

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER United States Food and Drug Administration (U.S. FDA) 10 Waterview Blvd, 3rd Floor Parsippany, NJ, 07054 (973) 331-4900	DATE(S) OF INSPECTION
	08/04/2026-08/18/2026
	FEI NUMBER
	3013024146
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Mr. Sanjay S. Samudre, Sr. Vice President & General Manager of Manufacturing Operations	
TO:	STREET ADDRESS
Imprimis NJOF, LLC	1705 Route 46 Ste 6B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ledgewood, NJ, 07852-9720	Outsourcing Facility

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

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

Release and stability specifications for (b) (4), potency, particle size distribution, uniformity of dose, and impurities for multiple sterile ophthalmic drug products are inadequate in the following respects:

A. (b) (4)

1. (b) (4) – Lack scientific basis for Finished Product Release Specifications

Your firm was unable to provide scientific data or justification demonstrating that a (b) (4) release specification is appropriate for the sterile ophthalmic drug products listed below. The applicable compendial standards for the individual active ingredients contained in these products establish (b) (4) ranges that reflect the established chemical stability and ocular safety profiles of those ingredients. Your firm's specification extends beyond those established ranges on both the lower and/or upper ends, permitting release of drug product at (b) (4) values that would not conform to applicable compendial standards. For example, for the following sterile drug products:

- DL003- Moxifloxacin Preservative-Free Solution Single-Use Intraocular Injection (4 mg/0.8 mL (5 mg/mL)), (b) (4) Specification (b) (4) (USP/NF Specification (b) (4))
- DL006- Dexamethasone Sodium Phosphate /Moxifloxacin Preservative-Free Solution Single-

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	SIMONE E. PITTS -S Digitally signed by SIMONE E. PITTS -S Date: 2026.08.18 07:20:24 -0400	Simone E. Pitts, Investigator	
	LUCILA B. NWATU -S Digitally signed by LUCILA B. NWATU -S Date: 2026.08.18 07:22:20 -0400	Lucila B. Nwatu, Investigator	

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Use Intraocular Injection (1 mg/mL and 5 mg/mL), ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specifications ^{(b) (4)})

- DL011- Moxifloxacin Preservative-Free Solution Single-Use Intraocular Injection (0.8 mg/0.8 mL) ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specification ^{(b) (4)})
- DL017- Vigamox® (Moxifloxacin) Preservative Free Solution Single-Use Intraocular Injection (4mg/0.8 mL), ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specification ^{(b) (4)})
- LD063- Tropicamide / Phenylephrine HCl (M2) Sterile Ophthalmic Solution (1%, 2.5%) 10ml, ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specifications ^{(b) (4)})
- LD064- Tropicamide / Phenylephrine HCl (M2) Sterile Ophthalmic Solution Single Use (1%, 2.5%) 5 ml, ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specifications ^{(b) (4)})
- LD065, LD066, LD067- Atropine Sulfate Preservative-Free Sterile Ophthalmic Solution (0.01%) (0.025%) (0.05%), ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specification ^{(b) (4)})
- LD075- Dorzolamide Preservative-Free Sterile Ophthalmic Solution (2%), ^{(b) (4)} Specification ^{(b) (4)} (USP/NF Specification ^{(b) (4)})

2. ^{(b) (4)} Stability specifications contain no acceptance criteria

Section 6.2.3.9 of SOP VV-QUAL-00475, Stability Program, Version 6.0, Effective Date 03/13/2026 states that "Stability Studies protocols shall contain the following, at a minimum: acceptance criteria (with or without OOT/OOE limits)."

Your firm was unable to provide scientific justification for the absence of ^{(b) (4)} acceptance criteria in the stability program for all commercially available sterile drug products produced by your facility. Your firm's stability program designates ^{(b) (4)} as a "^{(b) (4)}" or "^{(b) (4)} ^{(b) (4)}" parameter at all stability timepoints for all commercially available sterile drug products produced by your facility. No acceptance criterion, upper limit, lower limit, or range, is defined for ^{(b) (4)} at any stability timepoint. Because no acceptance criterion exists, no ^{(b) (4)} result obtained during stability testing can constitute a stability failure regardless of the value measured.

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As a result, your firm's stability program does not provide assurance that (b) (4) remains within an established specification range throughout the assigned BUD for any of the (b) (4) commercial drug products and cannot demonstrate that these drug products maintain their quality attributes with respect to chemical stability and product safety for the duration of their labeled storage period.

B. Potency

Your firm's potency acceptance criteria for Proparacaine Hydrochloride in LD085, Povidone Iodine/Proparacaine HCl Multi-Use Ophthalmic Solution (1.25%, 0.5%) is (b) (4). The applicable compendial standard for Proparacaine Hydrochloride Ophthalmic Solution establishes a narrower potency range. Your firm's specification permits release of drug product at active ingredient concentrations that would not conform to the applicable compendial standard without triggering an out-of-specification investigation or batch rejection. Your firm was unable to provide scientific justification for the lower and upper potency limits established for Proparacaine Hydrochloride, a topical ocular anesthetic for which sub-therapeutic concentrations may result in inadequate anesthesia during ophthalmic procedures.

