DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	8/3/2025-8/7/2025
	FEI NUMBER 3003028650

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Takahiro Jikihara, Vice President and Head of Suzuka Plant

FIRM NAME	STREET ADDRESS
Sumitomo Pharma Co., Ltd.	1450, Yasuzuka-Cho
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Suzuka, MIE, 513-0818 Japan	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:

OBSERVATION 1

The number of containers to be sampled is not based upon appropriate criteria.

Specifically, your firm samples [redacted] (b) (4) container per lot of incoming raw materials and excipients, regardless of the total number of containers received. You have not established documented rationale or scientific justification to support this practice. The current sampling procedure does not provide assurance that samples are representative of the entire lot when multiple containers are received.

OBSERVATION 2

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

Specifically, your [redacted] (b) (4) system has not been evaluated for the absence of objectionable microorganisms. There is no documented microbial risk assessment to determine whether the microbial control strategy for the [redacted] (b) (4) system is adequate to prevent contamination with objectionable microorganisms. [redacted] (b) (4) is used as a component in the manufacturing of drug products and for [redacted] (b) (4) of manufacturing equipment.

OBSERVATION 3

Failure to maintain a backup file of data entered into the computer or related system.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tekalign Wondimu, Investigator X Tekalign Wondimu Investigator Signed By: TEKALIGN WONDIMU -S Date Signed: 08-07-2025 21:12:26	8/7/2025

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Specifically, your firm does not maintain complete backups of original electronic data generated by the visual inspection instrument (Instrument ID# (b) (4) The instrument system is not configured to save or transfer electronic data to retrievable storage media for subsequent review, verification, or audit purposes. This visual inspection equipment is used to detect foreign matter, surface defects affecting tablet integrity, shape and size variations, and color inconsistencies.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Tekalign Wondimu, Investigator

X Tekalign Wondimu
Investigator
Signed By: TEKALIGN WONDIMU -S
Date Signed: 08-07-2025 21:12:26

DATE ISSUED
8/7/2025