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	3/3/2025-3/7/2025
	FEI NUMBER 3007498452

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Yuhang Gao, General Manager

FIRM NAME	STREET ADDRESS
Hangzhou Minsheng Binjiang Pharmaceutical Co., Ltd.	658 Bin'An Road, Binjiang District
CITY, STATE, ZIP CODE, COUNTRY Hangzhou, Zhejiang, 310051 China	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, during the inspection, we observed residue (b) (4) in the (b) (4) duct of your (b) (4) (b) (4) (equipment ID # (b) (4) which was labeled "cleaned". After analysis, your firm identified the residue to contain active pharmaceutical ingredient (b) (4) . (b) (4) is non dedicated and is used to manufacture multiple drug products, including (b) (4) (b) (4) Tablets for the U.S. Additionally, your firm failed to assess the (b) (4) duct of your (b) (4) during your cleaning validation study.

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, your out-of-specification (OOS) investigation is not thorough and complete. For example, OOS investigation # 20240601 was initiated when (b) (4) residue tests yielded OOS results for three (3) batches (b) (4) Tablets:

Batch #	Result (specification: NMT [redacted] ppm)
(b) (4) KANT 03/07/2025 (b) (4)	[redacted]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Khoa Nathan V Tran, Investigator Lillian S Wu, Investigator	Khoa Nathan V Tran Investigator Signed By: 2003029741 Date Signed: 03-07-2025 14:28:43	DATE ISSUED 3/7/2025

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(b) (4)

The investigation determined that the most likely root cause was glove contamination caused by analyst error. This root cause was not adequately supported with evidence or data. Instead, (b) (4) fresh sample solutions were prepared for each affected batch for retesting. The retest yielded passing results, and the batches were released.

OBSERVATION 3

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

Specifically, during the inspection, we observed torn and discarded GMP documents in the trash bin located in the QC laboratory. Your firm was unaware that these GMP documents were altered and discarded. GMP documents are not managed according to your procedures, document # 02-QA-2-001 and 02-QA-2-004.

X Lillian S. Wu -S Digitally signed by Lillian S. Wu -S Date: 2025.03.07 14:30:59 +08'00'

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	Khoa Nathan V Tran Investigator Signed By: 2000026741 Date Signed: 03-07-2025 14:28:43	DATE ISSUED
	Khoa Nathan V Tran, Investigator Lillian S Wu, Investigator		3/7/2025