DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	6/8/2026-6/12/2026
	FEI NUMBER 3016419927

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Hidekatsu Nishimura, Ph.D., President and Representative Director

FIRM NAME	STREET ADDRESS
TOYO Pharmaceutical Co., Ltd.	2-5-4, Tsurumi; Tsurumi-ku
CITY, STATE, ZIP CODE, COUNTRY Osaka, Osaka, 538-0053 Japan	TYPE ESTABLISHMENT INSPECTED Drug 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 OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,
On 08 June 2026, I observed the following discrepancies related to documentation in your QC laboratory:

-Numerous sticky notes containing handwriting in the QC laboratory on desks, computers, shelves, in cabinets, and in drawers. Your firm stated most of the sticky notes were non-GMP in nature, but I observed one sticky note related to revising the wording on change control number 260518-8. In addition, I observed a sticky note related to re-processing a chromatogram and changing the integration parameters.

-Correction fluid on a handwritten note in a drawer in the QC laboratory.

-Paper towel with growth promotion testing standard solution data in the QC laboratory.

Your SOP for printing and recording GMP documents (number GMP0219-12) does not include instructions related to sticky notes, paper towels, or correction fluid.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Wayne D Mcgrath, Investigator X Wayne D Mcgrath Investigator Signed By: 2001897192 Date Signed: 06-12-2026 13:42:04	6/12/2026

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OBSERVATION 2

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,
Your firm does not have unique usernames and passwords for each operator using electronic systems in production. Your firm only has one login password for each of the following production equipment using electronic systems for setting manufacturing parameters and operating:

(b) (4)

The (b) (4) is used to fill (b) (4) for the US market and the other equipment is used to manufacture (b) (4) mg tablets (b) (4)

(b) (4)

OBSERVATION 3

Drug product reserve samples are not stored in an immediate container-closure system that has essentially the same characteristics as the marketed product.

Specifically,
Your firm does not store batches of (b) (4) mg tablet retain samples in the same (b) (4) packaging as you distribute it in. Your firm packs bulk tablets of (b) (4) mg in (b) (4) which is then placed in (b) (4) bottle for shipment. However, your (b) (4) mg tablet retain

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samples are stored in (b) (4) bottle (b) (4) which is then placed in (b) (4)

OBSERVATION 4

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,
Your firm does not perform annual visual examination on your retain samples for (b) (4) (b) (4) and (b) (4) mg tablets.

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Wayne D Mcgrath, Investigator

X Wayne D Mcgrath
Investigator
Signed By: 2001897192
Date Signed: 06-12-2026
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