Review of the annual stability study for LD085 - Povidone Iodine/Proparacaine HCl Multi-Use Ophthalmic Solution (1.25%, 0.5%) revealed Proparacaine Hydrochloride potency values of 85.2-91.1% through (b) (4) of stability testing. These results fall below the applicable compendial lower limit for Proparacaine Hydrochloride Ophthalmic Solution and indicate that the drug product does not conform to the compendial standard throughout its assigned beyond-use date. Because your firm's stability acceptance criterion of (b) (4) is wider than the applicable compendial range, these failing results were not identified as out-of-specification, no OOS investigation was initiated, and the product continued to be distributed without evaluation of the impact of sub-compendial potency on patient safety and therapeutic adequacy.

There are currently (b) (4) batches of distributed Povidone Iodine/Proparacaine HCl Multi-Use Ophthalmic Solution (1.25%, 0.5%) within expiry on the market, Lots 26FEB015 Expiration Date (b) (4), and 26JAN035, Expiration Date (b) (4).

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C. Particle Size Distribution — No Release or Stability Specifications Established

Your firm does not have written stability acceptance criteria (e.g., (b) (4) for particle size distribution (PSD) for the following sterile ophthalmic suspension and injectable suspension drug products at any stability timepoint:

- DL016- TriMoxi+ (Triamcinolone Acetonide / Moxifloxacin Preservative Free Suspension Single-Use Intraocular Injection (9 mg/0.6 mL, 0.6 mg/0.6 mL)
- LD050/ LD051 - Prednisolone Acetate / Moxifloxacin / Nepafenac Sterile Ophthalmic Suspension (1%, 0.5%, 0.1%)
- LD052 - Prednisolone Acetate / Moxifloxacin Sterile Ophthalmic Suspension (1%, 0.5%,)
- LD055 - Prednisolone Acetate Preservative Free Sterile Ophthalmic Suspension (1%)
- LD056 - Prednisolone Acetate / Bromfenac Ophthalmic Suspension (1%, 0.075%)
- LD060/LD061 - Prednisolone Acetate / Moxifloxacin / Bromfenac Sterile Ophthalmic Suspension (1%, 0.5%, 0.075%), 5 ml and 8 ml
- LD082 - Prednisolone Acetate / Nepafenac Sterile Ophthalmic Suspension (1%, 0.1%)

D. Uniformity of dosage Unit

Your firm has not established acceptance criteria and does not perform Uniformity of Dosage Unit testing as part of release testing or stability studies for TriMoxi+ (Triamcinolone Acetonide / Moxifloxacin Preservative Free Suspension Intraocular Injection (9 mg/0.6 mL, 0.6 mg/0.6 mL). Your firm was unable to provide scientific justification for the omission of content uniformity testing for this suspension product.

E. Impurities

There is a failure to establish an impurity profile for sterile injectable and topical ophthalmic drug products manufactured since the last inspection conducted in April 2024. Your firm currently

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does not test the majority of your drug products for impurities or degradants at release or during stability and has continued to release and distribute drug products without this data. Your firm has failed to identify, characterize, qualify, and establish acceptance criteria for process related impurities, degradation products, and/or elemental impurities potentially present in 33 of (b) (4) finished drug products manufactured and released for distribution. To date, your firm has not completed and implemented method validation for impurities and degradants for thirty-three (33) drug products manufactured and distributed from your facility. Drug products that have been released and distributed without impurity or degradant testing include:

Product Code	Product Name	Strength	Beyond Use Date (BUD)	# of Lots Released /Total Units
DL003	Moxifloxacin Preservative-Free Solution Single-Use Intraocular Injection	4 mg/0.8 mL (5 mg/mL)	360 Days	(b) (4)
DL005	Dexamethasone Sodium Phosphate /Moxifloxacin / Ketorolac Tromethamine Preservative-Free Solution Single-Use Intraocular Injection	1 mg/mL, 0.5 mg/mL, 0.4 mg/mL	360 Days	
DL006	Dexamethasone Sodium Phosphate / Moxifloxacin Preservative-Free Solution Single-Use Intraocular Injection	1 mg/mL, 5 mg/mL	360 Days	
DL009	Phenylephrine HCl / Lidocaine HCl Preservative-Free Solution Single-Use Intraocular Injection	15 mg/mL, 10 mg/mL	360 Days	
DL011	Moxifloxacin Preservative-Free Solution Single-Use Intraocular Injection	0.8 mg/0.8mL	360 Days	
DL016	TriMoxi+ Triamcinolone Acetonide / Moxifloxacin Preservative-Free Suspension Single-Use Intraocular Injection	9 mg/0.6 mL, 0.6 mg/0.6mL	360 Days	
DL017	Vigamox® (Moxifloxacin) Preservative-Free Solution Single-Use Intraocular Injection	4 mg/0.8 mL	270 Days	
LD050	Prednisolone Acetate / Moxifloxacin /Nepafenac Sterile Ophthalmic Suspension	1 %, 0.5 %, 0.1 % 5 ml fill volume	270 Days	
LD051	Prednisolone Acetate / Moxifloxacin /Nepafenac Sterile Ophthalmic Suspension	1 %, 0.5 %, 0.1 % 8 ml fill volume	270 Days	

