DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	04/08/2024 - 04/12/2024
	FEI NUMBER 3003282619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tatsuya Shinjo, Director of the Corporate Planning Department

FIRM NAME	STREET ADDRESS
Taenaka Kogyo Co., Ltd.	452 Oshiba
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mobara, Chiba, 297-0033, Japan	Active pharmaceutical ingredient 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) (WE) OBSERVED:

OBSERVATION 1

Training is not regularly conducted by qualified individuals, does not cover the particular operations that employees perform and GMP as it relates to the employees' functions, and is not periodically assessed.

Specifically,

Your firm does not provide adequate training and assessment of employees performing visual examination of finished drug substances to ensure they are capable of observing the types of contaminants such examinations are intended to detect. Your production process for (b) (4) includes a 100% visual examination step in which the (b) (4) material is (b) (4) visually examined for contaminants. Your training process for operators performing these inspections does not include an assessment to determine whether or not the operators are capable of observing the types of contaminants such examinations are intended to detect. Since the beginning of 2022, your firm has manufactured, released, and distributed (b) (4) lots of this drug substance, totaling approximately (b) (4)

OBSERVATION 2

Ventilation systems, including equipment for control of air pressure, are not adequately designed and constructed to minimize risks of contamination.

Specifically,

The production suites used by your firm in the manufacturing of drug substance lots are not adequately equipped to prevent contamination of in-process substances from the neighboring outside environment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Chris Czajka	Christopher R. Czajka, Investigator	04/12/2024

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a) The heating, ventilation, and air conditioning (HVAC) system used to establish the specified differential pressure between the production suites and the neighboring outside environment are not sufficient to ensure this pressure differential is maintained. On 04/09/24, I observed the gauge displaying the pressure differential between the Plant (b)(4) No. (b)(4) Room and the outside environment drop to less than (b)(4) kPa, which is below the specified range of (b)(4) kPa. Across this differential, the No. (b)(4) Room is designed to be contain higher air pressure than the outside environment to prevent unfiltered air from entering the area while in-process drug substances are exposed.

b) The monitoring devices used to ensure the differential pressure between the production suites and the neighboring outside environment are not equipped with alarm systems to alert personnel to pressure excursions. The gauge displaying the pressure differential between the Plant (b)(4) No (b)(4) Room and the neighboring outside environment is not visible to production operators at work inside the suite, and no personnel are assigned to monitor the gauge while manufacturing operations are taking place inside the suite.

Lots of (b)(4) drug substance are (b)(4) in the Plant (b)(4) No. (b)(4) Room.

OBSERVATION 3

Facilities for the storage of materials under controlled temperature and humidity conditions are not sufficiently monitored to ensure the material characteristics of items stored inside them are maintained.

Specifically,

The controlled temperature storage chambers used by your firm to store various materials involved in GMP drug substance manufacturing operations are not monitored in a way that ensures temperature excursions are addressed in a timely manner. The alarm systems installed on such units throughout your facilities are configured to send email notifications to your Quality Control (QC) Manager, QC Test Manager, and Analytical Equipment Manager in the event one or more of the chambers experiences a temperature excursion. However, your firm has not established procedures or policies to ensure any of these personnel monitor their email for notifications outside of your office hours of 8:00 am to 5:00 pm, Monday - Friday. Chambers monitored per this system include but are not limited to the following:

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a) Stability chambers used to store drug substance samples held for stability studies.
b) Incubators used to promote microbial growth of finished drug substance, (b) (4) water, and environmental monitoring samples.

OBSERVATION 4

Testing designed to ensure that API specifications for microbiological purity and appropriate action limits for total microbial counts and objectionable organisms are met is not conducted in a way that ensures the validity of results.

Specifically,

(b) (4) of the growth media plates purchased by your firm in their (b) (4) form are tested (b) (4) to demonstrate their ability to grow colonies of microorganisms, regardless of the number of media plate lots received that (b) (4) In 2023, your firm received (b) (4) growth media plates each from manufacturer's lots (b) (4) however growth promotion testing was only performed on lot (b) (4) These plates are used to perform Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) testing for the release of (b) (4) and (b) (4) drug substance lots, of which your firm has released (b) (4) and (b) (4) lots respectively since the beginning of 2022.

*DATES OF INSPECTION
04/08/2024(Mon), 04/09/2024(Tue), 4/10/2024(Wed), 4/11/2024(Thu), 4/12/2024(Fri)

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