DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	3/12/2026-3/20/2026* FEI NUMBER 1000512361

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David Fidler , Vice President & General Manager

FIRM NAME	STREET ADDRESS
Bora Pharmaceuticals Injectables Inc	1111 S Paca St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Baltimore, MD 21230-2526	Sterile 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

A) Your firm failed to thoroughly investigate Out of Limit (OOS) investigations that were initiated in response to personnel monitoring samples that exceeded the specifications for the controlled classified spaces, specifically Grade A and Grade B, which are utilized to produce (b)(4) sterile drug products. The corrective and preventative actions instituted did not address the root cause of the persistent personnel monitoring recoveries to mitigate sterile drug product quality impact. There were approximately 189 personnel monitoring Out of Limit (OOL) investigations from 06/2023-03/2026; 80 of the investigations describe isolates that were classified as objectionable microorganisms. The following are some examples of the investigations which have inadequate corrective and preventative actions:

Investigation No.	Initiation Date	Sterile Drug Product	Summary	Batch Released Date
Deviation-008745	02/09/2024	(b) (4) lot # (b) (4) -	Recovered gram negative objectionable organis	04/05/2024

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Brandy N Lepage, Investigator
Zhong Li, FDA Center Employee
Sudipan Karmakar, FDA Center Employee
Hyung-Yul Lee, FDA Center Employee

X Tekalign Wondimu Investigator Signed By: TEKALIGN WONDIMU -S Date Signed: 03-20-2026 17:25:36

DATE ISSUED
3/20/2026

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		(b) (4)	m (i.e., *Moraxella* osloensis) during personnel monitoring following exit from syringe filling line in room # (b) (4)	
Deviation-008549	01/04/2024	(b) (4) Injection, lot #(b) (4)-(b) (4)	Recovered gram negative objectionable organism (i.e., *Moraxella* osloensis) during personn	06/05/2024

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			el monitoring following exit from vial filling line in room # (b) (4)	
Deviation-008968	03/04/2024	(b) (4) lot # (b) (4) - (b) (4)	Recovered gram negative objectionable organism (i.e., *Paracoccus yeei*) during personnel monitoring following exit from syringe filling	08/01/2024

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			line in room # (b) (4)	
Deviation-008969	03/04/2024	(b) (4) lot # (b) (4) (b) (4)	Recovered gram negative objectionable organism (i.e., *Roseomonas mucosa*) during personnel monitoring following exit from syringe filling line in room # (b) (4)	08/07/2024
Deviation-009444	06/11/2024	(b) (4) Injection,	Recovered gram negative objectionable	10/31/2024

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		lot # (b) (4)-(b) (4)	organism (i.e., *Acinetobacter ursingii*) during personnel monitoring following exit from vial filling line in room # (b) (4)	
Deviation-009556	07/05/2024	(b) (4) lot # (b) (4)-(b) (4)	Recovered gram negative objectionable organism (i.e., *Mixta calida*) during personnel monitori	09/03/2024

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			ng following exit from syringe filling line in room # (b) (4)	

B) The procedure that delineates analytical and microbiology laboratory out of specification investigations is SOP017591 and is titled "Out-of-Specification (OOS) Results: Preliminary Assessment and OOS Investigation." According to the procedure, sterility failure test invalidation must follow the guidelines of USP <71>. Hence, a sterility test may be invalidated if the growth of the identified species "may be ascribed unequivocally to faults with respect to the material and or the technique used in conducting the sterility test."

However, the following investigations that were initiated in response to (b) (4) lots that resulted in sterility test positives, were attributed to a laboratory microbiologist error, without definitively ruling out the possibility that the sterile drug products were contaminated during production. The following sterility test failure investigations did not have scientifically sound root cause assessments:

OOS/Deviation	Drug Product	Microorganism Isolated	Batch Release Date
PA-25-001M/DEV-010511	(b) (4) lot # (b) (4)	*Staphylococcus hominis*	09/11/2025
PA-25-002M/DEV-010514	(b) (4) (b) (4) , lot #	*Micrococcus luteus* and *Staphylococcus*	07/25/2025

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	(b) (4), lot # (b) (4)	*hominis*	

C) The quality unit released sterile drug products without conducting a scientifically sound assessment of how critical defects, such as human hair contamination found during visual inspection of finished products, would impact the quality, safety, and purity of the products. Furthermore, there is no assurance that these lots are free from additional particulate matter.