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LD052	Prednisolone Acetate / Moxifloxacin Sterile Ophthalmic Suspension	1 %, 0.5 %	270 Days
LD055	Prednisolone Acetate Preservative-Free Sterile Ophthalmic Suspension	1%	360 Days
LD056	Prednisolone Acetate / Bromfenac Sterile Ophthalmic Suspension	1 %, 0.075 %	360 Days
LD060	Prednisolone Acetate / Moxifloxacin /Bromfenac Ophthalmic Suspension	1 %, 0.5 %,0.075 %	300 Days
LD061	Prednisolone Acetate / Moxifloxacin /Bromfenac Ophthalmic Suspension (8 ml)	1 %, 0.5 %,0.075 %	300 Days
LD062	Tobramycin / Vancomycin Ophthalmic Solution	1.5 %, 5 %	180 Days
LD063	Tropicamide / Phenylephrine HCl (M2) Ophthalmic Solution Multi-use (10 ml)	1 %, 2.5 %	360 Days
LD064	Tropicamide / Phenylephrine HCl (M2) Ophthalmic Solution Single-Use	1 %, 2.5 %	360 Days
LD065	Atropine Sulfate Preservative Free Ophthalmic Solution	0.01 %	360 Days
LD066	Atropine Sulfate Preservative Free Ophthalmic Solution	0.025 %	360 Days
LD067	Atropine Sulfate Preservative Free Ophthalmic Solution	0.05 %	360 Days
LD071	Tobramycin / Vancomycin Ophthalmic Solution	1 %, 2.5 %	180 Days
LD072	Vancomycin Ophthalmic Solution	2.5 %	180 Days
LD074	Bimatoprost Preservative Free Ophthalmic Solution	0.01 %	180 Days
LD075	Dorzolamide Preservative-Free Ophthalmic Solution	2 %	180 Days
LD076	Timolol / Bimatoprost Preservative Free Ophthalmic Solution	0.5 %, 0.01 %	360 Days
LD077	Brimonidine Tartrate / Dorzolamide Preservative Free Sterile Ophthalmic Solution	0.15 %, 2 %	180 Days

(b) (4)

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LD078	Timolol / Brimonidine Tartrate / Dorzolamide Preservative Free Sterile Ophthalmic Solution	0.5 %, 0.15%, 2 %	270 Days
LD079	Timolol / Dorzolamide / Bimatoprost Preservative Free Ophthalmic Solution	0.5 %, 2 %, 0.01 %	270 Days
LD080	Timolol / Brimonidine Tartrate / Dorzolamide /Bimatoprost Preservative Freen Sterile Ophthalmic Solution	0.5 %, 0.15%, 2 %, 0.01	360 Days
LD082	Prednisolone Acetate / Nepafenac Sterile Ophthalmic Solution	1%, 0.1%	180 Days
LD085	Povidone Iodine / Proparacaine Sterile Ophthalmic Solution	1.25 %, 0.5 %	210 Days
LD087	Klarity A® (Azithromycin) Preservative Free Sterile Ophthalmic Solution	1 %	250 Days
LD088	Klarity L® (Loteprednol Etabonate) Preservative Free Sterile Ophthalmic Suspension	0.50%	180 Days
TR001	Midazolam / Ketamine / Ondansetron Troche	3 mg, 25 mg, 2 mg	360 Days

(b) (4)

The absence of validated impurity and degradant test methods, and the continued release and distribution of drug products without impurity or degradant data, does not provide assurance that these drug products conform to appropriate standards of purity prior to distribution.

*****This is a repeat observation from the April 2024 inspection*****

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process. Specifically,

Part 1- (b) (4) Qualification

- A. (b) (4), used to (b) (4) glass containers, bowls, and small metal tools for sterile compounding operations, has not been qualified for the (b) (4) shelf load configuration used during routine production.

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Your firm's Performance Qualification (PQ), QSR-VAL-2000-1766, was conducted using a (b) (4) shelf load configuration. Your firm's temperature mapping study identified the (b) (4) (b) (4) corner of the (b) (4) shelf on the (b) (4) door as the coldest location, the worst-case position least likely to achieve the required (b) (4) time and temperature, under the (b) (4) shelf configuration. The PQ did not include this shelf position and therefore did not challenge the (b) (4) at the confirmed worst-case location under production-representative conditions. There is no data demonstrating (b) (4) achieves the required (b) (4) time and temperature at the coldest location when operated with a (b) (4) shelf load.

Glass containers (b) (4) in (b) (4) under the (b) (4) shelf configuration have been used in the manufacture and distribution of compounded sterile drug products, including LD050 - Prednisolone Acetate / Moxifloxacin / Nepafenac Sterile Ophthalmic Suspension (1% 0.5% 0.1%), (5ml Fill Volume), Lots 26MAR033, 26JUN076.

