

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	<small>DATE(S) OF INSPECTION</small> 02/20/2013 - 02/28/2013*
	<small>FEI NUMBER</small> 2242985

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Walter T. Kelso, RPh, Center Manager**

<small>FIRM NAME</small> PharMEDium Services LLC	<small>STREET ADDRESS</small> 43 Distribution Blvd
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Edison, NJ 08817-6005	<small>TYPE ESTABLISHMENT INSPECTED</small> 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:**

For the aseptic production of all sterile drug products such as: Propofol 1% Injection Emulsion, USP, 10 mg/ml (Lot 13050021E Exp 3/21/2013); Nicardipine HCL 40mg added to 250mL 0.9% Sodium Chloride Injection USP (Lot 13052010E, Exp. 5/22/2013); Oxytocin 30 units added to 500mL 0.9% Sodium Chloride Injection USP (Lot 13051036E Exp 5/7/2013); and Vancomycin HCL 1.25g added to 250mL 0.9% Sodium Chloride Injection USP (Lot 1352018E Exp 3/23/2013):

**PRODUCTION SYSTEM**

**OBSERVATION 1**

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

Specifically, sterile drug products are aseptically manipulated by the cleanroom operators who wear (b) (4) gloves, per gowning procedure CPS-305, issue date 11/30/2012. The quality of the sterile gown may be compromised by the gowning sequence, which requires the operators to touch the sterile gown with their bare hands. Additionally, the cleanroom exit and re-entry process used by the operators may further compromise the quality of the sterile gown, because the gowns are re-used and re-handled.

**LABORATORY SYSTEM**

**OBSERVATION 2**

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

Specifically,

A.) Of the (b) (4) lots of sterile drug product produced in 2012, only 52 lots were tested for sterility.

B.) There is no endotoxin testing data for any of the lots of sterile drug produced from 1/2012 to the present date.

<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Russell Glapion, Investigator <i>Russell Glapion</i> James A. Liubicich, Investigator <i>James A. Liubicich</i>	<small>DATE ISSUED</small> 02/28/2013
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**OBSERVATION 3**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Identification and potency testing is not routinely performed on most of the firm's 30 or more sterile drug products produced. Specifically, only 12.7% of the lots produced in 2012 were tested; approximately (b) (4) of the testing that was done, 99.3% of it was restricted to only two products; Magnesium Sulfate Injection ((b) lots tested) and Oxytocin Injection ((b) lots tested).

**OBSERVATION 4**

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically, the firm's data that are supporting product expiration dates, such as 90 days for Nicardipine HCL (Preservative Free) and 30 days for Vancomycin, is not based on site specific, processing conditions.

All expiration dates were established based on drug products that were produced and tested at a contract laboratory. Additionally, some of the firm's drug products, such as Vancomycin, have not been re-evaluated since 1999.

**MATERIALS SYSTEM**

**OBSERVATION 5**

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

Specifically, there is no antimicrobial effectiveness testing data for sterile drug products containing preservatives, such as Custom Cardioplegia Solution and Propofol.

**OBSERVATION 6**

Written procedures are lacking which describe in sufficient detail the receipt, identification, sampling, testing, and approval of closures.

Specifically,

- A. The firm does not receive or review certificates of sterility for the sterile components used to process sterile drug products.
- B. The firm does not conduct any sampling or testing of sterile finished injectable drug product containers. They are approved and released for use without testing.

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**QUALITY SYSTEM**

**OBSERVATION 7**

Written records of investigation of a drug complaint do not include the findings of the investigation.

Specifically, the firm's complaint investigation # 3712, initiated on 10/05/2012, recorded that two patients experienced fever, chills and flu-like symptoms, after being administered Propofol Injectable Emulsion lot 12271033E. The firm's investigation, which was completed on 11/07/2012, was not thorough because the firm did not have retains available for visual examination and testing. The firm does not collect or store retains for any of their finished sterile drug product lots.

**\* DATES OF INSPECTION:**  
 02/20/2013(Wed), 02/21/2013(Thu), 02/22/2013(Fri), 02/28/2013(Thu)

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