (b) (4) (b) (4) Integrity Tester, (b) (4) Model (b) (4) Serial No. (b) (4) since March 2013.

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OBSERVATION #2
Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,
Your SOP entitled, "Handling of Market Complaint" SOP No. QA/GEN/030, Version 08, Effective April 18, 2026 states that if deemed necessary, "retain samples of the subjected batch" shall be "checked and analyzed to verify the quality attribute for which the complaint is received. However, on or about December 8, 2023, a complaint was received regarding a batch of (b) (4) Batch # (b) (4) regarding (b) (4) (b) (4) The complaint stated that the drug appeared to "lose potency completely" and "no longer working" for the (b) (4) Despite the nature of the complaint which directly implicated potency, your firm's quality unit determined the complaint as non-established (unsubstantiated) without testing the retain sample which was insufficient to adequately invalidate the complaint.

MATERIALS SYSTEM

OBSERVATION #3
Each lot of components are not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,
A. Your firm uses (b) (4) a raw material (solvent) used in the production of your bulk drug substances however, you have not tested any incoming material for (b) (4) contamination. The firm received at least (b) (4) lots/batches of (b) (4) since January 2023 that was used to manufacture bulk drug substances such as but not limited to (b) (4) (b) (4) that were distributed in the United States.

B. Your SOP entitled, "Vendor Evaluation" SOP No. QA/GEN/009, Revision No. 19, Effective April 1, 2026 states that "(b) (4) batches sample for analysis" is required to establish the reliability of the vendor. In addition, an initial physical audit is to be performed "within (b) (4) " as part of vendor re-

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qualification which may be performed by a third party before placement of the vendor on the approved supplier list. However, the vendors of the following materials were approved after establishing the reliability of the COA of just one sample and without conducting a physical audit as written in your SOP:

(b) (4)

LABORATORY SYSTEM

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. According to the Analytical Quality Assurance-AGM, QC analysts have been trained and qualified to perform the USP Chapter 711, Dissolution test which is a release parameter for finished drug products which allows Stage (b) (4) testing if results obtained during the initial stages fail to meet specification. However, on or about January 28, 2025, an incident investigation QC/IN/26/012 was initiated after a Stage (b) (4) dissolution failure during release testing for (b) (4) Batch # (b) (4) Specification is not less than (b) (4) % release at (b) (4) (b) (4) however, the incident was initiated when no test was above (b) (4) %. Stage (b) (4) testing was not performed, sample was reanalyzed, and the batch was released by QA for distribution to the United States. Your standard test procedure for (b) (4) mg, STP No. QC-QCM-806-04 Revision 02, Effective February 16, 2022 for dissolution does not define acceptance criteria for Stage (b) (4) results nor does it state that Stage (b) (4) testing must be initiated if Stage (b) (4) results are unacceptable.

B. Your firm failed to perform secondary verification of sterility and bacterial endotoxin test results obtained during release testing of the three process validation batches of your sterile drug substance to ensure the integrity, accuracy and reliability of the microbial data used to support batch release. Furthermore, your firm's sterility and endotxoin SOPs do not require secondary verification for these critical microbial tests.

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PRODUCTION SYSTEM

OBSERVATION #5

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

Specifically,

A. At time of inspection, no dynamic smoke studies were performed to demonstrate that unidirectional airflow in the (b) (4) is maintained during aseptic production of your sterile drug substance (DS). For example, dynamic smoke studies representing actual sterile production have not been conducted to evaluate whether adequate airflow protection is maintained during critical operations, including but not limited to:

(b) (4)

Without dynamic smoke studies, the firm cannot demonstrate that unidirectional airflow is maintained during actual operating conditions and that the sterile DS is adequately protected from potential contamination.

B. Your most recent static smoke study performed on May 19, 2025 did not fully evaluate airflow patterns at all critical locations within the (b) (4) to ensure that proper unidirectional airflow is maintained during, at rest conditions. For example, transfer of materials from (b) (4) to the (b) (4) was not captured and the (b) (4) canister staging area where the sterile DS would be exposed to the Grade A were not fully captured in the static smoke study.

OBSERVATION #6

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

A. The interior surfaces of the Grade A aseptic (b) (4) are not smooth to facilitate cleaning. The (b) (4) surfaces of the (b) (4) located in (b) (4) Equipment ID# (b) (4)

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was observed to contain rough textures, pitting, a hole and uneven weld seams that may impede effective cleaning and decontamination. Surfaces that are not smooth and free of crevices or imperfections that present a risk of product residue accumulation, microbial contamination and inadequate decontamination contact which may compromise the sterility assurance of operations conducted within the (b) (4) This (b) (4) was used to manufacture the process validation batches of your sterile drug substance.

B. Your disinfectant efficacy study performed on your preparation of (b) (4) a (b) (4) disinfectant used during the (b) (4) decontamination cycle of the Grade A (b) (4) prior to aseptic production has not demonstrated that it is effective on all surfaces located within the (b) (4) Specifically, the study did not challenge (b) (4) gaskets located inside the (b) (4) Therefore, there is no scientific evidence that the (b) (4) preparation used during the (b) (4) cycle is capable of achieving the required log reduction of microbial contamination on all contact surfaces within the Grade A environment.

