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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768 | 4/20/2026-6/1/2026*<br>FEI NUMBER<br>3017374013 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hale Dimetry, President/CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| PQ Pharmacy LLC | 15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Brooksville, FL 34604-0690 | 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

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

Specifically,

Media Fills

A) Your facility failed to follow written procedure S601002, entitled "Validation of Aseptic Processes by Simulation (Media Fill)" version 12 dated 12/02/2025 that requires you to revalidate the media fill process with (b)(4) runs if you obtain a turbid unit. On 06/16/2025, a media fill out of specification (OOS) occurred for lot (b) (4) during dropper bottle operations recovering one (1) turbid unit. Your response to this OOS was limited to decertifying the individual suspected of causing the contamination. You did not assess the aseptic integrity of the manufacturing process itself or evaluate its impact on the products you manufacture.

B)Your media fill process is deficient as you have not ensured interventions required by the protocol are comprehensive and are simulated by all operators. Additionally, you use (b)(4) vials to simulate your (b)(4) vialing process. You have not evaluated whether turbidity can be adequately detected in these vials. These vials are used to package drug products Phenylephrine/Lidocaine 15mg/10mg/mL (1.5%/1%) 1mL, Moxifloxacin HCL 1mg/mL 1mL, and

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Saundrea A Munroe, Investigator<br>Michael Z Weigman, Investigator | X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 06-01-2026 16:07:15 | 6/1/2026 |

Moxifloxacin HCL 5mg/mL 1mL.

C)Personnel monitoring (PM) conducted following media fill activities is not representative of locations which may contribute to microbial contamination during aseptic operations. For example, PM is limited to (b)(4), which you identify as (b)(4), while sampling of the head and chest areas are not performed, despite these regions routinely breaching the ISO-5 environment during operations.

Process Validation

D)You have not performed process validation for any of the sterile drug products you manufacture to demonstrate that the manufacturing processes are in a state of control and capable of consistently producing results with minimal variability between batches.

E)You have not adequately validated your hold time process to demonstrate you can effectively store in-process USP grade bulk drug products for the established (b)(4) day time period. For example, for cyclosporine USP, you have not evaluated loss on drying, residual solvents, and related compounds, all elements required by the USP monograph to support drug purity. You do not have scientific rationale for excluding these elements in your study.

**E: This is a repeat observation from the warning letter issued 10/10/2025.**

F)On 07/07/2025, your quality unit initiated investigation DEV2025048 in response to a sterility failure Lot (b) (4) (BUD: (b) (4)), Tropicamide/Phenylephrine 10mg/25mg (1%/2.5%) 5mL. The investigation identified the root cause as insufficient tightening of dropper caps during the (b)(4) process thereby implicating (b)(4) units. Despite this determination, the identified defect type was never incorporated into the established defect

library or a relevant procedure. Furthermore, you have not implemented and validated an inspection process capable of detecting incompletely tightened dropper caps to adequately address this failure mode.

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**OBSERVATION 2**

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, your firm has not established adequate procedures and controls for the maintenance, certification, and qualification of HEPA filters, laminar air flow hoods (LAFH), biological safety cabinets (BSC), and cleanroom HVAC systems used for sterile drug production. HVAC failures have recurred without effective corrective action and oversight by the quality unit. For example,

A)Your firm has not performed installation and operational qualification (IQ/OQ) for the HVAC systems and HEPA filtered air supply in the hazardous and non-hazardous ISO 7 and 8 cleanrooms, as confirmed by you, the CEO. Additionally, your firm has not established a written procedure governing routine qualification of your facility used in production of sterile drug products.

B)According to your Quality Manager, cleanroom, LAFH, and BSC qualification acceptance criteria were not formally established between your firm and your contractor. Your Quality Manager stated test and acceptance criteria are based on industry standards but could not produce documentation of the criteria communicated to your contractor or the basis for their application.

C)Your firm's quality unit has failed to thoroughly review preventive and corrective maintenance

reports. During review of your firm's work orders of HEPA certifications, records contain unexplained failures, errors, and missing source data. HEPA certification reports for March/April 2025 and October 2025 indicate that a visual smoke pattern test was performed with passing results for all LAFHs, but source documentation from your contractor does not support that these tests were performed. Additionally, leak test results for LAFH and BSC HEPA filters were reported in the March/April 2025 certification report, however, the source data was not included. Your Quality Manager stated that HEPA certification reports provided by your vendor are reviewed by QA but that review is not documented.

