

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	02/17-21/2025
Industry Information: www.fda.gov/oc/industry	FEI NUMBER
	3002806336

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Akiko Sumikawa, General Manager

FIRM NAME	STREET ADDRESS
Ajinomoto Company Inc.	Kawasaki Plant, 1-1 Suzuki-Cho, Kawasaki-Ku
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Kawasaki-City, Kanagawa, 210-8680, Japan	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Five out of five investigations into production deviations and laboratory out-of-specification results reviewed did not identify the true root cause and supported action to be taken to prevent a reoccurrence of the issue. For example:

a. Deviation investigation DEV_KW_2024-073 was opened on 10/18/24 due to a lower than normal yield of (b) (4) during (b) (4) of (b) (4) lot (b) (4). The investigation found that the (b) (4) for the (b) (4) tank was incorrectly wired, causing the (b) (4) to (b) (4) and the failure was attributed to this. On investigation, the miswiring was found to be due to a request from the Engineering department to the contractor providing the maintenance of the (b) (4) which occurred without being entered in the change control system and without proper oversight. The investigation identified the wiring as the root cause and a correction was implemented to change the wiring; however, the investigation does not discuss the unreported change or what actions should be taken to correct and prevent a reoccurrence of the issue.

b. Deviation investigation DEV_KW_2024-075 was opened on 10/22/24 due to a lower than normal yield of (b) (4) during (b) (4) of (b) (4) lot (b) (4) (the subsequent batch to the batch in deviation investigation DEV_KW_2024-073). The investigation found that the issues identified in deviation investigation DEV_KW_2024-073 were not responsible for the abnormal (b) (4) yield, and that the actual cause of the issue was (b) (4) due to a difference in design between the (b) (4) and the (b) (4). The investigation attributed the issue to the different design of the (b) (4) and a correction was implemented to clean the (b) (4) off the (b) (4) to allow the process to continue properly; however, the investigation does not discuss why the difference in design was not address during design qualification of the (b) (4) or in the change control that was intended to prevent this issue, nor does

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Matthew B. Casale -S Digitally signed by Matthew B. Casale -S Date: 2025.02.21 04:51:46 -05'00'	EMPLOYEE(S) NAME AND TITLE (Print or Type) Matthew Casale, Investigator	DATE ISSUED 02/21/2025
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it discuss what actions should be taken to correct and prevent a reoccurrence of the issue.

c. Deviation investigation DEV_KW_2024-020 was opened on 4/17/24 to investigate an unusually low yield during the (b)(4) step of (b)(4) lot (b)(4). The investigation found that the low yield was caused by the solution (b)(4) and (b)(4) while the employee responsible for (b)(4) was busy supervising a (b)(4) process. The investigation included a reassessment of the instructions and additional instruction as to what to do in similar situation, as well as an assessment of automating the (b)(4) process; however, there was no discussion of why the SOP did not correctly include all operations needed for the job and whether or not any changes need to be made to prevent a reoccurrence of the issue.

d. Deviation investigation DEV_KW_2024-063 was opened on 8/19/24 due to a missed balance inspection after a power breaker was reset. The SOP required a (b)(4) calibration of the balance after power is restored, but the employees did not record a (b)(4) calibration after power was restored. The investigation determined that the (b)(4) check record in use was not sufficient to allow the employees to properly and reliably record a (b)(4) check and the form was revised; however, there is no discussion of why the form was not designed correctly originally and whether or not any changes need to be made to prevent a reoccurrence of the issue.

e. Out-of-specification investigation OOS_KW_2024-001 was opened on 2/16/24 due to an out-of-specification result for (b)(4) unknown impurity during related substances testing of (b)(4) lot (b)(4). The investigation found that the out-of-specification result was caused by improper cleaning of the balances and balance areas during sample weighing, which caused sample contamination. The investigation attributed the improper cleaning to inadequate instructions on cleaning in the SOP and included a correction to add more detail to ensure proper cleaning; however, the investigation does not discuss why the SOP was issued with inadequate instructions and whether or not any changes need to be made to prevent a reoccurrence of the issue.

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2. The laboratory sample preparation worksheets used for preparation of all samples in the laboratory do not have a system to control and record issuance of the worksheets or to identify issuance of multiple worksheets for the same sample preparation.

3. There is no data to support that the (b) (4) material used in the construction of (b) (4) production tanks, including the (b) (4) Tank, (b) (4) Tank, (b) (4) Storage Tanks, and the (b) (4) Tank, used to produce all APIs manufactured at the site is not additive to the APIs.

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