DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	05/25-29/2026
	FEI NUMBER 3002807722

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Norihisa Sato, Plant Manager

FIRM NAME	STREET ADDRESS
Nippon Kayaku Co., Ltd.	239, Iwahana-Machi
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Takasaki, Gunma, 370-1208, Japan	API and Finished Dosage 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
Supervisory oversight over the laboratory electronic systems and data is deficient.

Specifically,
A. Your firm does not reconcile official GMP documents issued from your ArcSuite Engineering document management system. Your firm uses ArcSuite Engineering to issue test records used for GMP testing and to issue manufacturing batch records. You stated the documents are approved by QA in the electronic system prior to printing out, but your firm does not have an audit trail or document history tracing each document that has been printed out. In addition, your firm does not reconcile all of the official GMP documents printed from ArcSuite Engineering. Your firm implemented ArcSuite engineering in April 2020 and uses it to issue official GMP records for manufacturing and testing of (b) (4) API.

B. Your firm does not review 100% of the audit trails and electronic data in your Lab Solutions chromatography software. Your firm reviews the audit trails related to batch release testing, but your firm does not review all of the data generated between batch release testing. You are unable to confirm the presence or the absence of trial injections or other illegitimate testing due to the lack of 100% review. Your firm uses Lab Solutions for performing finished product testing on (b) (4) API.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	WAYNE MCGRATH -S Digitally signed by WAYNE MCGRATH -S Date: 2026.05.29 00:36:24 -05'00'	Wayne D. McGrath, CSO	05/29/2026