

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/05/2014 - 03/13/2014*
	FEI NUMBER 3008213711

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Paul J. Elmer, President	
FIRM NAME Pharmakon Pharmaceuticals, Inc.	STREET ADDRESS 14450 Getz Road
CITY, STATE AND ZIP CODE Noblesville, IN 46060	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

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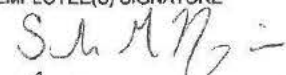
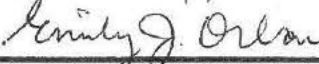
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically,

- i. The following aseptic practices were observed:
 - a. During processing of Ropivacaine HCl 0.2% in 0.9% Sodium Chloride 500mL fill in a 500 mL (b) (4) bag lot #E61055584R on 3/10/14, the operator was observed to place gloved hands between unidirectional airflow and open drug component vials while handling such. Additionally, filling of Ropivacaine into syringes was performed in the laminar flow hood in close proximity to the repeater pump, and with an empty syringe container and sterile bag filling tube blocking unidirectional airflow from the HEPA filters.
 - b. Operators were not observed to exhibit slow, deliberate movements while performing aseptic operations in the laminar flow hoods or moving about the aseptic filling rooms in which the hoods are located. For example, during filling of Bupivacaine HCl 0.5% 500mL fill in a 400mL (b) (4) lot #E34240DK2R on 3/5/14 and Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot #E0711812R on 3/6/14.
 - c. Sterile utensils are not always used to handle sterile materials. For example, on 3/5/14, an operator was observed to use gloved hands to pour vials of Bupivacaine into a sterile bag used as bulk to fill finished product containers (lot #E34240DK2R). Additionally, on 3/10/14, an operator was observed to remove stoppers with gloved hands from two vials when they did not come off with the use of pliers (Ropivacaine HCl 0.2% in 0.9% Sodium Chloride 500mL fill in a 500 mL (b) (4) bag lot #E61055584R).
 - d. Gloved hands are not always sanitized after touching items outside the laminar flow hoods prior to continuing aseptic filling operations inside the laminar flow hoods. For example, on 3/5/14, an operator working in laminar flow hood 3 was observed to touch cords of the repeater pump and operate a product scale outside the laminar flow hood prior to continuing with aseptic operations in the laminar flow hood during filling of Fentanyl Citrate 2mcg/mL & Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 100mL fill in a 150mL (b) (4) bag, lot

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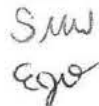
#E29396DK1C
 e. (b) (4) are used for some aseptic filling operations (sterile drug components to sterile drug product) depending on packaging configuration and batch size, however, (b) (4) testing of these (b) (4) is not performed before or after use to ensure the (b) (4) of such.

ii. Adequate validation of aseptic processing operations, specifically, process simulations (media fills), have not been performed under worst case conditions to assure that sterile processing techniques are adequate to ensure the sterility of drug products. Currently, each operator involved in aseptic processing must (b) (4) perform a "Personal Aseptic Technique Test", in which sterile media is transferred from a vial using a syringe and needle, to a bag containing sterile media. This process does not include, for example, use of all representative container closure systems, worst case lot sizes, most complex/difficult aseptic operations, or equipment used in normal aseptic processing such as (b) (4) and repeater pumps. For example, the "Personal Aseptic Technique Test" was not representative of filling operations for Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot #E0711812R, in which drug components are exposed when transferred from opened glass ampules.

iii. Procedures detailing proper gowning technique and controls for operators entering the aseptic processing area were not provided. The following pertaining to operator gowning were observed:

- a. Bare hands were observed to contact the outer surface of sterile gloves while donning.
- b. The Tyvek coverall was observed to touch the floor of the gowning room while being donned.
- c. Segregation of the gowning room into areas for operators entering from the unclassified area and areas for operators which are gowned for the aseptic processing rooms has not been established.
- d. The frequency of viable surface monitoring for gloves of operators working in the aseptic processing laminar flow hoods is not justified. Currently, this monitoring is performed (b) (4). No other personnel monitoring is performed.

iv. No documentation was provided to support that the (b) (4) Autoclave, used to sterilize pliers used in aseptic filling operations, has been adequately validated for its intended use, or that periodic maintenance of such is performed according to the user manual.

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OBSERVATION 2

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

Specifically,

- i. In situ air pattern analysis has not been performed in the laminar flow hoods, where sterile drug products are processed and filled, to demonstrate unidirectional airflow over the product during static or dynamic conditions.
- ii. The monitoring frequency of pressure differentials between the aseptic processing rooms and surrounding areas of lower air quality is not justified. Currently, such pressure differentials are checked and documented by operators (b) (4). Assurance was not provided to support that a temporary loss in differential pressure during filling operations would be detected and appropriately handled.


The above applies to aseptic processing areas used to process and fill all sterile drug products, for example, Bupivacaine HCl 0.5% 500mL fill in a 400mL (b) (4) lot #E34240DK2R on 3/5/14 and Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot #E0711812R on 3/6/14.

OBSERVATION 3

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

Specifically,

Gowning of operators performing aseptic operations in the laminar flow hoods is inadequate in that face masks and shoe covers worn are not sterile. Additionally, the current gowning method leaves facial skin and facial hair exposed.

