DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2037, Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov (b) (4) Industry Information: www.fda.gov/oc/industry	05/18/2026-05/22/2026 FEI NUMBER 3006494603

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Wen Du, General Manager	
FIRM NAME Shanghai AmbioPharm, Inc.	STREET ADDRESS 399 Yingong Rd.
CITY, STATE, ZIP CODE, COUNTRY Fengxian District, Shanghai, CN 201417	TYPE ESTABLISHMENT INSPECTED Drug 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.

OBSERVATION 1

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

Specifically,

Your firm utilizes third-party testing from multiple contract testing laboratories. Your firm has not established a Quality Agreement with the third-party laboratories or provided approval for any subcontracted testing not performed by your headquarters.

OBSERVATION 2

Equipment used in the manufacturing, processing, packing or holding of drug products is not installed, qualified, maintained and/or suitably located to facilitate operations for its (b) (4) use.

Specifically,

A. Equipment identified as being used in the manufacturing of exhibit batches, post-exhibit batches, and (b) (4) (b) (4) commercial manufacturing of (b) (4)

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(b) (4) Solution (DMF (b) (4) is not currently installed, qualified, or demonstrated to be suitable for its (b) (4) use. For example, the following impacted equipment (b) (4) (b) (4) used during the manufacturing of the (b) (4) drug product (b) (4) for the U.S. market.

(b) (4)

[redacted]

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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS**

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(b) (4)

[redacted]

B. Additionally, I observed equipment (i.e., (b) (4) [redacted] is transferred between different manufacturing rooms and/or buildings. However, your firm does not initiate any change controls and there has been no risk assessment to support the transfer of equipment and evaluate potential effects on product quality, facility suitability, qualification status, and (b) (4) [redacted] use.

C. During the walkthrough of the (b) (4) [redacted] system on 05/18/2026 in Building (b) (4) [redacted] I observed (b) (4) [redacted] leaking from the connection point between the (b) (4) [redacted] pipe and the attachment associated with the utility system.

OBSERVATION 3

Master production records lack complete manufacturing and control instructions.

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Specifically,

During the review of the batch records for (b) (4) (b) (4) Solution (DMF (b) (4) I observed not all parameters are recorded in the batch records.

A. During the review of the qualification document, "Validation Protocol/Report, (b) (4) Re-Validation Protocol/Report (SE.400), SE.400-2019-02, Effective Date: 04/12/2019, I observed the (b) (4) qualification was performed at (b) (4) However, during the review of the batch record for Batch No: (b) (4) I observed the actual (b) (4) and parameters are not recorded.

B. During the review of the qualification document, SY.289-2025-03, "(b) (4) (b) (4) Requalification Report", Effective Date: 06/27/2025, I observed the (b) (4) assessed during the qualification were (b) (4) However, during the review of the batch record for Batch No: (b) (4), I observed the actual (b) (4) and parameters are not recorded.

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