DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	3/16/2026-3/27/2026* FEI NUMBER 3005674517

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tim Lin, General Manager

FIRM NAME	STREET ADDRESS
Bora Pharmaceutical Laboratories Inc. Zhongli Plant	Zhongli Industrial Zone, No. 3-1 Ziqiang 4th Rd.; Zhongli Dist.
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Taoyuan City, 320023 Taiwan	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) (WE) OBSERVED:

OBSERVATION 1

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

Your firm's cleaning validation studies and cleaning procedures for non-dedicated equipment, including (b) (4) (b) (4) equipment, are inadequate.

A. On March 16, 2026, (b) (4) residues were observed in the (b) (4) ducts of (b) (4) that had been documented as cleaned and released for use.

(b) (4)

This (b) (4) is non-dedicated and used for commercial manufacture of the following drug products:

(b) (4)

(b) (4) was documented as cleaned and verified on March 13, 2026; however, (b) (4) residues were observed

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in the (b) (4) duct. Your firm's swab results identified multiple active pharmaceutical ingredients (APIs) from previously manufactured drug products within the (b) (4) duct, including:

(b) (4)

The cleaning validation for (b) (4) does not evaluate the (b) (4) duct. The cleaning procedure for (b) (4) does not specify to clean this area.

(b) (4)

This (b) (4) is non-dedicated and used for commercial manufacture of the following drug products:

(b) (4)

(b) (4) was documented as cleaned and verified on March 11, 2026; however (b) (4) residues were observed in the (b) (4) duct. Your firm's swab results identified multiple APIs from previously manufactured drug products within the (b) (4) duct, including:

(b) (4)

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(b) (4)

The cleaning validation for (b) (4) does not evaluate the (b) (4) duct. The cleaning procedure for (b) (4) does not specify to clean this area.

(b) (4)

This (b) (4) is non-dedicated and used for commercial manufacture of the following drug products:

(b) (4)

(b) (4) was documented as cleaned and verified on January 15, 2026; however, (b) (4) residues were observed in the (b) (4) duct. Your firm's swab results identified multiple APIs from previously manufactured drug products within the (b) (4) duct, including:

(b) (4)

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(b) (4)

The cleaning validation for (b) (4) does not evaluate the (b) (4) duct. The cleaning procedure for (b) (4) does not specify to clean this area.

(b) (4)

(b) (4)

(b) (4) are used in the manufacture of U.S. drug products. These units were not examined during the inspection; however, the associated cleaning validation studies and cleaning procedures do not include evaluation or cleaning of (b) (4) ducts. Your firm's swab results identified multiple, different APIs in these (b) (4)

(b) (4)

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(b) (4)

[redacted]

B. On March 16, 2026, (b) (4) residues were observed in the (b) (4) ducts, (b) (4) and chambers of (b) (4) equipment that had been documented as cleaned and released for use.

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(b) (4)

This (b) (4) is non-dedicated and used for commercial manufacture of the following drug products:

(b) (4)

(b) (4) was documented as cleaned on December 31, 2025, and verified on January 1, 2026; however, (b) (4) residues were observed within the (b) (4) equipment. Your firm's swab results identified multiple APIs from previously manufactured drug products within (b) (4) including:

(b) (4)

(b) (4)

This (b) (4) is non-dedicated and used for commercial manufacture of the following drug products:

(b) (4)

(b) (4) was documented as cleaned and verified on January 29, 2026; however, (b) (4) residues were observed within the (b) (4) equipment. Your firm's swab results identified multiple APIs from previously manufactured drug products within (b) (4) including:

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(b) (4)

The cleaning validation for (b) (4) does not evaluate the (b) (4) ducts. The cleaning procedure for (b) (4) does not specify to clean the (b) (4) ducts.

(b) (4) Equipment
(b) (4) equipment (b) (4)
(b) (4) are used in the manufacture of U.S. drug products. These units were not examined during the inspection; however, the associated cleaning validation studies and cleaning procedures do not include evaluation or cleaning of (b) (4) ducts. Your firm's swab results identified multiple, different APIs in these (b) (4) equipment.

(b) (4)

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(b) (4)

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm failed to adequately investigate repeated OOS dissolution results for (b) (4) (b) (4) at the (b) (4) sampling time point from 2021 through 2026 as effective corrective and preventative actions (CAPAs) were not implemented to prevent recurrence. For example:

Deviation COM-IR-21017 (March 2021): Initiated for OOS dissolution result of (b) (4)% (specification: (b) (4) %) at the (b) (4) for batch (b) (4) The investigation attributed the OOS to a combination of different lots of (b) (4) impacting (b) (4) content and the use of (b) (4) from a new vendor. The CAPA did not address the identified root cause.

Deviation COM-IR-21088 (November 2021): Initiated for OOS dissolution result of (b) (4)% at the (b) (4) for (b) (4) The investigation attributed the OOS to (b) (4) (b) (4) The CAPA did not address the identified root cause.

