

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/10/2025-3/14/2025
Industry Information: www.fda.gov/oc/industry	FEI NUMBER
	3016784508

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Xianglong Zhong, General Manager

FIRM NAME	STREET ADDRESS
Hubei JXBio Pharmaceutical Co., Ltd.	No. 9 Lvshan Road, Xian'an Economic Development District
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Xianning, Hubei 437000 China	API Manufacturer

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

OBSERVATION 1

Deviations and Out-of-Specifications (OOS) are not clearly documented, explained, or investigated in production discrepancy reports.

Specifically,

A. An investigation for deviation PC-C005-24002 was initiated on 04-12-2024 for a test result that did not meet requirements for ^{(b) (4)} Batch ^{(b) (4)} Intermediate ^{(b) (4)} purity due to improper use of a balance during material weighing. The CAPA for replacement of all the electronic scales in the workshop with those having a printing function was not implemented using the established change control process.

B. An investigation for deviation PC-C005A-24002 was initiated on 04-04-2024 for a single impurity test result that did not meet requirements during the ^{(b) (4)} of ^{(b) (4)} Batch ^{(b) (4)}. The deviation was opened following the closing of OOS-C005A-24001 on 04-05-2024 but did not reference the OOS investigation and conclusion.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE S Lisa R. Hilliard - Digitally signed by Lisa R. Hilliard -S Date: 2025.03.14 17:34:30 +08'00'	EMPLOYEE(S) NAME AND TITLE (Print or Type) Lisa R. Hilliard, Investigator	DATE ISSUED 03/14/2025
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CITY, STATE AND ZIP CODE Xianning, Hubei 437000 China	TYPE OF ESTABLISHMENT INSPECTED API Manufacturer

C. An investigation for deviation PC-C007-2023-001 was initiated on 12-05-2023 for ^{(b) (4)} Batch ^{(b) (4)} ^{(b) (4)} that did not meet process requirements. The investigation report did not clearly document the discrepancy, explain the process used to determine the root cause of contaminated ^{(b) (4)} or document the change control for update of the ^{(b) (4)} specification and test method. In addition, the investigation did not extend to other batches that may have been affected by the contaminated ^{(b) (4)}

D. An investigation for out-of-specification OOS-C005A-24002 was initiated for a related substance impurity OOS for ^{(b) (4)} Batch ^{(b) (4)}. During the investigation an additional impurity related OOS was discovered, but the OOS was closed before the root cause and corrective actions and preventative actions (CAPA) for the second OOS were determined and documented. No additional OOS investigation was initiated for the second impurity OOS.

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