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OBSERVATION 4

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

Specifically,

i. On 3/6/14, a white colored residue was observed on the HEPA filter grate of laminar flow hood 1, during the processing of Cefazolin 3gm added to a 100mL (b) (4) Bag lot # E137096.26R and Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot # E0711812R.


ii. Scientific justification was not provided to support that the sterilization frequency of pliers used in aseptic filling operations is adequate. Additionally, documented procedures were not provided which include the frequency of sterilization in the autoclave, the autoclave cycle used, and cleaning procedures for such prior to autoclaving. Firm management stated that pliers are to be autoclaved (b) (4) however the most recent record of pliers going through an autoclave cycle is on 12/12/2013, at which time aseptic operations were performed in a different building. Pliers were observed on 3/6/14 and 3/10/14 to be used to remove the cap and crimp from drug product vials used as components in finished products Bupivacaine HCl 0.5% 500mL fill in a (b) (4) (b) (4) lot #E34240DK2R and Ropivacaine HCl 0.2% in 0.9% Sodium Chloride 500mL fill in a 500 mL (b) (4) bag lot #E61055584R.

OBSERVATION 5

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

Specifically,

Environmental monitoring is not performed daily during sterile filling activities to evaluate the quality of the aseptic processing environment and assess whether aseptic conditions are maintained. The environmental monitoring program is deficient in that:

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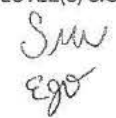
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- i. Viable passive air monitoring is performed inside the aseptic processing laminar flow hoods, and the rooms in which such are located, under static conditions immediately after cleaning/sanitization.
- ii. Viable surface monitoring is not always representative of worst case conditions in the aseptic processing laminar flow hoods, as such monitoring is performed under static conditions immediately after cleaning/sanitization. Additionally, (b) (4) Media Paddles Directions for Use states that media paddles should be pressed firmly against a surface, and "Do NOT drag the agar across the surface", however on 3/6/14 operators performing environmental monitoring were observed to drag the media across the work surface of laminar flow hoods 2, 3 and 4.
- iii. Non-viable particulate monitoring is not performed during dynamic conditions.
- iv. No data was provided to support that the incubator used to incubate environmental monitoring samples has been qualified for its intended use. (b) (4) Media Paddles Directions for Use states, "Incubate at an elevated temperature (USP <797>) 30°-35°C for 48 to 72 hours". The incubator temperature is specified to operate between 30-35°C, however the thermometer used to monitor this temperature has not been calibrated and continuous temperature monitoring of the incubator is not performed. On 3/5/14, a technician stated the thermometer appeared to be reading 28-29°C. Additionally, environmental monitoring surface contact media paddles are not always incubated for the specified period of 48 to 72 hours. For example, the results of surface contact media paddles used for monitoring surfaces in the aseptic processing rooms on 3/6/14 were read on 3/10/14.
- v. No documentation was provided to support that environmental monitoring media plates used for surface swab samples of equipment and operator glove monitoring on 3/4/14 contain disinfectant neutralizers to assure microbial contamination can be detected.

The above applies to aseptic processing areas used to process and fill all sterile drug products, for example, Bupivacaine HCl 0.5% 500mL fill in a 400mL (b) (4) lot #E34240DK2R on 3/5/14 and Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot #E0711812R on 3/6/14.

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OBSERVATION 6

The flow of components, drug product containers, and closures though the building is not designed to prevent contamination.

Specifically,

Procedures which describe the process for moving components and materials from the unclassified area into aseptic processing areas were not provided. All components (sterile drug products in vials and bags) and materials (e.g. sterile alcohol wipes, sterile packaged syringes) are brought into the "materials in" room from an unclassified area and (b) (4) before being transferred to the aseptic processing rooms and used for aseptic processing operations performed in laminar flow hoods. No assurance is provided that (b) (4) is applied evenly across the surface of all materials.

On 3/11/14, an operator was observed to place components and materials in a (b) (4) type bag in the unclassified area, bring this bag into the "materials in" room, and (b) (4) only the outside of the (b) (4) bag prior to bringing it into the aseptic processing rooms. This bag was then opened inside the aseptic processing room, the operator reached into the bag to remove needed items, and items were (b) (4) here prior to being brought into the laminar flow hoods for use in processing Promethazine 0.25mg/mL in 0.9% Sodium Chloride 50mL fill in a 100mL bag lot #E123337.111R.



OBSERVATION 7

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

Given the observed inadequate environmental controls, testing is deficient in that:

- i. Aseptically filled sterile injectable drug products are released and distributed prior to receiving laboratory results for sterility.

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- ii. Method suitability studies using representative organisms in the presence of product have not been performed.
- iii. Scientific justification was not provided to support the number of units sampled from each finished batch of drug product to be tested for sterility, and written procedures describing the sampling plan for such were not provided. For example, the lot size of Hydromorphone 1mg/ml in 0.9% Sodium Chloride 1mL fill in a 3mL BD syringe lot #E30415DD30C was (b) (4) units; (b) (4) units were pulled from this lot for sterility (and potency) testing.
- iv. Finished lots of sterile injectable drug products are not tested for endotoxins.