Deviation COM-IR-22092 (November 2022): Initiated for OOS dissolution results of (b) (4)% and (b) (4)% at the (b) (4) (b) (4) for batches (b) (4) respectively. The investigation identified high (b) (4) content in (b) (4) as the root cause. The CAPA included revising the formulation.

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Deviation COM-IR-22110 (December 2022): initiated following the formulation revision. OOS dissolution results of (b) (4)% at the (b) (4) were observed for batches (b) (4) The investigation attributed the results to the inability of the revised formulation to mitigate the impact of high (b) (4) content of (b) (4) The CAPA included reverting to the previous formulation.

Deviation COM-IR-23014 (April 2023): Initiated for OOS dissolution result of (b) (4)% at the (b) (4) for batch (b) (4) The investigation attributed the result to high (b) (4) content of (b) (4) The CAPA included revising the (b) (4) content range and adjusting processing parameters.

Deviation COM-IR-23027 (July 2023): Initiated for OOS dissolution result of (b) (4)% at the (b) (4) for (b) (4) The investigation did not identify a definitive root cause.

Your firm ceased production of (b) (4) from (b) (4) (b) (4) to evaluate the manufacturing process and subsequently revalidated the process in (b) (4) (b) (4) However, following revalidation, similar OOS dissolution results continued to occur at the same sampling time point:

Deviation 1377906 (November 2024): Initiated for OOS dissolution result of (b) (4)% at the (b) (4) for batch (b) (4) The investigation did not identify a definitive root cause.

Deviation 1519593 (January 2026): Initiated for OOS dissolution result of (b) (4)% at the (b) (4) for batch (b) (4) The investigation did not identify a definitive root cause.

B. Your firm failed to adequately investigate the presence of foreign matter identified during manufacturing operations. Investigations did not include appropriate identification testing and did not evaluate all potential sources of contamination. For example:

1. Deviation COM-IR-23056
Prior to (b) (4) of (b) (4) Tablets, (b) (4)mg (b) (4) batches (b) (4) an operator observed (b) (4) particles in the bulk material. No analytical identification testing was performed to determine the identity of the particles. Your firm attributed the material based on visual examination. These

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batches were manufactured using the (b) (4) however, the investigation did not include evaluation of the (b) (4) duct of (b) (4) as a potential source of the foreign material. No other batches were evaluated as part of the investigation.

2.. Deviation COM-IR-22013
A QC analyst observed (b) (4) foreign matter in (b) (4) Capsules, (b) (4) mg, batch (b) (4) No analytical identification testing was performed to determine the identity of the foreign material. Your firm attributed the material based on visual examination. No other batches were evaluated as part of the investigation. Batch (b) (4) was released.

OBSERVATION 3
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 has not established adequate controls for the (b) (4) Capsule Check Weigher (b) (4) computerized system used to verify capsule fill weight. The (b) (4) Capsule Filling and Closing Machine (b) (4) is used to fill capsules; however, capsule fill weight is adjusted (b) (4) through the (b) (4) and is not captured, controlled, or monitored by the (b) (4) system. The (b) (4) system is used to verify capsule fill weight and automatically rejects capsules outside of the recipe range.

Operators have the ability to modify recipe parameters within the (b) (4) system. For example, during review of recipes for (b) (4) Capsules, (b) (4) mg, recipe versions were observed that exceeded the validated target fill weight range.

During routine operations, your firm does not review the raw electronic capsule weight data generated by the (b) (4) for each batch. Additionally, your firm does not review the audit trail generated by the (b) (4) for each batch.

Operators have the ability to create and deleted recipes within the (b) (4) system. Approximately (b) (4) deleted recipes were observed. Metadata associated with these deleted recipes could not be accessed; therefore, the content and use of these deleted recipes could not be evaluated. Your firm has not performed any review of these deleted recipes.

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Your audit trail review procedure (SOP-2491) requires that audit trails for the (b) (4) system be reviewed (b) (4) and specifies that the review include parameter setting changes, deletion, or modification of records, and deletion or modification of recipes or settings.

OBSERVATION 4
The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm's management of manufacturing materials is inadequate.

On March 17, 2026, in the Manufacturing Department Holding Area for Disposal, an unlabeled bag containing approximately (b) (4) of tablets was observed. There was no information to identify the product, associated batch number, or reason for disposal.

Additionally, a separate bag containing tablets was observed with a partially completed label; however, the label did not identify the individual who disposed of the material or the individual who approved the disposal.

Both bags were staged for disposal in a drum; however, the associated rejection record for the drum did not include any documentation accounting for these materials.

Your procedure governing disposal of manufacturing materials (1SOP-0301) requires that rejected materials be appropriately labeled with the item name, batch number, process step, weight, disposing personnel, and verifying personnel. The procedure further requires that materials designated for destruction be labeled and documented on the rejection record.

*DATES OF INSPECTION
3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri)

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