- B. Your firm's (b) (4) (Model (b) (4)) is routinely operated with load quantities that exceed the maximum load established during qualification. The 2025 Performance Qualification PQ QVP-VAL-1000-1939 qualified a maximum load of (b) (4) glass bottles; however, a review of the (b) (4) cycle logbook identified the following production cycles exceeding the qualified maximum:

Cycle Date/ Reference #	Load Quantity
03/24/2026 03242601	(b) (4) glass bottles
04/01/2026 04012601	glass bottles
04/15/2026 04152602	glass bottles
06/01/2026 06012603	glass bottles
06/11/2026 06112602	glass bottles
06/23/2026 06232603	glass bottles

Operating (b) (4) beyond the qualified load increases the (b) (4) mass within the (b) (4) reduces airflow, and may prevent the coldest location from achieving the minimum validated

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(b) (4) conditions of (b) (4) for (b) (4) required to demonstrate a (b) (4)-log reduction in endotoxin. There is no data demonstrating that the (b) (4) cycle achieves the required endotoxin reduction under these overloaded conditions.

Glass containers (b) (4) in (b) (4) under unqualified load conditions have been used in the manufacture and distribution of compounded sterile drug products, including for example:

- LD050 - Prednisolone Acetate / Moxifloxacin /Nepafenac Sterile Ophthalmic Suspension (1% 0.5% 0.1%), (5ml Fill Volume), Lots 26MAR033, 26JUN076
- LD051- Prednisolone Acetate / Moxifloxacin /Nepafenac Sterile Ophthalmic Suspension (1% 0.5% 0.1%) (8ml Fill Volume), Lots 26MAR034, 26APR035, 26APR057, 26JUN077
- LD056- Prednisolone Acetate / Bromfenac Sterile Ophthalmic Suspension (1% 0.075%) 5 ml, Lot 26APR042
- LD061- Prednisolone Acetate / Moxifloxacin /Bromfenac Sterile Ophthalmic Suspension (1% 0.5% 0.075%) 8 ml Fill Volume, Lots 26APR031, 26MAY056

Part 2- Media Fill and (b) (4) Assessment

A. Your firm's aseptic process simulation (media fill) for the (b) (4) filling line does not simulate the most challenging and stressful conditions of actual drug production. When filling operations on the (b) (4) extend (b) (4) your firm's production procedure requires that the (b) (4) the bulk drug solution glass bottle and the liquid (b) (4) for (b) (4) prior to resuming filling on the (b) (4) This (b) (4) step, performed after (b) (4) hold of product in the filling line, is a routine component of your firm's actual production process for batches that extend beyond (b) (4). Your firm's media fill protocol, as documented in Media Fill on (b) (4) (b) (4) lot # 26MAR037, dated 3/13/2026, did not include the (b) (4) (b) (4) step. As a result, the media fill does not simulate the conditions under which drug products are routinely

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aseptically filled and does not demonstrate that the (b) (4) step following an (b) (4) hold does not introduce microbiological contamination into the drug product or filling system prior to resuming aseptic filling operations.

- B. Your firm has not evaluated the risk of microbial contamination associated with product remaining in the (b) (4) of the (b) (4) filling line during production pauses or (b) (4) holds and has not established controls to address that risk prior to resuming filling operations. Your firm has not validated that its procedure for managing product (b) (4) in the (b) (4) of the (b) (4) during (b) (4) holds, specifically the (b) (4) step performed prior to resuming filling, is effective in preventing microbiological contamination of subsequently filled drug product. During the Media Fill on 03/13/2026, the filling operation carried over to (b) (4), during which the filling operations were paused for approximately (b) (4). The filling continued without (b) (4) or (b) (4) the product remaining in the (b) (4) of the (b) (4) nor did it reflect the (b) (4) step. Your firm was unable to provide a risk assessment, validation data, or scientific justification demonstrating that product (b) (4) in the (b) (4) of the (b) (4) during a filling pause does not pose a risk of microbial contamination to subsequently filled units.

Your firm's failure to evaluate and control the risk of microbial contamination in the (b) (4) of the (b) (4) filling line during production pauses and (b) (4) holds represents an inadequately controlled step in your aseptic manufacturing process for drug products intended to be sterile.

The (b) (4) filling machine is used in the manufacture of TriMoxi+ (Triamcinolone Acetonide / Moxifloxacin Preservative Free Injectable Suspension (9 mg/0.6 mL, 0.6 mg/0.6 mL).

Part 3: Airflow Visualization and Aseptic Processes

- A. Airflow visualization (smoke) studies, conducted in the (b) (4) ISO 5/Class 100 cleanroom dated 30 SEP 2025, did not demonstrate adequate evaluation of airflow behavior

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FOOD AND DRUG ADMINISTRATION

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10 Waterview Blvd, 3rd Floor Parsippany, NJ, 07054 (973) 331-4900		FEI NUMBER 3013024146
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Mr. Sanjay S. Samudre, Sr. Vice President & General Manager of Manufacturing Operations		
TO:	STREET ADDRESS	
Imprimis NJOF, LLC	1705 Route 46 Ste 6B	
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at all critical locations. The airflow study recording of the Plunger, Rails, and Bowls Set-up failed to include the complete range of camera angles necessary to evaluate whether the smoke pattern generated indicates turbulence, eddies, or non-unidirectional airflow at the HEPA filter faces.

