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 ORAPHARM2_RESPONSES@fda.hhs.gov	10/11/2022-10/27/2022* FEI NUMBER 3017374013

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hale N. 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 (503B)

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:
Quality System

OBSERVATION 1

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

The quality control unit (QCU) did not fully investigate laboratory test results before releasing finished drug products.

Specifically,

A. Your firm did not have a validated test method for assay testing of your drug products, Prednisolone Sodium Phosphate/Moxifloxacin HCL/Bromfenac 1%/0.5%/0.09% and Prednisolone Sodium Phosphate/Moxifloxacin HCL 1%/0.5% ophthalmic solutions before release and distribution of final product. Lot (b) (4) assigned no beyond use date (BUD) was used for your (b) (4) test method validation for both ophthalmic solutions that was completed on (b) (4). Prior to 10/27/2022, the following lots were distributed to customers with final assay results using an unvalidated test method:

- (b) (4) 8.6mL starting on 05/16/2022- (b) (4) units
- (b) (4) 5.6mL starting on 07/06/2022- (b) (4) units
- (b) (4) 5.6mL starting on 08/10/2022- (b) (4) units

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joanne E King, Investigator Kayla V Sprague, Investigator X Joanne E King Investigator Signed By 1300174867 Date Signed 10-27-2022 15 08 59	10/27/2022

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- (b) (4) 8.6mL starting on 08/15/2022- (b) (4) units
- (b) (4) 5.6mL starting on 09/20/2022- (b) (4) units
- (b) (4) 5.6mL starting on 09/23/2022- (b) (4) units

B. The quality control unit (QCU) did not fully investigate the (b) (4) assay test result of an in process drug sample and the (b) (4) assay test result for the finished drug product sample of mitomycin 1 mg/ml (40 mg/40 ml) syringes for bladder irrigation before the release of the batch for use in patients. The in-process sample consisting of (b) (4) syringe containing (b) (4) contract lab test result under lab # (b) (4) was obtained following an unwritten (b) (4) test method for mitomycin 1mg/ml (40 mg/40ml) syringes for bladder irrigation lot (b) (4) beyond use date (BUD) 6/5/2022 for assay and was out of the specification (b) (4) % as follows:

: (b) (4)

Based on the in-process test result (b) (4) obtained on (b) (4) the bulk in process mitomycin 1mg/ml in (40 mg/40 ml) syringes for bladder irrigation lot (b) (4) BUD 6/5/2022 was adjusted and reworked on (b) (4) with (b) (4) of mitomycin C USP bulk drug substance lot (b) (4). This batch was assigned the adjusted lot number (b) (4) and resubmitted for finished product testing. The finished product sample consisted of (b) (4) 50 ml syringes each containing 40 mg/40 ml of mitomycin (1mg/ml) lot (b) (4) BUD "5/6/2022" under the lab # (b) (4).

The finished product contract lab test result following (b) (4) test method for mitomycin

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(1mg/ml) 40 mg/40 ml syringes for bladder irrigation lot (b) (4) BUD "5/6/2022" for assay was out of the specification (b) (4) as follows:

- (b) (4)

The finished product contract lab test result following the test method *Analysis of Mitomycin by* (b) (4)) (b) (4) for mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot (b) (4) BUD "5/6/2022" for assay was within specification (b) (4) as follows:

: (b) (4)

The average of the (b) (4) contract lab test results, (b) (4), was reported as the test result for the assay and used for the release testing for (b) (4) syringes, according to the batch record documentation, of mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot (b) (4) BUD "5/6/2022" on (b) (4). Documentation provided listed that (b) (4) of these syringes were distributed for use from 4/4/2022-4/13/2022.

Mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot (b) (4) BUD "5/6/2022" was used for the test method validation under lab # (b) (4) and the validation was completed on (b) (4).

OBSERVATION 2
The responsibilities and procedures applicable to the quality control unit are not fully followed.

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Specifically,

Your firm compounded Prednisolone Sodium Phosphate/Moxifloxacin HCL 1%/0.5%/mL Ophthalmic Solution Lot number: (b) (4) on May 26, 2022, into (b) (4) bulk bag and held it for (b) (4) before filing into its finished form (droptainers) on June 8, 2022. Your firm's established hold time for this drug product is (b) (4). This discrepancy was not identified by anyone including your quality unit and no investigation was performed. Additionally, operator (b) (6) who performed the manufacturing of this compound was only qualified for (b) (4) according to your media fill hold time study. This batch was released by your quality unit on July 01, 2022 for sale but was not distributed due to no client need before its product expiration date.

Laboratory Control System

OBSERVATION 3

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically, the beyond use date (BUD) for mitomycin (1mg/1ml) 40mg/40 ml in 50 ml syringe for bladder irrigation was changed from (b) (4) on (b) (4), (b) (4) on (b) (4) and from (b) (4) for lot (b) (4). This BUD was extended based on the stability batch contract lab test results for lot (b) (4). This stability batch was not tested using a contract test lab validated test method for assay until after the validation of the test method which according to documentation occurred on (b) (4).

OBSERVATION 4

The written stability program for drug products does not include reliable test methods.

Specifically, the stability batch (b) (4) was tested at the time points (b) (4) using an un-

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X Joanne E King Investigator Signed By 1300174867 Date Signed 10-27-2022 15:08:59

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validated contract test lab test method for assay.

Facilities and Equipment System

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the (b) (4) contact time listed in you *SOP S110108 Deactivation, Decontamination, Cleaning, and Disinfection Program (DDCD) for Receiving, Storage, and Manufacturing Areas Sections 7.1.1.1 and 7.2.4* and *SOP S302002 Facility Cleaning and Maintenance Section 7.1.5.4.1* was not in keeping with the (b) (4) manufacturer's recommended (b) (4) contact time.

Food, Drug, and Cosmetic Act

OBSERVATION 6

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, the following products were compounded during the reporting period 2022-1 according to your production log batch record, but were not identified on your report dated May 31, 2022 (2022-1):

1. Prednisolone Sodium Phosphate/ Moxifloxacin HCL/Bromfenac 1%/0.5%/0.09% Ophth Solution produced March 3, 2022, in 5 mL volume was not reported for 2022-1
2. Prednisolone Sodium Phosphate/Moxifloxacin 1%/0.05% Ophth Solution produced May 26, 2022, in 5 mL volume was not reported for 2022-1
3. Prednisolone Sodium Phosphate/Moxifloxacin 1%/0.05% Ophth Solution produced May 26, 2022, in 8 mL volume was not reported for 2022-1.

OBSERVATION 7

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Your outsourcing facility did not submit a report to FDA upon initial registration as an outsourcing facility identifying the drugs compounded during the previous six month period.

Specifically,

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded or no products to report at the time of initial registration, October 29, 2020, and December 2020.

***DATES OF INSPECTION**
10/11/2022(Tue), 10/12/2022(Wed), 10/13/2022(Thu), 10/14/2022(Fri), 10/17/2022(Mon), 10/18/2022(Tue), 10/19/2022(Wed), 10/20/2022(Thu), 10/26/2022(Wed), 10/27/2022(Thu)

X Kayla V. Sprague -S Digitally signed by Kayla V. Sprague -S Date: 2022.10.27 16:16:40 -04'00'

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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."