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	11/4/2022-15/4/2022
	FEI NUMBER 3013166187

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Yon-Lian Wu, CEO

FIRM NAME	STREET ADDRESS
SUNNY PHARMTECH INC	Longtan District, 255 Longyuan 1st Rd.; Longtan Dist.
CITY, STATE, ZIP CODE, COUNTRY Taoyuan City, 32542 Taiwan	TYPE ESTABLISHMENT INSPECTED Drug & 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

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

Specifically,

(b) (4) is used as an ingredient in pending application product, (b) (4) solution (exhibit batches manufactured in February of 2020), and during the manufacturing of commercial (b) (4) dosage forms.

Your quality unit approved for production (b) (4) from your system that is not fit for use as follows:

-Investigation from UDR 2020006, dated February of 2020, ultimately identified the presence of B. cepacia in your (b) (4) system, to include a point of use, (b) (4) stage.

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-Your firm does not speciate during (b) (4) testing unless action limits are exceeded. As such, points of use were not sampled going forward to ensure B. cepacia had been removed from your system.

-Your (b) (4) sampling procedures use a (b) (4) step which is not clearly indicated during dispensing of (b) (4) for production.

-Initial qualification of your (b) (4) system failed shortly after in 2018, at numerous points of use with microorganisms "to numerous to count (TNTC)". Your only corrective action thus far has been treatment of your (b) (4) system via (b) (4) with (b) (4) water, which is not sufficient to remove biofilm. Your firm failed to requalify the (b) (4) system in a manner that adequately justified resolution of said failure.

OBSERVATION 2

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,

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Taoyuan City, 32542 Taiwan	Drug & API Manufacturer

During visual inspection of your production line and equipment, used for submission batches and commercial batches, it was explained that a "(b) (4) Hose (b) (4) mm x (b) (4) mm" is used to transfer product from the (b) (4) L (b) (4) (ID EM2202) to the (b) (4) " (b) (4) filtration housing (ID CFL2901 or ID CFL2902).

This tubing line is not identified in your cleaning validation and is used as a non-dedicated piece of equipment. Cleaning description of this equipment line by your quality unit is inadequate and can not be assured to be free of contamination.

OBSERVATION 3

Batch production and control records do not include the identity of individual major lines used for each batch of drug product produced.

Specifically,

The "(b) (4) Hose (b) (4) mm x (b) (4) mm" used to transfer product from the (b) (4) L (b) (4) (ID EM2202) to the (b) (4) " (b) (4) filtration housing (ID CFL2901 or ID CFL2902) is not identified.

The (b) (4) lines used to transfer (b) (4) during production from distribution point (b) (4) and (b) (4) were not identified at the time of visual inspection on 04/12/2022.

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OBSERVATION 4

Records are not kept for the maintenance of equipment.

Specifically,

During examination of your (b) (4) system it was observed that pressure gauges used to monitor adequate pressure throughout the (b) (4) system, are not regularly calibrated. Request for records to demonstrate when pressure gauges were last calibrated was not provided.

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