DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 407-475-4700	03/12/2026-03/20/2026
	FEI NUMBER 1000113778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert T. Fulop, Director of Site Operations

FIRM NAME	STREET ADDRESS
Bausch and Lomb Incorporated	8500 Hidden River Parkway
CITY, STATE, ZIP CODE, COUNTRY Tampa, FL 33637	TYPE ESTABLISHMENT INSPECTED Sterile Drug Product 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
Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

A. Your firm failed to adequately investigate customer complaints that were received as Adverse Events. The following adverse events were reviewed and deemed inadequate; this is not an exhaustive listing:

i. **Complaint# 1406005** opened on 08/03/2025 as an Adverse Event and critical complaint. Customer found a shard of metal in the ointment that was on their (b) (4). The product was (b) (4) (b) (4) Ointment (b) (4), Lot# (b) (4) Expiration (b) (4).

ii. **Complaint# 1285238** opened on 12/20/2023 as an Adverse Event. Customer stated they immediately felt a burning, intense itching, and what felt like "shards of glass," resulting in their (b) (4) becoming (b) (4). This product was (b) (4) (b) (4) Solution USP (b) (4), Lot# (b) (4), Expiration (b) (4).

iii. **Complaint# 1269630** opened on 11/15/2023 as an Adverse Event. Customer had a severe reaction to the (b) (4) utilized. The product was (b) (4) (b) (4), Lot# (b) (4) Manufacturer Lot# (b) (4), Expiration (b) (4).

B. Additionally, your firm failed to file a Field Alert Report (FAR) for Complaint# 1329875 opened on 08/07/2024 as an Adverse Event (AE). Customer stated they noticed a "black" substance inside the (b) (4) and on the inside of the cap. The product was (b) (4)

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Lot# (b) (4), Expiration (b) (4). The firm reviewed, evaluated and tested the black substance internally and isolated *Pseudomonas aeruginosa.* However, your firm failed to characterize the black foreign matter that was in the cap and (b) (4) of the container.

The following complaints were observed in relation to the complaints related to black foreign substances, include but are not limited to:

Core#	Complaint#	Description Provided by Customer	Firm's Primary Reason
(b) (4)	1377182	"small black ball of matter dispense from the bottle"	Foreign Matter
	1329875	"black" substance inside the (b) (4)	Foreign Matter
	1284170	"black residue inside the (b) (4)	Foreign Matter
	1385008	"black buildup in the cap"	Other
	1248441, 1249159	"something black in the ointment"	Appearance (Product), Consistency/Viscosity
	1285748	"black blob (looked like a smashed bug)"	Counterfeit Product
	1361398	"black oily substance on the tubes and the tubes appear to have a 'fuzzy" substance on the tubes"	Counterfeit Product
	1263282	"black residue inside the cap and on the ridges of the tube"	Foreign Matter
	1411313	"black gummy residue around the nozzle of the bottle"	Foreign Matter
	1426384, 1436734	"blackish spots that appear to be mildew or something similar"	Foreign Matter, Foreign Matter
	1431442	"black or brown in the tip of the cap"	Foreign Matter

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OBSERVATION 2

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

Specifically,

A. Your operators are not following appropriate aseptic practices during active manufacturing activities. The following is not an exhaustive listing of the inadequate aseptic practices observed during the commercial manufacturing of (b) (4) Solution (b) (4) (Lot# (b) (4)) on Filling Line (b) (4):

i. Brisk movements and walking swiftly throughout the Grade B room near the (b) (4) Filling Line (Grade A).

ii. Donning a (b) (4) pair of sterile gloves and moving away from the glove donning station. We also observed some instances where they put on one glove and held the second one as they walked away from the station and utilizing the sterile (b) (4) pair to throw away trash.

iii. While changing the environmental monitoring plates within the Grade A area of Filling Line# (b) (4), the operator was seen moving quickly and reaching over areas where open and exposed empty bottles were located.

iv. During an intervention of removing a stuck empty bottle, we observed the operator manipulate the forceps at the end that comes in contact with the open container. Additionally, the operator abruptly manipulated a jammed bottle in a matter that the bottle was flicked into the (b) (4) (b) (4) sterile bowl.

v. Operator inadequately entered the (b) (4) to perform interventions. Horizontal (b) (4) donning was performed rather than a slow vertical donning to prevent reaching over open and exposed bottles to prevent airflow disruption.

vi. Operators were observed placing (b) (4) containing the components ((b) (4) plastic bottles, (b) (4) caps, and (b) (4) tips), directly touching the inside of the hopper and at times (b) (4) were thrown inside the hopper and (b) (4) pulled out of the hopper with tweezers. This is contrary to your procedure WI80-004A revision 5, effective, titled "Approved Methodology for Performing Aseptic Interventions on Filling Lines" which states in section 7.1 " 7.1.5. Aseptically pour the

components into the hopper paying close attention not to let the component (b) (4) touch the inside of the hopper. Do not shake the (b) (4) over the open hopper to remove all of the components."

B. Your firm failed to adequately investigate bacterial and mold contamination in your Grade A and B aseptic areas and Personnel Garment monitoring. Review of your Laboratory Information Management System ((b) (4)) report of organisms recovered from 2023 through present, revealed 223 Nonconformances (NCs) were initiated due to microbial contamination of garment personnel and 24 NCs were initiated due to mold contamination. In the Aseptic Grade A and B areas there were a total of 255 NCs (Grade A = 163 and Grade B = 92) initiated for microbial contamination and 24 NCs initiated due to mold contamination.