For example: During the initial 100% Visual Inspection of (b) (4) (b) (4) Injection), (b) (4) (b) (4), Batch #(b) (4), (b) (4) vials were identified to contain visible particles. During Level 1 evaluation, 135 of the (b) (4) units were confirmed to contain particles. The materials identified included polyester fiber (13), rayon fiber (2), fiberglass (5), cellulose fiber (28), human hair (1), degraded material (3), (b) (4) (1), cotton fiber (4), degraded silicone (73), (b) (4) (1), (b) (4) (2), degraded natural fiber (1), and nylon (1). Of the 135 particles analyzed, 134 were classified as process-related extrinsic and one human hair was classified as extrinsic critical. During the second 100% visual inspection, 122 vials were identified as containing visible particles. Level 1 evaluation of these 122 vials identified 101 particles. The materials identified and analyzed included: degraded silicone (62), cellulose fiber (15), degraded material (4), polyester fiber (8), (b) (4) (3), cellulose particle (3), regenerated cellulose fiber (2), cotton fiber (2), and fiberglass (2). All particles were classified as process-related extrinsic. The Quality unit determined that the extrinsic human hair and other particles identified did not impact the safety, identity, strength, purity, or quality of Batch #(b) (4) and that defects are identified and removed during 100% visual inspection and AQL. Batch #(b) (4) was released on July 31, 2025.

D) The firm failed to implement effective corrective actions to address the repeated presence of extrinsic foreign particles, including human hair and cellulose, in sterile injectable drug products. Despite an ongoing trend of hair and other "process-related extrinsic" particle contamination in sterile products, the firm has not fully evaluated or implemented additional corrective actions to mitigate this

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risk. Investigations repeatedly attributed extrinsic particles to contaminated sterile components, sterile gowning materials, and inadequate tube cleaning during preparation. Hair on (b) (4) and the use of non-dedicated (b) (4) for material movement in the filling room were identified as contributing factors. However, these findings are not thoroughly evaluated to identify true root causes or implement effective preventive actions to mitigate contamination sources.

OBSERVATION 2

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

The facility procedure and work instruction that describes the cleaning and disinfecting of controlled classified spaces (i.e., Grade A-Grade D) are titled "Baltimore (BPII) Production Facility Cleaning" and "Baltimore (BPII) Production Facility Cleaning Work Instruction," respectively. The firm produces (b) (4) sterile drug products in the facility controlled classified areas. The aseptic core facility cleaning is performed on a (b) (4) and (b) (4) basis. The procedure indicates for equipment, (b) (4) surfaces, and (b) (4) to be wiped with (b) (4) following a (b) (4) disinfectant (i.e., (b) (4) and (b) (4) Solution) contact time; however, it is not effective in removing the disinfectant residue. During the walkthrough on 03/12/2024, we observed apparent disinfectant residue on the (b) (4) panels that encompasses the (b) (4) Vial Filler (Equipment ID # (b) (4)), (b) (4) and a (b) (4) table located in the controlled classified areas.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

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Specifically,

A. The following deficiencies in aseptic processing were identified through observation of the (b) (4) filling suite operations (filling line setup/assembly on March 16, 2026 and filling operations on March 18, 2026) and review of smoke study videos for the (b) (4) syringe filling suite, (b) (4) vial filling suite, (b) (4) , (b) (4) , (b) (4) Aseptic Storage:

i. Aseptic operators failed to follow standard procedures for good aseptic practices, as evidenced by the following observations:

a. Operators did not adhere to the principle of slow and deliberate movement required in aseptic environments. Specifically, on March 18, 2026, operators were observed walking rapidly through narrow passages between the room wall and sections of the (b) (4) (b) (4) in the area where the vial turntable and (b) (4) stopper bowl are located. This rapid movement can generate air turbulence, creating a risk of Grade B air ingress into the (b) (4) through gaps between panels and potentially compromising the Grade A environment inside the (b) (4).

b. Operators were observed removing vials from the vial transfer turntable on March 18, 2026 while blocking first air over the vials with a (b) (4) . This is also evidenced in smoke study video footage titled "Dynamic (Operating) Filling (b) (4) ".