D)Your firm's hazardous cleanroom HVAC intake HEPA filter failed leak testing in October 2025. In response, your vendor performed a pressure differential ("(b)(4)") test; however, leak testing was not repeated and passing leak test results were not obtained or evaluated by your quality unit. You, the CEO, stated that a passing leak test was not required because the HVAC HEPA filter serves as a redundant filtration step. Your firm's quality unit did not document review of these results or any follow-up actions in response to the failed leak test.

**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, investigations into failures and adverse circumstances lack the depth necessary to adequately determine root cause. A review of several investigations revealed either unsubstantiated conclusions or a failure to identify root cause, particularly in cases involving repeated occurrences. Examples of these occurrences include but are not limited to:

A) DEV2025047, initiated on 07/02/2025 in response to a turbid media fill unit from lot (b) (4) identified "operator error" as the root cause without evaluating potential

impacts of other process inputs such as gowning, material sterility and handling, and environmental controls. Additionally, the root cause was attributed to an individual based on speculation, without an established process for tracing the timing of when units were filled/handled.

B) DEV2025048 was initiated on 07/07/2025 in response to out-of-specification sterility results recovered from lot (b) (4) . This investigation identified loosely applied drop container caps as the root cause, citing the (b) (4) capping process, but failed to identify the reason for the increased defect rate as compared to other lots. Additionally, the investigation scope was not broadened to consider potential impact to other batches manufactured by the same process. This batch was ultimately rejected.

C)DEV2026001 was initiated on 02/03/2026 in response to microbial recovery on an operator's sleeve during aseptic filling of lot (b) (4) (Prednisolone Sodium Phosphate/Moxifloxacin HCL/Bromfenac Sodium 1%/0.5%/0.09%). Your investigation concluded "the contamination occurred without evidence of skin exposure," or "procedural non-compliance," despite including evidence that both were contributing factors to the excursion. Per your QA Manager, the investigative efforts have been completed, however, this deviation is currently open pending closure of associated corrective/preventive actions. Its original due date was 03/20/2026 and an extension was issued without a new target due date or approval by Quality Assurance. Deviation is remains open, but batch was destroyed.

D)Three (3) deviations in 2025 and two (2) deviations in 2026 were initiated to document HVAC failures resulting in out of specification (OOS) temperature and humidity in the ISO 7 cleanrooms. The root causes for each of the events are documented as indicated below. Despite repeated HVAC failures, your quality unit has not initiated preventative actions. Your quality unit released approximately (b)(4) lots of product without verifying HEPA suitability after

HVAC repairs.

| Deviations | Date Initiated | Root Cause Assigned |
|---|---|---|
| DEV2025039 | 05/19/2025 | A/C unit for non-hazardous suite was "frozen over" and not working properly. |
| DEV2025050 | 07/26/2025 | The air conditioning unit responsible for maintaining environmental control in the ISO Classified areas experienced a mechanical failure. |
| DEV2025053 | 08/28/2025 | Complete failure of the cleanroom AC unit, attributed to advanced coil corrosion, and inadequate preventative maintenance, specifically a lapse in routine inspection and servicing of the HVAC coils. |
| DEV2026005 | 04/13/2026 | Technician arrived at the facility at 4:00 pm on 13APR2026 and inspection the unit where he observed low coolant level. |
| *DEV2026006 | 04/17/2026 | Technician arrived at the facility at 20APR2026 and inspected the unit where he observed a leak in the evaporator coil. |

* Currently open

E)Consumer complaint CC-2026-002 was initiated 04/14/2026 for leaking bottles during transport for Prednisolone Sodium Phosphate/Moxifloxacin HCL/Bromfenac Sodium 1%/0.5%/0.09% Lot PMB030426EO BUD: 03/04/2027. Although the complaint was logged and acknowledged, to date, there has been no investigation conducted into the root cause of this issue.

**Investigation handling is a repeated observation from your warning letter issued 10/10/2025.**

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**OBSERVATION 4**

Records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

A)During post-use (b)(4) of the sterilizing (b)(4) used for prednisolone sodium phosphate 1% / moxifloxacin HCl 0.5% / bromfenac 0.09% PF, Lot PMB121525CH BUD 12/15/2026, two (2) consecutive tests resulted in the error message "Error: (b)(4) Not Obtainable"; neither were recorded in the batch record, subjected to (b)(4)(b) (4) operations

review, or reviewed by your quality unit.

B)Procedure S403400, "Use and Maintenance of (b)(4)" Version 3, dated 12SEP2025, does not address "error" results and provides no instruction for their documentation, escalation, or investigation.

C)Quality Assurance does not periodically review audit trails or test results stored in the (b)(4) instrument. Your Quality Manager confirmed these reviews are not performed.

