DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration, 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Email: CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	11/10/2025 - 11/14/2025
	FEI NUMBER 3002806404

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Yasunori Matsumura, Director/General Manager/Plant Manager of Nobeoka Plant

FIRM NAME	STREET ADDRESS
Asahi Kasei Finechem Co., Ltd.	6-2633-7 Asahi-machi
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Nobeoka, Miyazaki, 882-0847 Japan	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) (WE) OBSERVED:

OBSERVATION 1
Methods used in testing must meet proper standards of accuracy and reliability as applied to the product tested.

Specifically,

Your firm has not performed method validation studies on in-house developed test methods, nor method verification studies on USP methods, used to perform finished product release testing on (b) (4) API drug products (b) (4) manufactured for the US market.

A) The following are examples of unvalidated in-house analytical methods used for finished product release testing:
1. Heavy Metals Method used for testing (b) (4)
2. E. coli Method used for testing (b) (4)
3. Salmonella Species method used for testing (b) (4)

B) The following are examples of unverified USP analytical methods used for finished product release testing:
1. Loss on Drying (LOD) USP method for (b) (4)
2. Identification (IR) USP method for (b) (4)
3. Loss on Drying (LOD) USP method for (b) (4)

This failure compromises your firm's ability to demonstrate that test results accurately reflect product quality and compliance with specifications.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	VICTORIA SPIVAK -S Digitally signed by VICTORIA SPIVAK -S Date: 2025.11.14 12:42:04 +09'00'	Victoria Spivak, Investigator	11/14/2025