B. During filling operations for Moxifloxacin Preservative-Free Solution Single-Use Intraocular Injection, Lot #26JUN091 on the (b) (4) vial filling line (surrounded by an ISO 5 (b) (4), located in an ISO 7 filling room) on 08/10/2026, we observed the following deficiencies:

1. The sterile and support technician did not adhere to the principle of slow and deliberate movements required inside the cleanroom as per the firm's procedure # VV-QUAL-00019 "Aseptic Behavior Inside the Cleanrooms" Step 6.14 which states that "the principle of slow, careful movement should be followed at all times inside the cleanroom". We observed the technicians make rapid movements in the cleanroom and while performing interventions such as loading 2 mL vials into the infeed tray under the ISO 5 (b) (4)
2. We observed the following instances in which the sterile technician did not wipe down the ISO 5 (b) (4), (b) (4) after opening them to perform interventions, exposing the interior of the (b) (4), (b) (4) to the ISO 7 filling room environment, as required by the firm's procedure # VV-QUAL-00019 "Aseptic Behavior Inside the Cleanrooms", Step 6.27 which states "When the intervention is complete, wipe the (b) (4), (b) (4) /door before closing with (b) (4) wipes". Specifically:
 - a. At approximately 3:55 P.M., the sterile technician opened the (b) (4) on the (b) (4) close to the stopper bowl and introduced a bag of stoppers into the ISO 5 environment. After placing the bag inside, the operator did not wipe the interior surface of the (b) (4), (b) (4) prior to closing.
 - b. At approximately 3:58 P.M., the sterile technician opened (b) (4), (b) (4) simultaneously on the (b) (4) close to the stopper bowl and inserted both (b) (4) into the ISO 5 enclosure. Using sterile scissors, the technician opened the bag of stoppers and

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filled the stopper bowl. Upon completing the intervention and exiting the (b) (4), the technician did not wipe the interior surfaces of the (b) (4) (b) (4) prior to closing.

*****This is a repeat observation from the April 2024 inspection*****

3. The interior surface of the vial exit tray door of the ISO 5 (b) (4) on the (b) (4) filling machine was observed to have scratches, rendering the surface non-smooth and not easily cleanable. The scratches appear to be located at the point of repeated contact between the protruding exit tray and the (b) (4) door.
- C. During the personnel media fill qualification (Lot # 26JUL009) on the (b) (4) bottle Filling machine (surrounded by an ISO 5 (b) (4), located in an ISO 7 filling room) on 08/04/2026, on two separate occasions during the media fill operations, we observed an operator manually loading a bag of sterile caps into the (b) (4) bowl located within the ISO 5 (b) (4) during which the bag was held directly above the caps already present in the (b) (4) bowl, blocking first air to those components. This practice is not in accordance with Step 6.25 of the firm's procedure VV-QUAL-00019 "Aseptic Behavior Inside the Cleanrooms" which states "Proper aseptic manipulation should be approached from the side and not above the product or sterile components".

Part 4: Deficient Environmental Monitoring Program

The firm's environmental monitoring (EM) program for the (b) (4) bottle filling line and (b) (4) (b) (4) vial filling line is inadequate. Specifically,

- A. The frequency of Active Air Sampling on the (b) (4) bottle filling line is insufficient. For example, the fill for Timolol/Brimonidine Tartrate/Dorzolamide Preservative Free Ophthalmic Solution, Lot# 25MAY045 began on (b) (4) at (b) (4) and ended on (b) (4) at (b) (4) (Total Filling Duration: (b) (4) and (b) (4) The following active air samples were collected during the filling:

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Sampling Location	First Collection Time	Second Collection Time
Active	(b) (4)	
Active-(b) (4) Entry		

The frequency of viable air samples collected (b) (4) collected during the (b) (4) and (b) (4) filling operation, is not scientifically justified to provide adequate assurance of environmental control or to optimize detection of contamination events throughout the full duration of a filling operation.

B. The frequency of Active Air Sampling on the (b) (4) Vial Filling Line during filling operations is insufficient. For example, the fill for Phenylephrine HCl-Lidocaine HCl Preservative Free Solution Single-Use Intraocular Injection (15 mg/mL, 10 mg/mL), Lot # 26JUN114, began on (b) (4) at (b) (4) and ended on (b) (4) at (b) (4) (Total Filling Duration: (b) (4) and (b) (4)). An active air sample was collected ((b) (4) (b) (4)) on (b) (4) at (b) (4) and a second active air sample was collected on (b) (4) at (b) (4). This frequency is not scientifically justified to provide adequate assurance of environmental control or to optimize detection of contamination events throughout the full duration of a filling operation.

C. Insufficient Surface Sampling (b) (4) and (b) (4) Filling Lines): Per Step 6.8.1.1 of procedure VV-QUAL-00252 "Environmental Monitoring Program-New Jersey Facility," surface samples are collected (b) (4) from the (b) (4) and (b) (4) direct compounding areas (area (b) (4) to the filling needle operations) within the (b) (4) and (b) (4) filling lines (b) (4) of each product fill. However, the following surfaces are not sampled (b) (4) of filling despite being locations with which sterile technicians routinely interact with during filling operations:

- (b) (4) Bottle Filling Machine (ISO 5): Bottle tip bowl and cap bowl
- (b) (4) Vial Filling Machine: Vial crimp bowl and stopper bowl

Although the firm completed Environmental Monitoring Performance Qualification (EMPQ) for the (b) (4) and (b) (4) filling lines and support rooms, which included recommendations to increase active

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air sampling frequency and expand sampling locations, the firm failed to conduct a risk assessment to evaluate the impact of the current, inadequate sampling plan on drug products filled on the respective lines.

