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	03/24/2025-03/28/2025
	FEI NUMBER 3015142388

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bao Haitao, General Manager

FIRM NAME	STREET ADDRESS
Nanjing Hanxin Pharmaceutical Technology Co., Ltd.	Building C5, No. 9 Weidi Road, Xianlin Street, Qixia District
CITY, STATE ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Nanjing City, Jiangsu Province, China 210046	API 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 I OBSERVED:

OBSERVATION 1

Quality unit oversight for manufacturing and release of API was deficient.

Specifically, records indicate your firm subpacked, released, and distributed [redacted (b) (4)] API lot [redacted (b) (4)] to approximately [redacted (b) (4)] customers for additional manufacturing without completing process validation, documenting adequate stability data to support the [redacted (b) (4)] expiration date. There was no specific exemption or justification documented. Your firm made significant material changes before manufacturing the subsequent process validation lots. QA department personnel approved more than [redacted (b) (4)] requests for samples from these [redacted (b) (4)] lots per YL-SRP-QA-031-03, Sample Request for Additional or Investigational In-Process/Finished Products. There are inadequate written processes and procedures established to ensure API requested internally as samples are not released and distributed for commercial manufacturing and compounding. For example:

- Label specimens in the executed subpack records for these purported samples contain statements such as, "Caution: For manufacturing, processing or repacking", and "Caution: For Use and Distribution in Prescription Compounding. Manufacturing, Processing, Or Repacking ONLY".
- Your firm does not have approved, written quality agreements or other written contracts with the [redacted (b) (4)] customers that clearly indicate your API was not intended to be used for commercial manufacturing or compounding.

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

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OBSERVATION 2

Environmental controls designed to minimize contamination risk are deficient for API manufactured by [redacted] that includes [redacted] processing steps.

Specifically,

A. YL-SMP-QA-024.02, Environmental Monitoring Management SOP, requires personnel collect nonviable particulate, [redacted] viable air, and air settling plate EM samples in static conditions [redacted] to establish cleanroom classifications and [redacted] when manufacturing workshops in-service. Your firm has never collected dynamic EM samples in the Grade C downstream processing suites, and there is no written requirement to perform dynamic sampling. The Grade C downstream suite includes areas where [redacted] processing occurs such as [redacted] and Packaging. Your firm has recovered viable microorganisms from EM samples and QC release samples from process validation lots of [redacted] API and [redacted] API which are both intended for use to produce [redacted] drugs.

B. YL-SRP-QA-024-04.01, Airborne Microbe Monitoring Record (Grade C Clean Area of Workshop [redacted] documents personnel did not collect the required [redacted] viable air samples from Grade C locations [redacted] during the [redacted] sampling [redacted] The sampling records were approved without any investigation for the deviation. QA approved the [redacted] Review Report for Environmental Monitoring of Workshop [redacted] Attachment 3: Airborne Microbe Static Monitoring Data for Workshop [redacted] from [redacted] on 02/25/25, and did not document or investigate this deviation. This was the [redacted] EM sampling for Grade C areas as your firm began manufacturing [redacted] API process validation lots [redacted] and [redacted] in [redacted] Your firm has recovered viable microorganisms from EM samples and

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QC release samples from process validation lots of [redacted] API and [redacted] API which are both intended for use to produce [redacted] drugs.

C. YL-SRP-QA-024-06.01, Settling Microbe Monitoring Record (Grade C Clean Area [redacted] of Workshop [redacted] documents personnel did not collect the required settling plate samples from Grade C locations [redacted] during the [redacted] sampling [redacted] QA approved the [redacted] Review Report for Environmental Monitoring of Workshop [redacted] Attachment 4: Settling Microbe Static Monitoring Data for Workshop [redacted] from [redacted] on 02/25/25, and did not document or investigate this deviation. This was the [redacted] EM sampling for Grade C areas as your firm began manufacturing [redacted] API process validation lots [redacted] and [redacted] in [redacted] Your firm has recovered viable microorganisms from EM samples and QC release samples from process validation lots of [redacted] API and [redacted] API which are both intended for use to produce [redacted] drugs.

D. Your firm has not identified any microbial growth recovered from environmental monitoring (EM) and [redacted] water [redacted] samples. There is no written scientific justification to not conduct microbial identification (ID) at least periodically in critical areas of the Grade C downstream [redacted] suites where [redacted] processing steps occur such as [redacted] and Packaging. YL-SMP-QA-024.02, Environmental Monitoring Management SOP, only requires microbial ID for alert and action limit results. The approved [redacted] sampling and testing procedures do not require microbial ID. [redacted] API, process validation lot [redacted] is one example API produced in your facility that is intended for use to manufacture sterile [redacted] drugs. Your firm has recovered viable microorganisms from EM samples and QC release samples from process validation lots of [redacted] API and [redacted] API which are both intended for use to produce [redacted] drugs.

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OBSERVATION 3

(b) (4) water used in the (b) (4) steps during processing of nonsterile API that is intended for use to produce a sterile drug product, is not appropriately monitored and controlled for microbial quality.

Section 5.1.4.6 of YL-SOP-QA-001.01, Sampling and Monitoring of (b) (4) Water, states sampling should be consistent with manufacturing conditions. I observed this SOP instructs personnel to collect (b) (4) water samples in a manner that is not representative of manufacturing. Examples of instructions found in the approved sampling procedure that are not included in executed batch production records for (b) (4) API or (b) (4) API include:

- Section 5.1.4.3 requires personnel to (b) (4) (b) (4) before collecting physical and chemical samples.
- Section 5.1.4.4 requires personnel sanitize the (b) (4) (b) (4) (b) (4) before collecting microbial limit and endotoxin samples.

Microbial enumeration sampling (YL-SOR-QA-001-01) and testing (SOP-E-3201 - Attachment 8) records for (b) (4) water samples collected on 06/03/24 and 07/01/2024 indicate personnel followed the instructions in YL-SOP-QA-001.01. Samples collected on these dates included (b) (4) which is used to supply water for (b) (4) and packaging of all (b) (4) API process validation lots (b) (4) and (b) (4) Your firm recovered viable microorganisms from QC release samples for process validation lots of (b) (4) API and (b) (4) API which are both intended for use to produce (b) (4) drugs.

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OBSERVATION 4

Instructions and documentation in executed batch production records were not always clear and deviations were not always investigated.

Examples of deficiencies I observed in the batch records include:

A. The [(b) (4)] cycle printout indicated product [(b) (4)] did not reach the setpoint required during the [(b) (4)] phase for [(b) (4)] API process validation lot [(b) (4)] and appeared significantly different than the [(b) (4)] cycle charts for the two other process validation lots. There was no documented review of the cycle chart and no investigation or other justification documented for not reaching the setpoint.

B. Operators did not follow the raw material ratio listed in the instructions when producing the [(b) (4)] solution during [(b) (4)] of API in [(b) (4)] API process validation lot [(b) (4)] There was no deviation investigation opened.

C. Operators used a different vessel than specified and did not document the [(b) (4)] met the range prescribed in the instructions for producing the [(b) (4)] solution during [(b) (4)] n [(b) (4)] API process validation lot [(b) (4)] There was no justification documented.

D. Operators did not clearly document [(b) (4)] of the [(b) (4)] solution during [(b) (4)] in [(b) (4)] API process validation lot [(b) (4)]

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