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 Fax:(407)475-4768	3/25/2025-4/4/2025* FEI NUMBER 3017374013

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

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 I OBSERVED:

OBSERVATION 1

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

Specifically,

a) Your firm failed to conduct hold time studies to justify the (b) (4) day hold times for your bulk solution bag before dosing into final product containers for all products. While a media fill was performed to challenge the (b) (4) day hold period, your firm has not assessed potential risks or the impact of extended hold times on the finished product and its shelf life. Batches that underwent hold times during processing were not included in stability studies. Additionally, no studies have been conducted to define the storage conditions, nor do they address the container closure system (packaging integrity), chemical stability, or sampling timepoints. For example, the following lots underwent hold times during processing and were released without scientific data to support the hold times:

Drug Name	Volume	Dosage Form	Lot Number	Bulk Bag Hold Time

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EMPLOYEE(S) SIGNATURE
Jose R Lopez, Compliance Officer

X Jose R. Lopez Martinez -S Digitally signed by Jose R. Lopez Martinez -S Date: 2025.04.04 16:03:09 -04'00'

DATE ISSUED
4/4/2025

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Prednisolone Sodium Phosphate/Bromfenac 1%/0.09% WITH BAK	5.6mL	Droptainer	(b) (4) (b) (4)	Days
Mitomycin 40mg/40mL Phaseal	40mL	Syrige		Days
Semaglutide 2.5mg/mL	2mL	Vial		Days
Semaglutide 2.5mg/mL	4mL	Vial		Days
Tirzepatide 10mg/mL	1mL	Vial		Days
Tirzepatide 20mg/mL	3mL	Vial		Days
Semaglutide 2.5mg/mL	4mL	Vial		Days
Moxifloxacin HCl/Bromfenac 0.5%/0.09%	5.6mL	Droptainer		Days
Semaglutide 2.5mg/mL	2mL	Vial		Days
Semaglutide 2.5mg/mL	4mL	Vial		Days
Prednisolone Sodium Phosphate/Moxifloxacin HCl/Bromfenac	5.6mL	Droptainer		Days

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1%/0.5%/0.09%				

b)Moreover, when the (b) (4) day hold time for the bulk solution bag is exceeded, your firm routinely (b) (4) the bulk bag to further extend the hold time. However, the (b) (4) process has not been validated and no studies have been conducted to systematically assess the potential risks or evaluate the impact of (b) (4) on the stability, quality, and shelf life of the finished product. From October 2024 to March 2025, you have surpassed the (b) (4) day hold time and bulk bags were (b) (4) approximately 11 times. In addition, you have also (b) (4) bulk batches due to particulate contamination observed within the bulk bag, (b) (4) failures, and corrective actions taken in response to microbiological recovery during environmental monitoring and other deviations. For example, the following lots underwent (b) (4) and were released for distribution:

Drug Name	Volume	Dosage Form	Lot Number
Tirzepatide 10mg/mL	3mL	Vial	(b) (4)
Semaglutide 2.5mg/mL	3mL	Vial	
Tirzepatide 10mg/mL	3mL	Vial	

c)Your firm has not established written procedures prescribing a system for (b) (4) batches,

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and the steps to be taken to insure that the (b) (4) batches will conform with all established standards or specifications. Additionally, there are no instructions indicating that (b) (4) should not be performed without the review and approval of the Quality Control unit and documented through an investigation.

d)Your procedure S700360.1, "Particulate and Defect Inspection Procedure for All Sterile Products", effective date 04/05/2022, lacks defined specifications for light level conditions, documentation of light intensity measurements, and established frequency requirements for recording illumination levels. Additionally, your firm did not perform quantitative assessment or maintain records of the light source intensity using a calibrated illuminometer to ensure compliance with visual inspection requirements.

e)Furthermore, procedure S700360.1 does not incorporate defined quality inspection criteria for the Acceptance Quality Limit (AQL) assessment, including specifications for sample size determination relative to total lot quantity, the designated sampling plan, and acceptance thresholds for defect tolerance.

f)Your procedure S203005.3 "Qualification of Personnel for Particulate and Defect Inspections Activities" does not incorporate a requirement for the assessment and qualification of visual inspection personnel under fatigue-induced conditions to evaluate potential impacts on inspection accuracy and defect detection reliability. In addition, the inspection time is not documented during qualification activities.

OBSERVATION 2

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

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Specifically,

a)During production from March 25 to March 28, 2025, operators' gown sleeves, wrists, and hands were observed laying down in contact with the ISO-5 classified LFH/BSC work surface. Your aseptic operators (b) (4) along the inside surface of the ISO 5 hood during aseptic production of drug products. Furthermore, the sleeves (b) (4), making contact with the clean area. For example, on 3/28/2025, during dosing process for Semaglutide 5mg vials, lot (b) (4), I observed the aseptic operators hands, wrists, and gowning sleeves in contact with the ISO-5 work surface (b) (4). As per procedure S600200, "Environmental Monitoring of Personnel, PEC, and Supporting Areas," Revision No. 6, Effective 04/29/2024, personnel monitoring requires sampling from operator sleeves during production. Following the dosing of Prednisolone Sodium Phosphate/Moxifloxacin HCL/Bromfenac PF lot (b) (4), the personnel monitoring sample was taken at the (b) (4) level of the gloves. However, personnel monitoring do not include sampling the (b) (4) which were observed entering the ISO 5 environment and in contact with the ISO 5 surface beyond the armrest.

