DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/Division of Pharmaceutical Manufacturing Assessment VI 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPFBLAInspection483Responses@fda.hhs.gov	12/30/2024-01/06/2025
	FEI NUMBER 3015786877
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Hongwei Wang, Ph. D., General Manager	
FIRM NAME Suzhou Suncadia Biopharmaceuticals Co. Ltd.	STREET ADDRESS No. 350 Fengli Street, Industrial Park
CITY, STATE, ZIP CODE, COUNTRY Suzhou, Jiangsu Province, China 215028	TYPE ESTABLISHMENT INSPECTED Drug substance and 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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not fully established or followed. Specifically,

A. Your media fill program is not adequately performed to validate the aseptic operations for (b) (4) drug product (DP) manufacturing.
   1) Aseptic manufacturing operations are not closely simulated to incorporate appropriate, worst-case activities and conditions. According to the most recent process simulation batch records (b) (4) and (b) (4) aseptic assembly of equipment was simulated by only (b) (4) operators. However, observed during filling operation of (b) (4) DP Batch (b) (4) on December 31, 2024, were up to (b) (4) operators performing distinct equipment assembly activities at multiple locations in the RABS.
   2) The current media fill run is designed to have (b) (4) line speeds. Durations for simulating the (b) (4) line speed, according to process simulation batches (b) (4) and (b) (4) were (b) (4) respectively. They do not closely simulate aseptic manufacturing operations intended for (b) (4) DP manufacturing.
   3) Duration for simulating (b) (4) operation was designed to last for (b) (4)
   4) (b) (4) share one filling line in (b) (4) Filling Room. You plan to rotate the (b) (4) during the (b) (4) media fill runs which effectively renders each (b) (4) to be evaluated (b) (4)

B. Your environmental monitoring (EM) program does not provide assurance that environmental contaminants are reliably monitored and detected.
   1) Non-viable Air monitoring and (b) (4) Air monitoring (settling plates) in the RABS are not

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Jiangsong Jiang	Yiwei Li, Ph.D., Supervisory Chemist Jiangsong Jiang, Ph.D. Pharmaceutical Scientist	01/06/2025

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performed for the full duration of critical aseptic operations.

2) Surface monitoring of floor, wall, and wall joints in Grade B areas, including those surrounding Grade A RABS, are performed [redacted] (b) (4)
3) Portable stands holding settling plates are used in the RABS without clear marked positions. Operator was observed to move the portable stand with settling plate during equipment assembly.
4) Operator was observed to sanitize his/her hands with [redacted] (b) (4) spray prior to taking the personnel monitoring at the end of the batch production.

C. Aseptic processing system and procedures are not designed to prevent potential microbiological contamination.

1) [redacted] (b) (4) is positioned above the stopper bowl which potentially blocks and prevents the first air from coming into contact with stoppers that are positioned directly under the [redacted] (b) (4)
2) An electrical outlet located approximately one (1) foot above floor level is used for power supply to the [redacted] (b) (4) device. Operator was observed to crouch down to connect power during filling operation.
3) A gap between protective goggles and gowning cap was observed on a QA personnel in the filling room (Grade B) during the filling operation of [redacted] (b) (4) DP Batch [redacted] (b) (4) at 11:49 am on December 31, 2024. Upon notification, operation management and quality unit did not take immediate action to remove the personnel from the production floor. The personnel exited the production floor at the [redacted] (b) (4)

OBSERVATION 2

Appropriate visual inspection (VI) procedures designed to assure drug product quality are not fully established. Specifically,

A. Testing kit used to qualify VI inspectors contains [redacted] (b) (4) defected vials out of a total [redacted] (b) (4) testing vials.
B. [redacted] (b) (4) is observed in majority of vials containing [redacted] (b) (4) drug product [redacted] (b) (4)

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(b) (4) However, the same effect is not reflected in the testing kit based on SOP PO-801 016 SOP for Visual Test Position.

OBSERVATION 3

Automatic or electronic equipment, including computers or related systems, are not routinely calibrated, inspected, or checked according to written programs designed to assure proper performance. Specifically,

A. Software settings for (b) (4) Non-viable Particle (NVP) monitoring systems were not verified to ensure proper performance after system upgrades.
B. (b) (4) SCADA software validation requirements are not documented, maintained, and updated.