DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	02/09-13/2026
	FEI NUMBER 3003992082

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Masahito Horiuchi, Plant General Manager	
FIRM NAME MicroBioPharm Japan Co., Ltd.	Street Address 1808 Nakaizumi
CITY, STATE, ZIP CODE, COUNTRY Iwata, Shizuoka, 483-0078, Japan	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

Your firm failed to establish adequate written procedures for cleaning and maintenance of equipment used in the manufacture, processing, or holding of drug substances, and failed to validate cleaning procedures to ensure that equipment is routinely cleaned to prevent contamination.

Specifically,

Your firm has not validated cleaning procedures for major manufacturing and processing equipment used in the production of active pharmaceutical ingredient (API) (b) (4) and API intermediates for (b) (4) The equipment that lacks validated cleaning procedures include, but are not limited to the following:

API/Intermediate	Process	Equipment Name	Equipment ID
	(b) (4)		

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(b) (4)

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(b) (4)

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OBSERVATION 2

Your firm failed to establish and follow appropriate written procedures for equipment qualification.

Specifically,

Your firm has failed to establish and follow appropriate written procedures designed to ensure that equipment used in the manufacture of active pharmaceutical ingredients (APIs) and API intermediates is qualified for its intended use. The equipment that lacks adequate qualification or requalification include, but are not limited to, the following:

API/Intermediate	Process	Equipment Name	Equipment ID

(b) (4)

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Mr. Masahito Horiuchi, Plant General Manager

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Iwata, Shizuoka, 483-0078, Japan	API Manufacturer

(b) (4)

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When requested during the inspection, your firm was unable to provide IQ/OQ documentation for the equipment listed above.

OBSERVATION 3
Your process validations are inadequate.

Specifically,

You have performed a process validation for the manufacturing of the API (b) (4) (DMF# (b) (4) using production equipment that have not been qualified. For example, the process verification protocols, (b) (4) have used major production equipment that have not been adequately qualified.

(b) (4)

The lack of equipment qualification undermines the validity of the process validation study, as there is no documented evidence that the equipment performs consistently and reliably within its intended operating ranges.

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