ii. Review of the smoke study video for the syringe filling line in the aseptic filling suite (Room (b) (4)) revealed the following aseptic technique deficiencies: (1) operators' (b) (4) hands contacted direct product-contact components of the (b) (4) pumps and indirect product-contact components of the stopper delivery system and stoppering station during aseptic assembly and setup; (2) operators' (b) (4) hands obstructed first air over the direct and indirect product-contact surfaces of these components; (3) operators manipulated filling needles and syringe tubs containing exposed syringes with (b) (4) hands; and (4) operators obstructed first air over stoppers in the stopper bowl with a non-sterile stopper bag.

iii. The video footage titled "Dynamic (Operations) (b) (4) " shows that during aseptic assembly of the sterile receiving vessel in the (b) (4) filling suite, operators' (b) (4) hands obstructed first air over exposed direct product-contact surfaces of the following components: receiving vessel tubing assembly, (b) (4) (b) (4), and connecting tubing.

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iv. The video footage titled "Dynamic (Operations) Filler Setup (b) (4) Part 1" and "Dynamic (interventions) Filling Stoppering (b) (4) Part 1" show that during aseptic assembly of the filling stations and filling nozzle realignment in the (b) (4) filling suite, the operators were observed touching the nozzle and nozzle holding brackets. In addition, operators' (b) (4) hands obstructed first air over exposed direct product-contact surfaces of the filling nozzles.

v. The video footage titled "(b) (4) ", "(b) (4) ", and "Dynamic (Operating) Filling (b) (4)" shows that during loading and unloading of the HEPA (High-Efficiency Particulate Air) (b) (4), the operator's head and upper torso were in close proximity to (b) (4) vials in the trays, thereby obstructing first air over the vials.

vi. The video footage titled "(b) (4) Dynamic" shows that during unloading of depyrogenated vials in the sterile storage suite (b) (4), the operators' (b) (4) hands contacted the exterior surface of the (b) (4) boxes that contain the depyrogenated vials.

B. Your firm's qualification of airflow in the aseptic filling suite (room (b) (4)), RPT063352 (version 1.0, approved May 12, 2023) is deficient.

i. The airflow visualization study (smoke study) failed to meet acceptance criteria for unidirectional, turbulence-free airflow. Specifically, the airflow to the critical aseptic processing areas inside the (b) (4) is provided by (b) (4) HEPA filters. An approximately (b) (4) gap exists between the ceiling and the upper section of the (b) (4). Smoke study video footage titled "Static Part 2" demonstrates air turbulence and upward airflow in the areas above the (b) (4) beams.

ii. The smoke study failed to provide evidence supporting Change Control CC-001486 (closed August 20, 2024), which reclassified the (b) (4) background environment from Grade A to Grade B. Specifically, the study did not demonstrate the following:

a. That the (b) (4) prevents ingress of viable and non-viable particulates from the surrounding Grade B environment into the filling line Grade A area through gaps between barrier panels under dynamic conditions, including maximum personnel and equipment movement permitted during routine production operations.

b. That the (b) (4) provides unidirectional airflow at sufficient velocity, directed outward toward the surrounding Grade B environment, to sweep over and away from exposed sterilized

materials, product, and container closures under dynamic conditions during open-door interventions.

C. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

i. The environmental monitoring (EM) sampling plan for the Grade B background surrounding the Grade A (b) (4) in the (b) (4) filling suite during operations is inadequate due to insufficient scientific justification for sampling locations. The firm has failed to establish a documented, risk-based rationale demonstrating that the selected sampling locations adequately detect microbiological contamination associated with routine operations in areas adjacent to the critical zone. For example:

a) During HEPA (b) (4) loading operations, neither continuous non-viable particle monitoring nor active air sampling is conducted in the process-specific Grade A zone.

b) No passive air sampling is conducted in the area where operators routinely remove filled vials for weight verification during filling operations. This location involves active product manipulation and direct operator interface within the aseptic processing environment.

ii. EM contact plates used for surface sampling on disinfected cleanroom surfaces were not demonstrated to be suitable for recovery of microorganisms in the presence of residual disinfectants. Specifically, the (b) (4) contact plates used for routine surface monitoring were not qualified with appropriate neutralizing agents to inactivate residual disinfectant carryover. As a result, the environmental monitoring program lacks assurance that microbial recovery is not inhibited, which may lead to false-negative results and may not provide an adequate assessment of the microbiological condition of cleanroom surfaces.