OBSERVATION 3

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 conduct an adequate investigation to determine the root cause of cellulose, non-cellulose, and other fiber-like material that have been observed in the sterile injectable finished drug products containing API Moxifloxacin Hydrochloride bulk powder from 2023 until present day. The firm's root cause report VV-QUAL-02496 "Report for the presence of natural cellulose fibers in DM, DMK and Moxi 5" (Approved: 05/06/2025) was initiated to address a trend of an increase in the level of fibers detected in several injection products. The firm attributed the most probable root cause of the presence of natural cellulose fibers to the API Moxifloxacin, specifically the use of the bulk drug substance; however, the exact mechanism of fiber generation from use of Moxifloxacin bulk drug substance has not been identified. The firm has not initiated an investigation with the current Moxifloxacin supplier to assess any changes to the manufacturing process that could potentially contribute to the fibers. The firm has initiated change controls to use a commercially available ophthalmic solution containing Moxifloxacin from a new supplier; however, your firm continues to manufacture ophthalmic drug products using the Moxifloxacin API bulk powder from the existing supplier.

The firm continues to identify fibers in sterile ophthalmic drug products; for example, the deviation investigations listed below were initiated and the root cause of the fibers have not been identified:

1. **QE-000873 (Occurred: 11/11/2025):** Initiated for Moxifloxacin Preservative-Free Intraocular Solution Single Use Intraocular Injection Lot# 25OCT045 (Batch Disposition: Rejected) failed for exceeding the critical defect limit (b) (4) (Limit of (b) (4) in which critical

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defects identified included (b) (4) vials with fibers.

2. **QE-000908 (Occurred: 12/09/2025):** Initiated for Moxifloxacin Preservative-free Intraocular Solution Single Use Intraocular for Injection Lot # 25NOV001 (Batch Disposition: Rejected) failed for exceeding the critical defect limit (b) (4) (Limit of (b) (4) in which critical defects identified included (b) (4) vials with fibers.
3. **QE-000912 (Occurred: 12/11/2025):** Initiated for Dexamethasone Sodium Phosphate/Moxifloxacin Preservative Solution Single-Use Intraocular Injection Lot # 25NOV012 (Batch Disposition: Rejected) failed for exceeding the critical defect limit (b) (4) (Limit of (b) (4) in which critical defects identified included (b) (4) vials with fibers.
4. **QE-000932 (Occurred: 12/30/2025):** Initiated for Dexamethasone Sodium Phosphate/Moxifloxacin/Ketorolac Tromethamine Preservative Free Solution Single Use Intraocular Injection Lot# 25DEC002 (Batch Disposition: Rejected) failed for exceeding the critical defect limit (b) (4) (Limit of (b) (4) in which critical defects identified included (b) (4) vials with fibers.

B. Deviation investigation (QE-000458) into sterility failure of Dexamethasone Sodium Phosphate/Moxifloxacin/Ketorolac Tromethamine (1 mg/mL, 0.5 mg/mL, 0.4 mg/mL) (DMK), Stability Batch #23NOV035 (Compounded: (b) (4)), Time Point: Day (b) (4) (Date Occurred: 12/24/2024) is deficient. The third-party laboratory reported that all (b) (4) media enrichments from USP (b) (4) sterility test had mold in it during an intermediary read of DMK batch 23NOV035. The third-party investigation concluded that (b) (4) used to wash the (b) (4), was the source of contamination. However, the specific lot of (b) (4) used during the original test was no longer available for investigation at the time of the review, and (b) (4) and the negative control (b) (4), both of which were rinsed with the same batch of (b) (4) did not have mold growth. Upon the firm's request, the third-party conducted (b) (4) (b) (4) Microbiological test on (b) (4) retain vials of this product and no fungal contaminants were noted and invalidated the original sterility test result. The investigation did not identify an

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obvious, documented root cause assignable to laboratory error or equipment failure before proceeding to invalidate the original sterility test results and no documented scientific justification was provided for the use of (b) (4) results as a basis to invalidate the results of the compendial USP (b) (4) Sterility Test.

C. The Corrective and Preventative Actions (CAPA) implemented are not commensurate with the scope of the identified root causes for the following investigations:

1. (b) (4) separate (b) (4) test failure investigations (as listed below) were conducted for (b) (4) of the same lot number (Lot (b) (4)), each of which returned an "Error Leak Test Failure" message across multiple repeat test attempts. The (b) (4) in each investigation were submitted to the (b) (4) manufacturer for investigation. The manufacturer's investigation determined that the (b) (4) were non-integral and exhibited damage consistent with exposure to excessive forward differential pressure. The root cause for all three investigations was identified as method due to the firm's internal procedure VV-QUAL-00131 "(b) (4) (b) (4) Test Using (b) (4) Tester" allows for (b) (4) supply up to (b) (4) psi while the (b) (4) maximum rate forward differential pressure at ambient temperature is (b) (4) psi" and root cause for the deviation was due to over-pressurization during the post use (b) (4) (b) (4) test. The CAPA did not include an assessment to update the internal procedure to ensure that pressure applied during (b) (4) testing does not exceed the manufacturer's validated maximum forward differential pressure and/or incorporate a verification step to confirm that (b) (4) pressure applied to the (b) (4) hardware remains within the manufacturer's validated operating parameters.

