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	07/15/2025-07/21/2025
	FEI NUMBER 3007184570

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tom Chang, Senior VP, Taiwan Site Operations

FIRM NAME	STREET ADDRESS
Bora Pharmaceuticals Laboratories, Inc	Hsinchu Science Park No. 1 Kedong 3rd Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Zhunan Township Miaoli County 350401 Taiwan	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.

OBSERVATION 1

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your firm has not conducted any protocol-driven production process validation studies for (b) (4) (b) (4) Capsules, (b) (4) mg, following a change in the technical grade of (b) (4), a (b) (4) excipient in the drug product formulation. The technical grade of (b) (4) was changed in 2024.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, according to procedure titled "Deviation Handling Instruction" SOP-2209, deviation impact analysis includes but is not limited to, placing the affected "GMP lots" to "stability monitoring"; however, there were approximately 25 deviations between 07/01/2019-05/03/2024, related to OOT analytical testing results for the drug product (b) (4) Capsules, (b) (4) (b) (4) mg that were released without placing samples on stability, or performing a written impact assessment. The following are some examples of manufacturing deviations that are related to OOT analytical dissolution results that were not assessed for stability in the deviation impact analysis by the Quality Unit:

DEVIATION	DATE	SUMMARY	AFFECTED LOTS
1147547	05/24/2021	Out of QCAL results on Dissolution testing for (b) (4)	(b) (4)
1159384	03/02/2022	Out of QCAL on Dissolution Testing	

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			(b) (4)
1228703	02/07/2024	(b) (4) Lots of (b) (4) (b) (4) out of action-QCAL	
1290865	04/15/2024	(b) (4) Lots Revealed OOT DS Results	

OBSERVATION 3

Procedures describing the handling of written and oral complaints related to drug products are not followed.

Specifically, the procedure title "Product Complaints" SOP-0591, indicates that retain inspections are required for product complaints that have a lot number supplied in the complaint; however, the following product-related complaints that included lot numbers, but did not include the examination of customer samples, were not visually inspected for the reported appearance-related aberrations:

A. Complaint #PR 1111394, a customer complaint regarding (b) (4) Tablets, (b) (4) g, lot # (b) (4) that was initiated due to tablets that were "splitting." There was no visual inspection of retain samples conducted during the investigation.

B. Complaint #PR 1109495, a customer complaint regarding (b) (4) Tablets, (b) (4) g, lot # (b) (4) that was initiated due to tablets that were "splitting." There was no visual inspection of retain samples conducted during the investigation.

C. Complaint #PR 1109384, a customer complaint regarding (b) (4) Tablets, (b) (4) g, lot # (b) (4) that was initiated due to tablets that were "splitting." There was no visual inspection of retain samples conducted during the investigation.

D. Complaint #PR 1111478, a customer complaint regarding (b) (4)

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(b) (4) Capsules, (b) (4) mg, lot #(b) (4) that was initiated due to "foreign tablets in bottle." There was no visual inspection of retain samples conducted during the investigation.

OBSERVATION 4
Master production and control records lack complete manufacturing and control instructions.

Specifically, the line clearance work instructions titled "Packaging Line Clearance Checklist" FORM-0062, for the bottle packaging lines (i.e., Line(b) (4) lack detailed descriptions of the packaging equipment parts that the operators are required to clean and check to ensure that previous products are not present, to minimize the risk of product mix-up and cross contamination. The firm utilizes bottle packaging Line (b) (4) to perform (b) (4) packaging on approximately(b) (4) drug products. The following consumer complaints were related to drug product mix-ups that were packaged on Line (b) (4)

COMPLAINT #	DESCRIPTION	PRODUCT
1189349	"mixed-up capsules"	(b) (4)
1111478	"foreign tablets in bottle"	
1103929	"bottles contain different strength of (b) (4) Capsules"	
1129191	"foreign tablet"	
1133928	"mixed capsule"	
1155882	"mixed up capsule"	
1146215	"medication bottling error"	
1327231	"medication Mix-up"	
1103930	One of "bottles contains different strength"	

OBSERVATION 5
The procedures for the annual quality standards record evaluation are deficient in that they do not address a review of a representative number of batches.

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Specifically, the annual visual inspections of drug product retention samples are not representative of all batches produced in a calendar year. According to the procedure titled "Management of Retain Samples" SOP-2456, the number of reserve lot samples selected for the annual visual inspection program is determined by the total batches produced using a "reduced sampling plan." For example, the drug product (b) (4) (b) (4) Capsules, (b) (4) mg, had the following range of batches selected for the annual drug product retention sample retain visual evaluation program:

DRUG PRODUCT	RANGE of BATCHES PRODUCED (2019-2024)	PERCENTAGE of BATCHES PRODUCED on VISUAL INSPECTION PROGRAM
(b) (4)		

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