

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 1/9/2019-1/29/2019* FEI NUMBER 3002946837	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Gregg N. Pederson, RPh, President			
FIRM NAME Pharmacy Resources Incorporated		STREET ADDRESS 5290 E Yale Cir Ste 101	
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80222-6927		TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products	
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 Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. Specifically, Aseptic processing areas, which are used for production of sterile, intrathecal, and epidural drug products for human use, consist of (b) (4) ISO-5 workstations located within an ISO-7 cleanroom. Personnel clean inside the ISO-5 workstations (b) (4) with sterile water followed by (b) (4) (b) (4), personnel clean inside the ISO-5 workstations using either a sporicidal disinfectant or (b) (4), which alternate each (b) (4) The following was observed regarding the cleaning and disinfection processes within these areas: A. Cleaning records dated between 01-Jun-18 and 30-Dec-18 report the use of (b) (4) disinfectant to clean the (b) (4) ISO-5 workbenches used to formulate sterile drug products. The manufacturer's product information does not state this disinfectant is sporicidal and no additional information was available to demonstrate (b) (4) disinfectant has sporicidal properties. B. Although the cleaning records document (b) (4) use of (b) (4), the Staff Pharmacist explained that (b) (4) (which is sporicidal) was used from mid-2017 until approximately mid-November 2018, and "(b) (4)" was documented incorrectly on the cleaning log. However, the sporicidal and disinfectant properties of the two (2) alternating disinfectants (b) (4) and (b) (4) used in the ISO-5 workbenches has not been established as follows: 1. Although the "Clean Room Cleaning" instructions posted inside the ante-room requires a (b) (4)			
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contact time for each disinfectant, the (b) (4) manufacturer's information sheet requires an undiluted contact time of (b) (4).

2. According to the dilution instructions posted in the ante-room on 09-Jan-19, (b) (4) is diluted to a concentration of (b) (4) ppm. A document provided by your firm titled, "Common disinfectants used in health care for inanimate surfaces and non-critical devices, and their microbicidal activity and properties" provided information regarding (b) (4) microbial inactivation properties at 100 – 5000 ppm and did not address microbial disinfection at a concentration (b) (4).

- C. Sporicidal disinfectant is not routinely used on the floors, walls, or ceilings of the ISO-7 cleanroom where the ISO-5 workbenches are located.
- D. Personnel clean ISO-5 workbenches with non-sterile cleaning wipes.
- E. On 11-Jan-19, a clock radio and a wall-mounted intercom were observed inside the ISO-7 cleanroom where the ISO-5 workbenches are located. These devices contain surfaces which are not easily cleanable.

This is a repeat observation.

OBSERVATION 2

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

Specifically,

Your firm has not conducted in situ air pattern analyses (smoke studies) under conditions that simulate normal operating conditions in the cleanroom, laminar-flow hoods, and biosafety cabinet.

This is a repeat observation.

OBSERVATION 3

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Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

Other than sterile gloves, the garments and protective apparel worn by sterile drug technicians consist of non-sterile shoe covers, a non-sterile bouffant hair cover, a non-sterile face mask/shield, and a non-sterile (b) (4) outer gown, which is sprayed with non-sterile (b) (4) prior to donning.

On 10-Jan-19, during aseptic preparation of Tri-mix 30-3-30 injectable, lot 100119, expiration date 10-Feb-19, an employee with exposed hair and skin on the back of their neck was observed placing non-sterile sleeves inside the ISO-5 biosafety cabinet.

This is a repeat observation.

OBSERVATION 4

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

Specifically,

Empty sterile vials used for sterile veterinary drugs are exposed to ISO-7 conditions prior to transfer to the ISO-5 workstation. For example, on 09-Jan-19, four (4) empty, uncovered, pre-sterilized 30-ml vials were observed on a cart located in the ISO-7 area adjacent to ISO-5 Hood (b) (4). The vials were subsequently transferred into Hood (b) (4) and Medroxy-Progesterone 100 mg/ml solution, lot 090119, was (b) (4) into the vials.

OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

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Your firm does not have finished product sterility data to support the current expiration dates for finished drug products formulated from stock solutions.

For example, the current finished product expiration dates of 90 days for (b) (4) (b) (4) Tri-Mix Injectable, lot 061118, expiry 06-Feb-19, and Quad Mix (Standard) 9-1-0.1-10 Injectable, lot 061118, expiry 06-Feb-19, are supported with the following sterility data from the stock solutions (ingredients used to prepare each of the finished products above):

- Papaverine HCl 30 mg/cc: expiry date of (b) (4) days is based upon (b) (4) (b) (4)
- Phentolamine Mesylate 10 mg/cc: expiry date of (b) (4) days is based upon (b) (4) (b) (4)
- Prostaglandin E-1 (PGE-1) 500 mcg/ml expiry date of (b) (4) days is based upon (b) (4) (b) (4) (D) (4)

A (b) (4)(b) (4) step is performed when each of these stock solutions is combined to compound one of the final products above.

OBSERVATION 6

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

Specifically,

The environmental monitoring program does not provide information about the aseptic processing environment during (b) (4) sterile operations. For example, viable monitoring (air, surface, and personnel) was not performed during the compounding of (b) (4) (b) (4) Tri-Mix injectable, lot 061118, expiration 06-Feb-19 or Quad Mix (Standard) 9-1-0.1-10 Injectable, lot 061118, expiration 06-Feb-19.

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In addition:

- A. Surface monitoring inside the ISO-5 workstations is conducted on a (b) (4) basis.
- B. Air is not sampled inside the ISO-5 workstations during (b) (4) aseptic formulation operations. For example:
- Air sampling (viable - settle plate) is conducted in the ISO-7 area on a (b) (4) basis.
 - Air sampling (viable - active) is conducted inside the ISO-5 workstations every (b) (4) during room qualification activities and is not completed during or immediately following sterile drug formulation activities.
- C. Personnel monitoring is conducted (b) (4) during employees' gowning re-qualification and media fill. Personnel monitoring only includes fingertip sampling. On 26-Sep-18, one (1) colony forming unit (CFU) was found during an employee's (b) (4) fingertip monitoring. The organism was not identified.
- D. Positive results are not investigated. Specific locations are sampled approximately (b) (4) on a rotating basis. Supply shelf (b) (4) located in the ISO-8 classified ante-room, showed growth during the its (b) (4) most recent consecutive sampling events dated (b) (4). An investigation was not performed to determine the cause, potential impact, or corrective actions to be taken in order to prevent recurrence.

This is a repeat observation.

OBSERVATION 7

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

Specifically,

Method suitability testing has not been performed to determine if in-house sterility test methods used for final product testing of sterile erectile dysfunction (ED) drugs are effective at recovering organisms from final

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compounded products. For example, Quad Mix (Standard) 9-1-0.1-10, lot 061118, expiry 06-Feb-19, is formulated with (b) (4); however, method suitability testing has not been performed to demonstrate the in-house sterility method is capable of recovering organisms in the presence of product.

This is a repeat observation.

***DATES OF INSPECTION**

1/09/2019(Wed), 1/10/2019(Thu), 1/11/2019(Fri), 1/14/2019(Mon), 1/15/2019(Tue), 1/16/2019(Wed), 1/17/2019(Thu), 1/22/2019(Tue), 1/29/2019(Tue)

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