C. Your firm has failed to establish written procedures to ensure that bioburden is adequately reduced on critical surfaces of the Grade A (b) (4) which is located in a Grade D environment. For example,

1. No written procedure exists on how to clean and maintain the (b) (4) used in aseptic production of your sterile drug substance. Your SOP entitled, "Operation procedure for (b) (4) leak test of (b) (4) (b) (4) SOP No. PRS/OPN/127 Revision No. 04, Effective December 11, 2025 addresses only (b) (4) integrity testing and requires (b) (4) replacement solely upon repeat test failure. The SOP does not address routine cleaning, disinfection or the maintenance of the (b) (4)
2. No written procedures have been established to require that all surfaces including but not limited to (b) (4) (b) (4) and interior surfaces of the (b) (4) that are or may be exposed to the Grade D air/environment are adequately cleaned and disinfected prior to return to the aseptic line when the (b) (4) is (b) (4) at the end of the sterile batch to remove (b) (4) and equipment.

OBSERVATION #7
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,
A. Your firm performs (b) (4) monitoring at the end of each sterile batch however, only the (b) (4)

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(b) (4) are sampled which is inadequate. Your aseptic production of your sterile drug substance requires operations such as but not limited to the transfer of materials from the (b) (4) to (b) (4) opening of (b) (4) (b) (4) lid, handling of (b) (4) scoops and (b) (4) canisters all which require contact with the (b) (4) surfaces of the (b) (4) and not just the (b) (4)

B. Your firm does not perform passive monitoring for the duration of the aseptic production process during review of the process validation batches of your sterile drug substance and media fill batch records to ensure that the environmental conditions within the Grade A (b) (4) is maintained during sterile operations. Your records shows that passive monitoring (settle plate) is performed (b) (4) of the aseptic batch and/or aseptic process simulation.

OBSERVATION #8
Written procedures have not been established for cleaning and preventative maintenance of equipment used in the production of your drug substance and/or drug products.

Specifically,
Your firm has not established written procedures to describe in detail how to disassemble, clean, reassemble and/or maintain the (b) (4) used to provide (b) (4) to the non-dedicated (b) (4) Equipment ID # (b) (4) This (b) (4) is used in the production (b) (4) (b) (4) of your drug products. On April 23, 2026, unknown (b) (4) liquid-like substance was observed on the (b) (4) According to the Associate Vice President-Production, the firm has not cleaned the (b) (4) since installation of the (b) (4) in March 2011. The following batches of finished drug products were dispatched to the United States using this (b) (4) since January 2023:

(b) (4)

OBSERVATION #9
Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to

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possess.

Specifically,
The performance qualification of the (b) (4) tablet inspection machine (b) (4) Equipment ID (b) (4) Visual Inspection Room (b) (4) Drug Product Formulation, (b) (4) Block (b) (4) is inadequate to demonstrate reliable detection and rejection of defective (b) (4) tablets. Per Performance Qualification Protocol/Report PQP 509/25-00, the challenge test evaluated only (b) (4) defect types: (b) (4) (b) (4) defects using (b) (4) challenge tablets per category for a total of (b) (4) challenge tablets. The prior validated inspection process for (b) (4) tablets in Block (b) governed by SOP PRP/GEN/047 required inspection for (b) (4) distinct defect types including (b) (4) (b) (4) variation, among others. The performance qualification for the new line challenged only (b) (4) of those (b) (4) defect types with no scientific justification for the reduction in scope. The following additional deficiencies were observed:

1. Inadequate defect characterization: The protocol does not specify the size, location, or severity of the challenge defects, making the challenge unreproducible and unverifiable as representative of worst-case commercial manufacturing conditions.
2. No scientific justification for defect selection or challenge quantity: There is no documented rationale for selecting only these (b) (4) defect types or for using (b) (4) challenge tablets per category for a total of (b) (4) challenge tablets to qualify a machine intended to inspect batches exceeding (b) (4) tablets.
3. (b) (4) loading of challenge tablets: All (b) (4) challenge tablets were introduced (b) (4) of the run. The machine's detection capability was not challenged across the full duration of commercial production.
4. Inadequate verification of challenge tablet recovery: A total of (b) (4) tablets were introduced during the challenge run; this total included the (b) (4) challenge tablets. Of the (b) (4) tablets rejected, (b) (4) were tablets other than the (b) (4) challenge tablets. The protocol provides no method to distinguish the (b) (4) challenge tablets from the (b) (4) other rejects. The sole documentation of passing the challenge is a statement that "all defective tablets are collected into the rejection bin," which is not sufficient to confirm the acceptance criterion was met.

OBSERVATION #10
Batch production and control records of your bulk drug substances do not include complete information relating to the production and control of each batch.

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Specifically,
The drug substance, (b) (4) batch manufacturing record # (b) (4) (Revision 01, effective November 13, 2025) does not specify (b) (4) settings for (b) (4) steps. For example, (b) (4) (b) (4) steps do not specify required (b) (4) settings; of these, (b) (4) are critical process parameters performed under (b) (4) of which (b) (4) does not document the (b) (4) used. There is no assurance that these steps are performed consistently from batch to batch. Since November 13, 2025, approximately (b) (4) batches of the drug substance, (b) (4) have been manufactured under this BMR.

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