

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternationalresponses@fda.hhs.gov		DATE(S) OF INSPECTION 09/12/2024-09/20/2024
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Duofang Liu, General Manager		FEI NUMBER 3005460102
FIRM NAME Sinopep-Allsino Biopharmaceutical Co., Ltd	STREET ADDRESS No. 28, Linpu Road, Economic & Technological Development Zone	
CITY, STATE, ZIP CODE, COUNTRY Lianyungang Jiangsu 222000 China	TYPE ESTABLISHMENT INSPECTED 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.

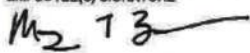

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Major production equipment is not cleaned at appropriate intervals to prevent build-up and carry-over of contaminants.

Specifically, major production equipment such as (b) (4) (equipment ID: (b) (4) and (b) (4) (equipment ID: (b) (4) used to manufacture (b) (4) API in manufacturing workshop (b) (4) Room (b) (4) is not cleaned appropriately to prevent build-up and carry-over of contaminants. For example:

- A. During the inspection of manufacturing workshop (b) (4) on 9/12/2024, we observed (b) (4) residue on the (b) (4) port (product contact surface) inside the (b) (4) (equipment ID: (b) (4). The firm analyzed this residue and confirmed the presence of (b) (4) API at (b) (4) ppm level. This is a dedicated equipment used to manufacture (b) (4) API for the US and ROW markets. This equipment was tagged as "Clean"; cleaned on 9/11/2024, cleaning expiration of (b) (4). The (b) (4) port is designed to (b) (4) during (b) (4) process without (b) (4) the equipment. After batch processing, this equipment is cleaned with (b) (4) water and rinsed with (b) (4). On 9/12/2024, when (b) (4) port was rinsed with (b) (4), foreign particles were observed coming out from the port. During laboratory analysis of these foreign particles, the firm confirmed presence of metals such as (b) (4). This is (b) (4).

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steps in the manufacturing of (b)(4) API (b)(4)
 (b)(4) During these steps the API does not (b)(4)

The cleaning validation performed for this (b)(4) in 2019 as per Cleaning Validation Report (VR-CV-(b)(4)028-2019-00) is deficient. During (b)(4)
 (b)(4) During cleaning validation, the firm identified (b)(4) worst-case (hard to clean) locations. However, none of these locations had a direct contact with the product. The (b)(4) port, product contact surface was not evaluated during the cleaning validation. Additionally, the equipment cleaning SOP (PM-(b)(4)W-02-188-02) does not specifically require cleaning of the (b)(4) port. Since 2019, the firm used this equipment to manufacture about (b)(4) batches of (b)(4) API. On (b)(4) the firm shipped (b)(4) batch (b)(4) for the US market.

B. On 9/12/2024, a foreign object (about 5 mm long) was observed inside the "Clean, Ready to use" (b)(4) (equipment ID: (b)(4) in manufacturing workshop (b)(4) The firm performed maintenance of this equipment on 9/10/2024. After the maintenance, the equipment was cleaned as per SOP PM-(b)(4)W-02-189-01 on 9/11/2024 with cleaning expiration date of (b)(4) The firm confirmed the foreign object was a piece of canvas glove that the maintenance worker used on 9/10/2024 during equipment maintenance. During equipment cleaning, the firm failed to ensure all the foreign objects that can contaminate the products are effectively removed from the equipment. The (b)(4) is the (b)(4) step in (b)(4) API manufacturing. After (b)(4) the API is (b)(4)

OBSERVATION 2

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Facilities used to store and test raw materials and APIs are not maintained in a good state of repair.

Specifically, facilities such as (b) (4) Raw, and Auxiliary Material storage (b) (4) area in General Warehouse (b) (4) and Microbe Culturing Lab (b) (4) (Room ID: (b) (4)) in Microbiology Lab are not maintained appropriately to prevent water leaking. For example:

- A. It was raining heavy on 9/12/2024 and we observed water leakage inside the Auxiliary Material Storage Room (b) (4) very next to the (b) (4) Material Sampling Room in General Warehouse (b) (4). The sampling room is about 3 feet from the warehouse door that opens to the outdoor environment. This room is used to sample (b) (4) materials used to manufacture APIs for the US market.
- B. On 9/12/2024, we observed leaking water inside the microbiology laboratory specifically inside the microbe culture lab (b) (4) room ID: (b) (4). The impacted room is used to incubate samples (APIs and (b) (4) water) for microbial evaluation.

As per the firm's control procedure PFE-01-025-06, the department head is responsible for (b) (4) inspection and maintenance of the plants and facilities under his/her jurisdiction. The site failed to follow this procedure and the Site Quality Head stated (b) (4) inspection records are not maintained.

OBSERVATION 3

Written procedures are not followed for the use of suitable rodenticides, insecticides, fungicides, and fumigating agents to prevent the contamination of raw materials used to manufacture APIs.

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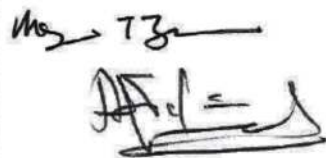
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Specifically, you failed to ensure that (b) (4) Raw, & Auxiliary Material storage (b) (4) area (used to store raw materials to manufacture APIs for the US market) in General Warehouse (b) (4) is free of insects and pests. For example:

On 9/16/2024, we observed cobwebs, live, and dead insects in the General Warehouse (b) (4) Auxiliary Material Storage (b) (4) area. Live and dead insects were observed next to a pallet with (b) (4) sealed containers of (b) (4) USP (b) (4) material code: (b) (4) vendor batch # (b) (4) inhouse batch # (b) (4) expiring on (b) (4). This raw material code is used to manufacture various APIs including (b) (4) for the US market.

A dead insect was observed next to the sampling room where the raw materials are opened for sampling. Additionally, the warehouse door (open to the outdoor environment) and the sampling room door (about 3 feet apart from the warehouse door) are not interlocked to prevent entry of undesirable objects/insects/rodents entering the warehouse and/or the sampling room.

The firm's control procedure MAT-01-016-14, "Management Procedure for pests and rodent control" is deficient as it requires routine inspection of the rodent sticky mats and insect light traps for the presence of live and dead insects/rodents. This SOP does not require inspection of the entire area for the insects/pests' activity.

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