

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 cder-oc-omq-international483response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/13-17/2025
	FEI NUMBER 3002806352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Takeshi Okada, President

FIRM NAME Alps Pharmaceutical Ind. Co., Ltd.	STREET ADDRESS 8 Furukawa, Kamino Diristrict
CITY, STATE AND ZIP CODE Hida City, Gifu Prefecture 509-4263, Japan	TYPE OF ESTABLISHMENT INSPECTED Active Pharmaceutical Ingredients 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
 QC laboratory established written procedure for synchronization of laboratory instruments time with the actual time was not followed. For example, QC laboratory SOP: 013-41, Quality Control Procedure, Effective Date: 2025-05-23, Version 41, states that QC laboratory instruments time shall be synchronized within plus or minus (b)(4) of the actual time. The hardware time display of the HPLC was not synchronized with the network LabSolution software.

On 10/16/2025 during the walk through inspection of the QC laboratory the hardware time display of #HPLC100-6-34 displayed the time difference of (b)(4) and #HPLC100-6-40 displayed the time difference of (b)(4) from the actual time which did not meet the requirement as per the established written procedure. HPLC #HPLC100-6-34 is used for release test of (b)(4) API and HPLC #HPLC100-6-40 is used for release testing of (b)(4) API that are either shipped directly or indirect to the US customers.

OBSERVATION 2
 Microbiological laboratory lacked established written procedure for cleaning of incubators and labeling of prepared media (b)(4). For examples,

A. There is no established written procedure for cleaning of incubators in which incubator H100- inside cabinet seal door was observed containing mold and mildews on 10/15/2025 during the walk through inspection. Incubator #H100-25-7 is used to incubate media (b)(4) plates for microbiological testing of finished APIs that are shipped to the US.

B. There is no established written procedure for proper labeling media (b)(4) plates. The current practice of labeling prepare media (b)(4) plates does not contain the initial of the analyst, the date of inoculation, and identification of the sample that can be tracked to the analytical worksheet.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kham Phommachanh -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) KHAM PHOMMACHANH Consumer Safety Officer Dedicated Foreign Drug Cadre	DATE ISSUED 10/17/2025
	Digitally signed by Kham Phommachanh -S Date: 2025.10.17 14:45:59 +09'00'		

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."