DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	08/24/2015 - 09/24/2015* FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Bruce W. Bagley, General Manager

FIRM NAME	STREET ADDRESS
PharMEDium Services, LLC	12620 W Airport Blvd Ste 130
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sugar Land, TX 77478-6200	Outsourcing Facility

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

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

Specifically,

On 08/24/2015, we observed your firm's pharmacist placing (b)(6) head inside your firm's ISO 5 Laminar Air Flow hood #(b)(4) while collecting the firm's produced drug product, Norepinephrine 4mg (b) (4) 250 mL 5% Dextrose Injection, USP, product code (b) (4), Expiration date 10/21/2015, Lot number 15236112S. Your firm's pharmacist failed to follow your firm's documented SOP, CPS-305, Effective Date: 04/01/2015, Version 13.0, titled Personnel Gowning and Aseptic Technique and Controls, which states "...Do not lean over, in, or against hood/hood surface and avoid having sleeves touch the surface or components."

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,

Given the observed inadequate aseptic processes at your firm, testing is deficient in that your firm failed to perform sterility and endotoxin testing on each produced lot of drug product prior to release and distribution. Your firm reported sterility testing is only performed on (b)(4)% ((b) (4) (b) (4)) of the sterile drug products produced at your facility (b) (4). For example, your firm distributed the following finished drug products prior to sterility testing:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jason R. Caballero, Investigator Stephen D. Brown, Investigator Camerson E. Moore, Investigator	09/24/2015

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- Norepinephrine 4mg (b) (4) 250 mL 5% Dextrose Injection, USP, product code (b) (4) total units compounded, Expiration date 10/21/2015, Lot number 15236112S, was prepared on 08/24/2015, was shipped on 08/25/2015;

- Magnesium Sulfate 4g (b) (4) 50mL 0.9% Sodium Chloride, USP, product code (b) (4) total units compounded, Expiration date 10/09/2015, Lot number 15237091S, was prepared on 08/25/2015, was shipped on 08/25/2015;

- Vancomycin HCl 2g (b) (4) 500mL 0.9% Sodium Chloride Injection, USP, product code (b) (4) total units compounded, Expiration date 09/25/2015, Lot number 15238397S, was prepared on 08/26/2015, was shipped on 08/26/2015;

- Oxytocin 30 Units (b) (4) 1000mL Lactated Ringer's, product code (b) (4) total units compounded, Expiration date 10/04/2015, Lot number 15237111S, was prepared on 08/25/2015, was shipped on 08/25/2015.

****THIS IS A REPEAT OBSERVATION FROM THE 2013 ESTABLISHMENT INSPECTION****

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.

Specifically,

Potency testing is deficient in that your firm does not perform potency testing on each lot of product prior to release and distribution. Potency testing is only performed on (b) (4) (b) (4) (b) (4) (b) (4)) of the drug products produced at your facility (b) (4) . For example, your firm distributed the following finished drug products prior to potency testing:

- Norepinephrine 4mg (b) (4) 250 mL 5% Dextrose Injection, USP, product code (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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total units compounded, Expiration date 10/21/2015, Lot number 15236112S, was prepared on 08/24/2015, was shipped on 08/25/2015;

- Magnesium Sulfate 4g (b) (4) 50mL 0.9% Sodium Chloride, USP, product code (b) (4) total units compounded, Expiration date 10/09/2015, Lot number 15237091S, was prepared on 08/25/2015, was shipped on 08/25/2015;

- Vancomycin HCl 2g (b) (4) 500mL 0.9% Sodium Chloride Injection, USP, product code (b) (4) total units compounded, Expiration date 09/25/2015, Lot number 15238397S, was prepared on 08/26/2015, was shipped on 08/26/2015;

- Oxytocin 30 Units (b) (4) 1000mL Lactated Ringer's, product code (b) (4) total units compounded, Expiration date 10/04/2015, Lot number 15237111S, was prepared on 08/25/2015, was shipped on 08/25/2015.

****THIS IS A REPEAT OBSERVATION FROM THE 2013 ESTABLISHMENT INSPECTION****

OBSERVATION 4

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

Specifically,

The upper and lower potency limits established by your firm for injectable drug products are outside of the USP acceptable range of 90%-110%. For example:

- Oxytocin 20 Units per Liter is (b) (4)
- Oxytocin 30 Units per Liter is (b) (4)
- Oxytocin 60 Units per Liter is (b) (4)

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OBSERVATION 5

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

Specifically,

Your firm uses a non-sterile cleaning agent ((b) (4)) for the internal and external cleaning and sanitization of all (b) (4) your firm's ISO 5 Laminar Air Flow hoods (b) (4) (b) (4) . Also, your firm uses a non-sterile cleaning agent (b) (4) in the cleaning and sanitization of the ISO 7 areas of the cleanroom on (b) (4) .
In addition, the environmental monitoring conducted in the ISO 5 Laminar Air Flow hoods and adjoining ISO 7 areas is deficient in that:

- The personnel working in the ISO 5 Laminar Air Flow hoods are monitored (b) (4) and not on (b) (4) .
- The walls in the ISO 7 adjacent area are monitored (b) (4) and not on (b) (4) (b) (4) .

OBSERVATION 6

The batch production and control records are deficient in that they do not include specimen and copy of labeling.

Specifically,

Your firm's batch production records do not include the shipper label which includes relevant labeling information such as the adverse event reporting contact information.

OBSERVATION 7

The labels of your outsourcing facility's drug products are deficient.

The labels and containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B).

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Specifically,

The following information is not found on some of your drug product labels, as required by 503B(a)(10)(A):

1. The statement "This is a compounded drug"
2. The date that the drug was compounded.
3. The inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

The following information is not found on the container labels for products you produce, as described in 503B(a)(10)(B)).

1. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug product labels that do not contain this information include:

- HEPARIN 25,000 USP Units (b) (4) 250 mL 5% Dextrose Injection USP
- MAGNESIUM SULFATE 25 g(b) (4) 250 ml Lactated Ringer's Injection USP
- Vasopressin 40 Units (b) (4) 100 mL 0.9% Sodium Chloride Injection USP

For purposes of 503B(a)(10)(B) container labeling, the clear plastic bag enclosing your bagged products should be considered the "container" for purposes of this requirement and bear the information required by 503B(a)(10)(B).

* **DATES OF INSPECTION:**
08/24/2015(Mon), 08/25/2015(Tue), 08/26/2015(Wed), 08/27/2015(Thu), 08/28/2015(Fri), 08/31/2015(Mon), 09/01/2015(Tue), 09/02/2015(Wed), 09/03/2015(Thu), 09/04/2015(Fri), 09/10/2015(Thu), 09/14/2015(Mon), 09/15/2015(Tue), 09/16/2015(Wed), 09/17/2015(Thu), 09/23/2015(Wed), 09/24/2015(Thu)

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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 judgement, 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."