b)On 3/26/2025, during dosing of Prednisolone Sodium Phosphate/ Moxifloxacin HCL/ Bromfenac PF 1%/0.5%/0.09%, 5.6mL droptainer, lot (b) (4), and on 3/28/2025 during the dosing of lot (b) (4) (5.6mL) and (b) (4) (8.6mL), the operators were observed picking up droptainer caps with gloved hands, potentially making contact with the interior surface where the sterile tip is positioned, and (b) (4) tightening the cap on the droptainers.

c)During observation of aseptic production of sterile drug products from March 25 to 28, 2025, your operators failed to limit unnecessary movement and make mindful, slow, deliberate movements within the ISO 5 laminar flow hoods and within the ISO 7 cleanroom suite. For example, on 3/28/2025, during dosing of Prednisolone Sodium Phosphate/Moxifloxacin HCL/Bromfenac PF, 1%/0.5%/0.09%, 8.6mL in 9mL droptainers, lot (b) (4), I observed an employee handling a bag of empty uncapped droptainers, reaching up to the hanging IV bar for the (b) (4)

bottle, returning the bottle to the bar, rubbing hands with (b) (4), reaching out to the filling needle and uncapping the needle in the ISO-5 laminar flow hood. These activities were performed next to a tray of empty exposed droptainers, without showing controlled, slow, and deliberate movements to prevent air disruption inside the ISO 5 Laminar Flow Hood PEC ID (b) (4). Your procedure, S602020 "Personnel Behavior in the Aseptic Core", instructs (b) (4) in clean room areas.

OBSERVATION 3

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

Specifically,

a) Your videos of smoke studies conducted on 09/23/2024 for PEC ID (b) (4) do not demonstrate the manipulations or conditions necessary to accurately represent the dynamic process used in the production of Semaglutide, Tirzepatide, Moxifloxacin HCL, and Phenylephrine/Lidocaine. For example, Smoke Study 23SEP2024, PEC ID (b) (4) S/N (b) (4), 5mL Vial Crimping Dynamic, does not include the steps for aseptically capping and crimping vials during the dosing process.

b) Smoke Studies conducted in September 2024 appear to exhibit turbulence in the Non-hazardous Cleanroom 1 ISO-7 area, the Laminar Flow Hood PEC ID (b) (4), and PEC ID (b) (4). For example, Non-Hazardous Suite Smoke Study, September 2024, Cleanroom (b) (4) shows upward air flow between the 15:00 and 16:00 minute marks. Similarly, the Smoke Study 23SEP2024, PEC ID (b) (4) S/N (b) (4) Static Smoke Study, shows upward turbulence in front of the PEC ID (b) (4) between 02:00 and 2:30 minutes, with additional air turbulence inside the ISO-5 area at 4:43 minutes. Additional turbulence is observed for Smoke Study 23SEP2024, PEC ID (b) (4) S/N (b) (4), 2mL Vials Static, occurring between 4:20 and 4:50 minutes. The quality unit failed to acknowledge these turbulence occurrences during the smoke study review.

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OBSERVATION 4

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically,

a) Deviation report DEV2024072, initiated on 09/18/2024, was opened to investigate the presence of visible particulate identified during the bulk bag inspection. The defect was detected (b) (4), prior to dosing stage of the sterilized 7.2L bulk solution containing Prednisolone Sodium Phosphate/Moxifloxacin HCl/Bromfenac 1%/0.5%/0.09% Ophthalmic Solution, Lot: (b) (4).

As a corrective action your firm (b) (4) the bulk solution bag and subsequently released the batch for distribution. However, the investigation was inadequate as it did not establish a definitive root cause for the presence of visible particulates following (b) (4). Additionally, the investigation failed to assess potential (b) (4) concerns or identify the source of particulate contamination, thereby limiting the implementation of effective corrective and preventive actions to mitigate recurrence.

b) Deviation report DEV2024075, initiated on 10/4/2024, was opened to investigate the presence of visible particulate in Tirzepatide 10mg/mL Sterile Injectable Solution, Lot: (b) (4). The particulate was detected at the initiation of the dosing process, specifically during the line priming stage, when fluid was drawn into the syringe.

As a corrective action, your firm (b) (4) the bulk solution bag and subsequently released the batch for distribution. The investigation concluded that the most probable source of the particulate was the syringe itself. However, the that the particulate came from the syringe

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itself. However, the investigation was inadequate, as no additional steps were taken to definitively confirm whether the particulate originated from the syringe or if it was present in the bulk solution prior to dosing. The absence of a conclusive root cause analysis may hinder the implementation of appropriate corrective and preventive actions to mitigate recurrence.

***DATES OF INSPECTION**

3/25/2025(Tue), 3/26/2025(Wed), 3/27/2025(Thu), 3/28/2025(Fri), 3/31/2025(Mon), 4/01/2025(Tue), 4/02/2025(Wed), 4/04/2025(Fri)

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."