D)Procedure S403400, Section 7.9.23 indicates (b)(4) data can be backed up to external storage. However, your CEO confirmed that no backup is performed to prevent data loss.

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**OBSERVATION 5**

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, you have not established a procedure to ensure critical data is reviewed and verified by a second person prior to batch release. For example,

A) Data generated from environmental monitoring (EM) plates post incubation are read by a (b)(4) (b) (4) and are not subject to a (b)(4) review. Observations interpreted from the original data (EM plates) are recorded on a form that is ultimately reviewed by the quality unit. Your quality unit has no process for reviewing the original data generated from the EM plates for accuracy.

B) (b)(4)) conducted by Pharmacists are not subject to (b) (4) review prior to evaluation by the quality unit. According to your written procedure S403400, titled "Use and Maintenance of (b)(4)" version 3 dated 09/12/2025,

(b) (4) electronic signatures are required to document and verify the performance for each (b) (4) test performed using the (b) (4) instrument. Your Operations Manager/Pharmacist stated that Pharmacists are exempt from the (b) (4) review requirement when independently performing (b) (4) which account for approximately "90% to 99%" of all non-hazardous (b) (4) An example of this includes Prednisolone Sodium Phosphate/Moxifloxacin HCl/Bromfenac 1%/0.5%/0.09% Lot: PMB121525CH BUD: 12/15/2026 was a released product reviewed.

**OBSERVATION 6**

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

Specifically,

Visual Inspection Operations

You have not ensured that operators conducting 100% (b) (4) visual inspection are capable of identifying all defined visible defects across your sterile drug product containers, including vials, syringes, and eye drop containers. This is evidenced by:

A) During the walk-through of your facility on 04/28/2026, we identified what appears to be bubbles in the plunger threads of syringe (b)(4) when reviewing the units used to qualify your visual inspection operators. Upon inquiry with your visual inspection operators, it was determined that this occurrence had neither been identified nor recognized as a potential defect type for the syringe product manufactured at your facility. The product manufactured in

the syringe is Mitomycin 1mg/mL 40mL. Syringe products, when distributed, are shipped via (b)(4), which may involve (b)(4) transport.

B) Your visual inspection defect limit acceptance criteria and criticality are not scientifically justified. Per written procedure S700360, "Particulate and Defect Inspection Procedure for All Sterile Products", Revision 3, dated 02/27/2026, applies a (b)(4) and (b)(4) limit for critical, major and minor defects, respectively, to all products you manufacture. You have not performed a risk assessment to determine which defects are critical, major, or minor. For example, a (b)(4) defect limit is applied to all particulate defects, regardless of type (e.g., intrinsic, extrinsic). Additionally, your Quality Manager stated defect limits were established based on (b)(4); they are not adjusted based on (b)(4)

Aseptic Operations

C) Your smoke study evaluations of your ISO-5 environments are inadequate, as they fail to simulate airflow patterns across all high-risk areas under representative operational conditions. For example, during the simulations, materials such as stacks of environmental monitoring (EM) plates and an air sampler were positioned at the (b)(4) of the hood, obstructing the recirculation vents. Because these areas were not evaluated, the smoke studies do not adequately characterize airflow behavior in the vicinity of these materials, leaving critical zones unassessed. These smoke studies are intended to simulate the production of sterile drug products manufactured in your facility.

**C: This is a repeated observation from your warning letter issued 10/10/2025.**

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|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768 | 4/20/2026-6/1/2026*<br>FEI NUMBER<br>3017374013 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Hale Dimetry, President/CEO | |
| FIRM NAME<br>PQ Pharmacy LLC | STREET ADDRESS<br>15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY<br>Brooksville, FL 34604-0690 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility |

**OBSERVATION 7**

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

Specifically,

A) Your finished product testing used to release finished drug products for commercial distribution and perform stability testing does not include an evaluation of impurities and degradants.

B) You do not have a scientific rationale for not performing identity testing for glycerin and propylene glycol, which includes evaluating acceptable levels of diethylene glycol and ethylene glycol. These components used in part for the manufacture of sterile drug products.

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***DATES OF INSPECTION**

4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri), 6/01/2026(Mon)

X Michael Z Weigman
Investigator
Signed By: MICHAEL Z. WEIGMAN -S
Date Signed: 06-01-2026 16:08:06

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Saundrea A Munroe, Investigator<br>Michael Z Weigman, Investigator<br>X Saundrea A Munroe<br>Investigator<br>Signed By: Saundrea A. Munroe -S<br>Date Signed: 06-01-2026 16:07:15 | 6/1/2026 |

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."