

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

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	DATE(S) OF INSPECTION 4/18/2016-5/11/2016* FEI NUMBER 3011756326
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Elizabeth A. Prokopik , Corporate Counsel

FIRM NAME Pharmakon Long Term Care Pharmacy, Inc.	STREET ADDRESS 14460 Getz Rd, Suite 200
CITY, STATE, ZIP CODE, COUNTRY Noblesville, IN 46060-3303	TYPE ESTABLISHMENT INSPECTED Producer of 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

- i. Environmental monitoring is not performed at least daily during drug production in the critical areas to evaluate the quality of the aseptic processing environment and assess whether aseptic conditions are maintained.
 - a. Non-viable particulate monitoring is performed in the aseptic processing areas (b)(4)
(b)(4)
 - b. Active viable air monitoring is performed in the aseptic processing areas every (b)(4)
(b)(4) Passive air monitoring is performed in the aseptic processing areas every (b)(4)
(b)(4)
 - c. Viable surface monitoring is performed in the aseptic processing areas every (b)(4)
(b)(4)
 - d. Personnel fingertip monitoring is performed for (b)(4) (b)(4)
- ii. Environmental monitoring excursions are not investigated. Management indicated Rooms (b)(4)
(b)(4) and the anteroom are classified as ISO 6. According to SOP *Environmental Control and*

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Monitoring, the microbiological active air action level for ISO (b)(4) CFU/m. During the anteroom certification on (b)(4), 8 CFUs were recovered.

- iii. No data was provided to support that the incubator used to incubate media fill containers and environmental monitoring surface and fingertip samples is qualified for its intended use. Management stated this incubator is maintained between (b)(4). In addition, there was no documentation provided to support that the (b)(4) thermometer was calibrated.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

- i. Gowning of operators performing aseptic operations in the ISO 5 laminar flow hoods is inadequate in that protective gowns, face masks, shoe covers, and hair nets worn during aseptic processing are not sterile. In addition, the current gowning method leaves facial and neck skin exposed, as well as personal clothing. For example, gowning worn as observed during the aseptic processing of Amikacin 400 mg/100 ml (Rx No. (b)(6)) Invanz 500 mg/100 ml (Rx No. (b)(6)) and Gentamicin 240 mg/100 ml (Rx No. (b)(6)) in Hood (b)(4) on 4/18/16.
- ii. On 4/19/16, prior to the aseptic processing of Invanz 1 gm/100 ml (Rx No. (b)(6)) in Hood (b)(4) the operator was observed straightening the sterile glove located on (b)(6) right hand with (b)(6) ungloved left hand during gowning.

OBSERVATION 3

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

Specifically,

The following aseptic practice was observed:

While exiting the ISO 6 Room (b)(4) the operator was observed to use (b)(7)(C), (b)(6) gownned elbow and forearm to activate the door mechanism leading into the ISO 6 anteroom. After this, (b)(7)(C), (b)(6) gownned forearm and elbow were observed making contact with the ISO 5 laminar flow hood work surface during aseptic operations.

The above example was observed during processing of Amikacin 400mg/100ml for Rx No. (b)(6) Invanz 500mg/100ml for Rx No. (b)(6) and Gentamicin 240mg/100ml for Rx No. (b)(6) on 4/18/16.

OBSERVATION 4

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

Specifically,

- i. (b)(4) cleaning using sterile (b)(4) to clean floors, laminar flow hoods, and work surfaces in ISO 5 and ISO 6 areas (b)(4) aseptic processing is not documented for all operational days. For example, (b)(4), (b)(4) sterile drug products were aseptically processed including Ampicillin Sulbactam, Cefazolin, and Cefepime; (b)(4) cleaning was not documented (b)(4). Similarly, from 4/16/16 to 4/17/16 (b)(4) sterile drug products were aseptically processed; however, (b)(4) cleaning was not documented (b)(4) of aseptic operations.

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- ii. Non-sterile sanitizing agents are used (b)(4), for sanitization of the aseptic processing areas. Sanitizing agents used by your firm include (b)(4) in the ISO 5 and ISO 6 areas.
- iii. On 4/18/16, prior to and during the aseptic processing of Amikacin 400 mg/100 ml (Rx No. (b)(6) Invanz 500 mg/100 ml (Rx No. (b)(6) and Gentamicin 240 mg/ 100 ml (Rx No. (b)(6)), the operator was observed (b)(4) sterile (b)(4) then resuming operations before (b)(4) was allowed to dry.

OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

- i. The pressure differentials between different air quality in the ISO 6 Areas (anteroom and Rooms (b)(4) and unclassified area are infrequently monitored. Currently, such pressure differentials are checked and documented by operators (b)(4). Additionally, no documentation of (b)(4) pressure checks was recorded in the (b)(4) *Record of Room Pressure Log* before 3/02/16.
- ii. In addition, the return air supply located in the anteroom on the adjoining wall to Room (b)(4) was observed to be partially obstructed by a cart containing the gowning materials and various supplies used in the aseptic areas.

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<p>The above examples were observed during processing of Amikacin 400mg/100ml for Rx No. (b) (6) Invanz 500mg/100ml for Rx No. (b) (6) and Gentamicin 240mg/100ml for Rx No. (b) (6) on 4/18/16.</p>					
<p>OBSERVATION 6 The operations relating to the processing of penicillin are not performed in facilities separate from those used for other drug products for human use.</p> <p>Specifically,</p> <p>Procedures have not been established for the separation of tasks and segregation of personnel handling cephalosporin drug products from those for all other human drug products. Your firm has (b)(4) hoods, none of which are dedicated to handling cephalosporin drug products. For example, on 2/14/16, the following drug products were processed: (b)(4)</p>					
<p>OBSERVATION 7 The responsibilities and procedures applicable to the quality control unit are not fully followed.</p> <p>Specifically,</p> <p>SOP <i>Compounding Sterile Preparations Guidelines</i> states (b)(4)</p> <p>Such examinations were not observed, nor are they documented for each finished drug product.</p>					
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OBSERVATION 8

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

Specifically,

Documentation was not provided to support beyond use dates assigned to sterile drug products. For example, Invanz 500mg/100ml (Rx No. (b) (6)) is given a beyond use date of 3 days, refrigerated. The Invanz product insert from the manufacturer states the product is stable for 24 hours at 5°C.

***DATES OF INSPECTION**

4/18/2016(Mon), 4/19/2016(Tue), 4/20/2016(Wed), 4/21/2016(Thu), 5/10/2016(Tue), 5/11/2016(Wed)

5/11/2016

5/11/2016

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