D. The aseptic processing areas are deficient with respect to the system for cleaning and disinfecting the (b) (4) and equipment necessary to maintain aseptic conditions. For example:

Irregularly shaped fixtures mounted on the top section of the (b) (4) exterior surfaces are not readily cleanable with (b) (4) mop heads. Additionally, the top surfaces of (b) (4) beams are inaccessible for cleaning and sanitization.

The top exterior surface of HEPA (b) (4) is not included in routine cleaning and sanitization procedures.

The cleaning technique used for the (b) (4) in (b) (4) does not provide assurance that contaminants

AMENDMENT 1

on the (b) (4) are effectively and fully removed. In addition, cleaning validation has not been validated to meet the user requirements.

E. Your firm's aseptic area HEPA certification program is deficient. Specifically, the airflow velocity testing conducted during (b) (4) requalification of Grade A and B areas fails to include work surface velocity testing.

OBSERVATION 4

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically,

A. There is a lack of assurance that your cleaning procedures for process equipment are effective in preventing cross contamination. For example,

i. The initial qualification of the (b) (4) (Equipment No. (b) (4)) with respect to cleaning verification (Protocol No. 20-1690-PQ), as well as the routine cleaning verification of the (b) (4) (b) (4) (Equipment No. (b) (4) ; FRM No. 019668), are deficient. Specifically, for both (b) (4) , (b) (4) swab sampling is limited to the (b) (4) only. No samples are collected from other relevant product-contact or adjacent internal surfaces, including the (b) (4) , doors, and (b) (4) . In addition, no rinse samples are collected. Accordingly, the cleaning verification program is inadequate and does not provide sufficient evidence to demonstrate that the cleaning procedure is effective.

ii. The cleaning verification for HEPA (b) (4) is limited to visual inspection. In addition, SOP 017803 v9.0 for (b) (4) cleaning and sanitization is deficient because it lacks validation data and predefined acceptance criteria to demonstrate cleaning effectiveness. Specifically, the SOP does not reference studies showing removal of product residues or microbial contamination, does not define sampling methods to verify cleaning effectiveness, and does not include recovery study data supporting the effectiveness of the specified cleaning agents, under actual use conditions. Therefore, there is no scientific evidence that the (b) (4) are consistently cleaned and sanitized to an acceptable state for

GMP use.

B. Your firm's new product introduction process, including multi-product manufacturing risk assessments, is not based on health-based exposure limits (HBELs) such as Acceptable Daily Exposure (ADE) or Permitted Daily Exposure (PDE) values determined by qualified toxicologists using available toxicological and pharmacological data. Additionally, your firm has not performed appropriate degradation (or (b) (4)) studies to demonstrate that disinfectants used for facility and equipment decontamination can effectively reduce product residues on non-product-contact surfaces to acceptable levels in drug product manufacturing facilities.

C. Your documented risk assessments, RPT059443 (version 1.0) and RPT062879 (version 1.0), do not provide adequate justification for current multi-product manufacturing strategy and controls to prevent potential contamination and cross-contamination. For example,

i. The risk assessments failed to identify and appropriately evaluate potential cross-contamination risks associated with open processes performed under the Grade C environment in the formulation suite ((b) (4)). During observation of the (b) (4) formulation process on 16 March 2026, multiple steps involved manually transferring drug substance solutions between vessels via (b) (4). Operators were observed placing (b) (4) inside containers with gloved hands and holding their hands over vessel openings for extended periods of time, creating risks of product contamination with environmental contaminants.

ii. The risk assessments did not evaluate the appropriateness or adequacy of your gowning practice for the aseptic manufacturing areas. For example, personnel are required to change into clean scrubs in locker rooms and wash their hands in controlled non-classified (CNC) areas (rooms (b) (4) and (b) (4), and corridor (b) (4) before entering classified areas. However, there is a potential for scrub contamination to occur prior to entry into Gowning Room (b) (4). There is a risk that the scrubs may already be contaminated before entering Gowning Room (b) (4). Recurring mold contamination has been detected in Gowning Room (b) (4) during the period from 2024 to 2025.