Deviation (Product and Lot #)	Date Occurred	(b) (4) Lot # (Serial #)	Number of (b) (4) Tests and Error	Batch Disposition
QE-000814 (Moxifloxacin PF Solution Single-Use Intracocular Injection, Lot# 25AUG049)	09/18/2025	(b) (4)	Six tests failed for "Error Leak Test Failure"	Rejected

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QE-000849 (Prednisolone Acetate/Moxifloxacin/ Bromfenac Sterile Ophthalmic Suspension (1%, 0.5%, 0.075%), Lot # 25OCT009)	10/15/2025	(b) (4)	Three tests resulted in "Error Leak Test Failure"	Rejected
QE-000901 (Prednisolone Acetate/Moxifloxacin/Bromfenac Steri le Ophthalmic Suspension (1%, 0.5%, 0.075%), Lot #25NOV026)	12/4/2025	(b) (4)	Five test attempts with same error message "Error Leak Test Failure"	Rejected

2. Deviation Investigation QE-000985 was conducted on 02/13/2026 following a failed (b) (4) (b) (4) test of (b) (4) lot# (b) (4) (Serial # (b) (4)) used to (b) (4) sterilize Povidone Iodine/Proparacaine Sterile Ophthalmic Solution (1.25%, 0.5%), Lot 26JAN035. Five (b) (4) (b) (4) tests yielded a result of "Leak Test Failure". The (b) (4) was sent to the manufacturer for evaluation; the manufacturer's investigation determined the (b) (4) was integral as it met acceptance criteria when the (b) (4) was (b) (4) with a (b) (4) solution and concluded that the observed failures were attributable to inadequate (b) (4) (b) (4) due to (b) (4) rather than a loss of (b) (4). The manufacturer's investigation concluded that it is "likely the product being processed has caused the (b) (4) to become (b) (4) making it difficult to (b) (4) (b) (4) with (b) (4) and recommended validating product (b) (4) (b) (4) test parameters for the product. However, the firm's CAPA was limited to a vendor-conducted training session on (b) (4) use and handling requirements. No assessment was performed to determine whether the formulation of (b) (4) is altering the surface (b) (4) characteristics of the (b) (4) and assess alternate (b) (4) protocols or product- (b) (4) (b) (4) test parameters.

D. Your firm failed to conduct an adequate investigation to determine the root cause of the recovery of *Bacillus cabrialesii* from a passive settle plate located near the unscrambler of the (b) (4) filling machine in the ISO 5 environment. The action level specification is greater than or equal to (b) (4) CFU, thereby exceeding the specification limit. Deviation report QE-000684 described the recovery of (b) (4) CFU of *Bacillus cabrialesii*, a spore-forming organism from the passive plate

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during the filling of Bimatoprost 0.01% Preservative-Free Sterile Ophthalmic Solution, Lot #25MAY040 on July 25, 2025. The investigation failed to establish a definitive root cause of the recovered organism, assess the potential source and the significance of the organism to adequately justify the release of the batch.

OBSERVATION 4

Your firm failed to establish 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,

Part A: Visual Inspection Automatic Reinspection

Your firm's procedure VV-QUAL-00606, (b) (4) Visual Inspection, Version 24.0, Effective Date: 05/12/2026, specifies that when a batch fails 100% visual inspection by exceeding action levels for critical or major defects, a deviation is initiated, and a (b) (4) (b) (4) inspection of the remaining accepted units is conducted in tandem with the deviation investigation. Your firm's procedure permits a batch to proceed to (b) (4) inspection and, if passing, to tightened AQL inspection and potential release, before the deviation investigation establishing the root cause of the initial 100% inspection failure has been completed. Proceeding to additional inspection passes prior to completing a thorough investigation of the initial failure does not constitute a thorough review of the batch failure and represents testing into compliance. This practice does not provide assurance that the root cause of the initial inspection failure has been identified, evaluated, and corrected prior to batch release, and does not ensure that released units are free of the defects that caused the initial inspection failure.

Part B: Lack of (b) (4) Compatibility Testing

The firm does not have a procedure governing the process for (b) (4) compatibility studies and has not conducted (b) (4) compatibility studies for all finished drug products that are (b) (4) sterilized to evaluate the effect of the sterilizing (b) (4) on the final product. For example, during the Process Performance

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Qualification (PPQ) of Povidone Iodine/Proparacaine Sterile Ophthalmic Solution (1.25%, 0.5%) (VV-QUAL-02204), bulk solution samples were collected from (b) (4) of the mixing vessel (b) (4) to (b) (4) and (b) (4) (b) (4) and were tested for potency; however, no (b) (4) compatibility studies such as extractables/leachable studies or chemical compatibility studies were conducted.