Examples include Bupivacaine HCl 0.5% 500mL fill in a 400mL (b) (4) (b) (4) lot #E34240DK2R and Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot # E0711812R.

OBSERVATION 8

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

- i. Evidence was not provided to support that a 100% visual inspection of sterile drug products for contamination is performed prior to the distribution of each finished product lot. Firm management stated that visual examinations are performed by both operators who fill and operators who package sterile drug products, however, performance of such was not observed to occur during aseptic processing or packaging operations occurring on 3/5/14 or 3/6/14, for example, for the following finished drug products: Hydromorphone HCl 1mg/mL in 0.9% Sodium Chloride 50mL fill in a 50mL (b) (4) bag lot #E30415DD34C and Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot #E0711812R. Additionally, procedures were not provided which describe the visual examination of drug products prior to distribution, including the method in which operators visually check products for contamination, the types of defects in container/closures employees are trained to look for, and the method in which operators are trained to perform such visual checks.

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ii. Finished lots of sterile injectable drug products containing preservative are not tested for preservative content, for example, Promethazine 0.25mg/mL in 0.9% Sodium Chloride 50mL in 100mL bag lot #E123337.111R.

OBSERVATION 9

Drug product container and closure test procedures are deficient in that containers and closures are not tested for conformance in accordance with appropriate written procedures.

Specifically,

No documentation was provided to support that caps used as closures for sterile drug products packaged in syringes are pyrogen-free. For example, the Certificate of Conformance and the packaging for the "Tamper Evident Caps White Sterile" lot #5232 do not state they are pyrogen-free. These caps were used to package Tetracaine 0.5% & Dextrose PF 5% - 4mL fill in a 5mL (b) (4) syringe lot #E0711812R.

OBSERVATION 10

The operations relating to the processing of penicillin are not performed in facilities separate from those used for other drug products for human use.



Specifically,

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. For example on 3/6/14, Cefazolin 3gm added to a 100mL (b) (4) Bag lot #E137096.26R was processed and filled in laminar flow hood 1. Subsequently, Vancomycin HCl 2gm added to 0.9% Sodium Chloride 500ml Bag lot #E61071041R was processed in laminar flow hood 1 on this same day.

OBSERVATION 11

The labels of your firm's drug products do not include information required by section 503B(a)(10) of the Act.

Specifically,

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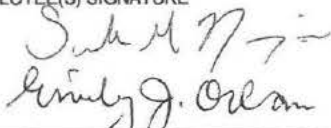
i. The following drug product labels do not contain the statement "This is a compounded drug": Hydromorphone HCl 1 mg/ml in 0.9% Sodium Chloride, Bupivacaine HCl 0.5%, Oxytocin 20 units added to 0.9% Sodium Chloride Injection USP 1000 mL, Tetracaine 0.5%/Dextrose 5% Preservative Free, Injection, Fentanyl Citrate 2mcg/mL and 0.125% Bupivacaine HCl in 0.9% Sodium Chloride, Ephedrine Sulfate 5mg/ml in 0.9% Sodium Chloride, Fentanyl Citrate (PF) 10 mcg/ml in 0.9% Sodium Chloride, Oxytocin 20 units added to Lactated Ringers Injection USP 1000mL, Diltiazem 1mg/mL in 5% Dextrose, Potassium Chloride 40 mEq added to 250ml 0.9% Sodium Chloride USP, Cefazolin 1gm/10mL in Sterile Water for Injection, Promethazine HCl 25 mg added to 0.9% Sodium Chloride Injection USP 50mL, Midazolam HCl 1 mg/mL 0.9% Sodium Chloride Injection USP 100 mL, Phenylephrine HCl 100 mcg/mL in 0.9% Sodium Chloride, and Morphine Sulfate 5mg/mL in 0.9% Sodium Chloride (Preserved).

ii. The following drug product labels do not contain the address and phone number of your outsourcing facility: Hydromorphone HCl 1 mg/ml in 0.9% Sodium Chloride, Bupivacaine HCl 0.5%, Tetracaine 0.5%/Dextrose 5% Preservative Free, Injection, Fentanyl Citrate 2mcg/mL and 0.125% Bupivacaine HCl in 0.9% Sodium Chloride, Ephedrine Sulfate 5mg/ml in 0.9% Sodium Chloride, Oxytocin 20 units added to Lactated Ringers Injection USP 1000mL, Diltiazem 1mg/mL in 5% Dextrose, Potassium Chloride 40 mEq added to 250ml 0.9% Sodium Chloride USP, Promethazine HCl 25 mg added to 0.9% Sodium Chloride Injection USP 50mL, and Midazolam HCl 1 mg/mL 0.9% Sodium Chloride Injection USP 100 mL.

iii. The following drug product label does not contain the dosage form: Bupivacaine HCl 0.5%.

*DATES OF INSPECTION:

03/05/2014(Wed), 03/06/2014(Thu), 03/07/2014(Fri), 03/10/2014(Mon), 03/11/2014(Tue), 03/13/2014(Thu)

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