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate

AMENDMENT 1

standards designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

*** Observation 5A is specific to (b) (4) ***

Specifically,

A. The (b) (4) HPLC ((b) (4)-HPLC) chromatographic integration method used for quantitation of the main peak lacks full optimization, accuracy, and robustness for its intended use. Current practice relies on an incompletely developed integration approach, and you have not demonstrated that the selected integration parameters consistently provide accurate and reliable quantitation of the main peak. In addition, your firm lacks an approved written procedure defining permissible integration events, including the scientific justification, documentation, review, and approval requirements for your current adjusted integration. Because method accuracy and robustness have not been confirmed, the validity of previously generated analytical data is in question and may require reassessment or repeat analysis once the integration method is fully optimized and appropriately controlled.

B. There is a lack of assurance that the vial stoppering/crimping process is capable of consistently maintaining container-closure integrity of the drug product. Your firm has not provided a scientifically sound justification for excluding container closure integrity test (CCIT) from in-process controls, and your release program does not include an adequate test or other validated control to assure container-closure integrity of the finished sterile drug product.

OBSERVATION 6

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

Specifically,

A- Your firm lacks adequate assurance that critical equipment and systems used in the manufacture of

sterile drug products are properly qualified and/or maintained in a validated state. Specifically,

i. There is insufficient assurance that stoppered vials are adequately protected from potential contamination during transfer from the aseptic processing room through completion of the crimping step. For example, your firm's airflow qualification for Capping Suite (b)(4) ((b)(4)) (Document 10-RM 141-PQ and ADD1, approved 01 Mar 2011) demonstrates significant air turbulence in the capping zone caused by the capping machine blocking Grade A air supply. Additionally, the system suitability for the in-line stopper-height/gap inspection system is not appropriately verified. Suitable challenge sets are not being used to ensure that all improperly seated stoppers are consistently rejected prior to capping during routine manufacturing operations.

ii. The (b)(4) used to sterilize drug product filling and stoppering components has not been properly validated or routinely revalidated with respect to sterilization of the (b)(4) (or as part of the (b)(4) or offline). In addition, your firm has not demonstrated that (b)(4) used to supply sterile (b)(4) or (b)(4) to the (b)(4) are sterilized before use. Therefore, the sterility assurance of the (b)(4) and its associated (b)(4) is not established.

iii. You failed to establish adequate written procedures for ongoing verification of the (b)(4) temperature mapping or performed to demonstrate continued uniformity of shelf temperature distribution across the chamber under routine operating conditions. Although the routine preventive maintenance program includes calibration of (b)(4), (b)(4), (b)(4) (b)(4), and (b)(4) checks, it does not include temperature mapping as part of ongoing verification of (b)(4) performance.

iv. The (b)(4) quality testing has never been performed for either (b)(4) without any written justification.

B. Your firm has not established adequate procedural controls to protect the electronic data acquisition systems. Specifically,

i. Prior to 25 Feb 2025, a (b)(4) validation system ((b)(4), Model (b)(4) ((b)(4)) installed on (b)(4) laptops ((b)(4)) was utilized to collect data from dataloggers during (b)(4) validation processes. This system was not validated to ensure the protection of original electronic records and relevant metadata, including audit trails. Your firm has not performed a comprehensive assessment to determine the reliability and

completeness of all GMP data produced by this system.

ii. User privilege configuration is deficient. Specifically, the "User" group for the (b) (4) thermal validation system (software version (b) (4)) has software privileges that allow for the deletion of thermal validation measurement reports.

C. The firm has not provided adequate justification for the clean air compressor's current air intake configuration. Source air is drawn from an adjacent enclosed area housing (b) (4) instead of from fresh outside air, which may compromise air quality and compressor performance.

D. Your quality unit has not conducted on-site GMP audits of all contractor service providers who perform critical qualification and validation activities at your DP manufacturing facility. For example, no audits have been conducted of the following providers:

i. (b) (4) – provider of qualification activities for the HVAC system (including HEPA filters), Unidirectional Air Flow (LAF) units, and Microbiological Safety Cabinets.

ii. (b) (4) – provider of (b) (4) quality testing

***DATES OF INSPECTION**

3/12/2026(Thu), 3/13/2026(Fri), 3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri)

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FDA Center Employee
Signed By: SUDIPAN KARMAKAR -S
Date Signed: 03-20-2026 17:27:36

X Hyung-Yul Lee
FDA Center Employee
Signed By: 2000396584
Date Signed: 03-20-2026 17:28:19

AMENDMENT 1

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 judgment, 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."