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use. Specifically,

The firm failed to conduct an airflow visualization study (smoke study), either under static or dynamic conditions with the door in its open position, to demonstrate proper unidirectional airflow is maintained during the filling operations of sterile manufactured ophthalmic drug products in the (b) (4) (b) (4). The exit door on the (b) (4) remains open, the door does not fully close, remaining ajar at an approximate 45-degree angle during filling operations. This design deficiency allows for the receiving tray of vials (capped and sealed) to protrude out, preventing the exit door from fully closing during filling operations thereby, exposing the ISO 5 classified sterile core to potential ingress of ISO 7 classified airflow.

In addition, the firm has not conducted a risk assessment to evaluate the impact of personnel exiting the ISO 7 classified area and the potential of ingress/blow back of ISO 7 classified air into the (b) (4) (b) (4) ISO 5 Sterile (b) (4) during filling operations. The firm has not evaluated when personnel exit the ISO 7 filling room through the room door if there is a disruption in the room pressure differential that can cause a momentary ingress of unclassified air into the ISO 7 room. Because the (b) (4) exit door remains open during filling, this pressure disruption in the ISO 7 room may propagate into the ISO 5 (b) (4), further compromising the integrity of the critical filling environment. The firm has not evaluated this risk through a smoke study, risk assessment, or pressure differential monitoring under dynamic conditions that include personnel movement. The (b) (4) has been in use since October 2016 with this design and is used to fill multiple sterile drug products specifically the product line of Moxifloxacin and other products such as TriMoxi+ Triamcinolone Acetonide/Moxifloxacin Preservative

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	ARR SEP	Annet R. Rajan, Investigator Simone E. Pitts, Investigator Lucila B. Nwatu, Investigator	08/18/2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER United States Food and Drug Administration (U.S. FDA) 10 Waterview Blvd, 3rd Floor Parsippany, NJ, 07054 (973) 331-4900	DATE(S) OF INSPECTION 08/04/2026-08/18/2026
	FEI NUMBER 3013024146
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Mr. Sanjay S. Samudre, Sr. Vice President & General Manager of Manufacturing Operations	
TO: Imprimis NJOF, LLC	STREET ADDRESS 1705 Route 46 Ste 6B
CITY, STATE, ZIP CODE, COUNTRY Ledgewood, NJ, 07852-9720	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Free Suspension Single Use Intraocular Injection (9 mg/0.6 mL, 0.6 mg/0.6 mL, 15/1 mg/mL), and Dexamethasone Sodium Phosphate / Moxifloxacin / Ketorolac Tromethamine Preservative Free Solution Single-Use Intraocular Injection (1 mg/mL, 0.5 mg/mL, 0.4 mg/mL) that are filled into vials.

OBSERVATION 6

The quality control unit lacks the responsibility and authority to approve and reject all components, in process materials and drug products. Specifically,

Your firm's Quality Control Unit (QCU) has failed to exercise its responsibility to approve or reject drug products, procedures, and specifications, and to ensure that all established written procedures are followed, as evidenced by the following examples:

- A. The quality control unit approved and released drug products for distribution without impurity and degradant testing having been performed, despite the absence of validated test methods for the vast majority of products manufactured by the firm. With the exception of one product, [PMB Solution, relaunched July 2026], no validated impurity or degradant test method exists for any drug product manufactured and distributed by the firm. The QCU released and approved these batches for distribution without this data, and without documented justification for the omission of a required quality attribute from the release testing program.
- B. The quality unit had the responsibility to ensure the Performance Qualification of the (b) (4) was scientifically sound and that all acceptance criteria were evaluated at the appropriate locations before approving the study. Approving a PQ that structurally excluded the confirmed worst-case location identified by the firm's own temperature mapping represents a failure of the quality unit's review and approval function. The quality unit approved a qualification that, on its face, did not demonstrate what it purported to demonstrate.
- C. The quality unit is responsible for reviewing production records and ensuring that manufacturing operations are performed within qualified and approved parameters. The cycle logbook entries showing (b) (4) and (b) (4) bottles are facially inconsistent with the (b) (4) bottle qualified maximum —

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a discrepancy that should have been identified during routine QC review of cycle logs. The quality unit failed to exercise its responsibility and authority to reject drug product containers processed outside of qualified conditions before they were used in sterile compounding operations.

- D. The Quality Unit did not implement Corrective Action and Preventative Actions that were commensurate with the root causes identified in Deviation Investigations QE-000814, QE-000849, QE-000901 related to critical (b) (4) test failures.

***DATES OF INSPECTION**

08/04/2026 (Tue), 08/05/2026 (Wed), 08/06/2026 (Thu), 08/07/2026 (Fri), 08/10/2026 (Mon), 08/11/2026 (Tue), 08/12/2026 (Wed), 08/13/2026 (Thu), 08/14/2026 (Fri), 08/18/2026 (Tue) (10 Days)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	ANNET RAJAN -S Digitally signed by ANNET RAJAN -S Date: 2026.08.18 07:21:36 -0400	Annet R. Rajan, Investigator	08/18/2026
	SIMONE E. PITTS -S Digitally signed by SIMONE E. PITTS -S Date: 2026.08.18 07:31:16 -0400	Simone E. Pitts, Investigator	
	LUCILA B. NWATU -S Digitally signed by LUCILA B. NWATU -S Date: 2026.08.18 07:32:51 -0400	Lucila B. Nwatu, Investigator	

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."