Recoveries revealed the following mold and gram-negative and positive bacterial species that include but are not limited to: *Pseudomonas spp., Burkholderia spp., Staphylococcus spp., Aspergillus spp., Penicillium spp., Fusarium spp., Cladosporium spp., Trichophyton spp.*, and *Curvularia spp.*

In addition, *Burkholderia Group* was found on personnel monitoring garment points on three separate occasions in 2024.Furthermore, your firm has also isolated *Burkholderia spp.* in the Aseptic Compounding Rooms ((b) (4)) on the floor near (b) (4) (sample site (b) (4)) and during your Cleaning Validation C630-H-00; PARTS WASHER in the rinse solution at the (b) (4) .

C. Your firm failed to identify gram negative environmental isolates from (b) (4) and (b) (4) systems even when action and alert limits are exceeded. The exceeded alert and action limit isolates are only characterized as "Absence Indicator Organisms." Between 2024 and 2026 there were 21 GNR (Gram Negative) isolates either exceeding alert or action limits that were not identified and only characterized as "Absence Indicator Organisms."

D. Your firm failed to review the integrity of environmental monitoring (EM) agar plates before and after performing plate reading. For example, according to your Microbiology Manager, after EM plates are read and recorded in the (b) (4) system, they are stored at room temperature in (b) (4) until management performs a (b) (4) check (b) (4) and discards them. We observed several plates that had split agars and some that had both split agars and cracked petri dishes.

Additionally, during the review of results entered into the (b) (4) system, we noted that recorded results are not contemporaneously reviewed by a second person to ensure data is correctly entered in the system. Plates with colony counts are transferred to the identification room, no pictures are taken as evidence of growth to ensure that no additional colonies are found before the plates are sub-cultured for identification.

E. Your firm failed to document all lots of (b) (4) media used in the preparation of In-House (b) (4) (b) (4) For example, during the review of worksheet SOP72-173 Form A-16 (02363), media prep technician stated that he combined two different lots of (b) (4) Medium (b) (4). He only recorded and documented Lot Number (b) (4), but he also used (b) (4) Lot Number (b) (4). Furthermore, no actual weights used from each lot was recorded or documented. Media is used in sterility testing for the isolation and cultivation of aerobic and anaerobic organisms.

F. Your firm failed to identify a water leak from the (b) (4) collection port (b) (4) (outlet side of (b) (4) pump (b) (4)). In 2024, your firm recovered gram negative *Burkholderia cepacia* twice in your (b) (4) monitoring in port (b) (4) located in the non-sterile compounding area ((b) (4)) next to the (b) (4) testing sink. No daily walkthrough log is in existence for water system monitoring to ensure the system is in a good state of repair. Water system operator stated that they perform walkthroughs at least (b) (4). However, they do not document it.

G. Your firm does not perform dynamic viable (active air) and nonviable (particle) environmental monitoring during sterility testing. During the sterility testing of (b) (4) Solution, (b) (4), Lots (b) (4); no environmental monitoring was performed during the duration of the sterility testing. Your Microbiology Supervisor stated that they do not perform active monitoring during testing. She stated that only active air and nonviable monitoring is performed (b) (4) of testing but not during or after test is performed.

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OBSERVATION 3

Written procedures are not followed for the receipt, storage and handling of.

Specifically,

A. Your firm failed to document and complete the Purchasing Notification of Missing Documents Form (SOP21-076 Form B) in your locked Quarantined cage for the following incoming shipments:

i. (b) (4) (Material# (b) (4) , Lot# (b) (4)) received on 16-FEB-2026

ii. (b) (4) (Material# (b) (4)) received on 11-MAR-2026

iii. (b) (4) materials (Lot# (b) (4)) received on 11-MAR-2026

These items have not been issued the SOP21-076 Form B.

This issue was not resolved within the required time or escalated to the Warehouse and Quality Management Team as required by SOP21-076, Receiving Process, Rev. 32, Effective Date: 24-NOV-2025 section 5.5.1. which states, "If the shipment is missing the proper documentation or is incorrect or incomplete, immediately email the Sourcing and Procurement, Materials Management and Incoming Quality departments a complete copy of SOP21-076 Form B (Purchasing Notification of Missing Documents). If the issue is not resolved within (b) (4) escalate the issue to the Warehouse and Quality Management team." Your Quality Assurance Manager stated that Form B has not been filled out for all materials missing documents upon receipt and the procedure has not been followed.

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B. Your firm failed to place materials in the specified locations in your (b) (4) Storage ((b)(4)°C-(b)(4)°C) area as assigned in your inventory management system ((b) (4)) for the following products:

i. Material# (b) (4) 1 ((b) (4)), Lot# (b) (4) , with Location# (b) (4) , was found in Location# (b) (4) .

ii. Material# (b) (4) ((b) (4)), Lot# (b) (4) with Location# (b) (4) , was found in Location# (b) (4) .

There is no assurance that materials received have been placed in the correct location as assigned in your inventory system to prevent product mix-ups

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."