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	3/17/2025-3/21/2025
	FEI NUMBER 3027129265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Henry Zhang, General Manager

FIRM NAME	STREET ADDRESS
Nanjing Cuccess Pharmaceutical Co., Ltd.	Nanjing Economic, 20 Xingang Avenue; And Technological Development Zone
CITY, STATE, ZIP CODE, COUNTRY Nanjing, Jiangsu, 210038 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 I OBSERVED:

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1
Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Workshop (b) (4) Room (b) (4) "Utensil Storage Room" contains cleaned equipment, utensils, and hoses storage. Examples of cleaning deficiencies I observed in this room on March 20, 2025 include:

i. I observed unknown (b) (4) residue inside all (b) (4) ports of the shared-use (b) (4) used to hold bulk drug product during filling for multiple (b) (4) products. (b) (4) which is a hazardous drug, are (b) (4) of the approximately (b) (4) commercial and R&D drugs filled using this (b) (4) This (b) (4) was designated as clean. Your firm filled three (b) (4) process validation lots (b) (4) (b) (4) using this (b) (4)

ii. Approximately (b) (4) shared-use (b) (4) that operators use to transfer API and other raw (b) erials from bulk packaging to temporary vessels during weighing operations for all drugs manufactured in Workshop (b) (4) tote. I observed unknown (b) (4) at the bottom of the tote with several (b) (4) visibly soiled with the unknown (b) (4). All the utensils in the tote were designated clean.

B. Workshop (b) (4) Room, contains equipment used during formulation of (b) (4) products. The (b) (4) (b) (4) equipment ID (b) (4), was designated as clean when I examined its interior surfaces on March 17, 2025. Examples of cleaning deficiencies include:

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EMPLOYEE(S) SIGNATURE
Nicholas L Hunt, Investigator

Nicholas L Hunt
Investigator
Signed By: Nicholas L. Hunt -S
Date Signed: 03-21-2025
15:45:47

DATE ISSUED
3/21/2025

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i. Approximately (b) (4) of the ports on the interior of the lid contained apparent unidentified (b) (4) and (b) (4) residue. Your cleaning procedures did not require personnel to remove the (b) (4) and covers to allow easier access to clean and inspect the ports.

ii. The seal around the (b) (4) probe at the bottom interior of the vessel appeared damaged and soiled.

iii. The sight glass on the interior of the lid contained unknown (b) (4) residue on approximately 1/3 of its surface.

iv. The gasket around the edge of the lid contained apparent unknown (b) (4)

v. The (b) (4) gasket under one of the bolts on the (b) (4) was bulging approximately 1 cm from its seat creating a gap. This recessed area is difficult to clean and could not be reasonably reached with manual wiping.

Your firm produced the three (b) (4) process validation lots (b) (4) using (b) (4), equipment ID (b) (4) This (b) (4) was formerly functionally dedicated to (b) (4) (b) (4) when the process validation lots were manufactured. The equipment is now shared-use because your firm recently manufactured (b) (4) drug products in this (b) (4)

OBSERVATION 2
Routine checking of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, I reviewed qualification, mapping, and routine monitoring records for the long-term (25° C/60% RH) stability chamber, ID 911C49003. I observed the following deficiencies:

A. Stability chamber requalification protocol VP1026-24-01-00 and report VR1026-24-01-00 indicate the chamber must be in a full load configuration prior to initiating the temperature and humidity mapping for (b) (4). Validation personnel confirmed they added large boxes to the chamber to fill the shelves before the most recent qualification in about June 2024. Your firm did not provide written scientific justification to add non-stability study materials to the chamber instead of requalifying the chamber in its as-is condition which would be most representative. Stability samples from the three (b) (4) process validation lots (b) (4) were placed into this long-term stability chamber in February 2024 and were inside the chamber during this requalification.

B. I observed the monitoring and control sensors for temperature and humidity were located directly in front of the circulation fans at the top rear of chamber 911C49003 when I examined the interior on March 17, 2025. Stability chamber requalification

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protocol VP1026-24-01-00 and report VR1026-24-01-00 indicate the lowest temperature sensor was (b) (4) located at (b) (4) (b) (4) of the chamber. Your firm did not document written scientific justification for the selected monitoring location.

C. Personnel used the lowest and highest single point readings for temperature and humidity to calculate extreme spread of values during the stability chamber requalification protocol VP1026-24-01-00 and report VR1026-24-01-00. The temperature and humidity logs from the qualification indicate the sensors with the lowest average values were not always the same as the sensor with the lowest single point reading. Your firm did not provide written scientific justification for the monitoring location.

LABORATORY SYSTEM

OBSERVATION 3
The written stability testing program is not followed.

Specifically, your firm assigned a (b) (4) shelf-life to the three (b) (4) (b) (4) manufactured in January 2024. There was no accelerated stability study conducted at 40° Celsius and 75% relative humidity for six months to support the (b) (4) expiration date. Your firm released (b) (4) process validation lot (b) (4) expiration date (b) (4) on (b) (4) and distributed the drug on about (b) (4)

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