DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973)331-4969 Industry Information: www.fda.gov/oc/industry	10/4/2016, 10/6, 10/7, 10/11, 10/13, 10/24/2016
	FEI NUMBER 3012837733

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. John F. Walker, COO

FIRM NAME	STREET ADDRESS
PharmScript, LLC	150 Pierce Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Somerset, NJ 08873-4185	Producer of Non-sterile and 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) (WE) OBSERVED:

OBSERVATION 1

The ISO 5 classified area is located (b) (4), which (b) (4). The design of your IV compounding room (until inspection date) included an unlocked door adjacent to the area designated for 'IV authorized personnel' and more specifically the (b) (4) ISO 5 (b) (4) (b) (4), in which sterile drug products are produced. IV room personnel were able to move in and out of the IV compounding room through this door and your firm has no procedures for providing adequate control of movement while gowning, hand washing, and other aseptic processing occurs.

The following deficiencies related to (b) (4) are noted:

A. Your Policy and Procedures: Sterile IV Admixtures (Revised 6/14/16) note that (b) (4) (b) (4), however it is not recorded if/when they are (b) (4) and for the months of August and September 2016, your personnel have not documented checking for the (b) (4)

B. Although the following deficiencies were recorded in your temperature / pressure / humidity logs, your firm continued production without corrective action:

i. Between 07/01/2016 - 07/25/2016, an IV technician recorded pressures (b) (4) of three significant figures; however, the display can only display up to two significant figures. Specification: (b) (4) (b) (4)). There is no assurance that the (b) (4) was working properly; however approximately (b) (4) prescriptions were produced and dispensed in this timeframe including: Rx (b) (6) (IV-TEFLARO 300MG/100ML NACL) produced and dispensed on July 4, 2016, Rx (b) (6) (IV-VANCO 1.5GM/D5W 250ML) produced and dispensed on 7/14/16, and Rx (b) (6) (IV-OCTREOTIDE 50MCG/50ML NACL) produced and dispensed on 7/21/16.

ii. On 07/28/2016 - 08/02/2016, the reading of the (b) (4) was documented as 0.00 (specification: (b) (4) (b) (4); however, no investigation into this excursion was conducted and approximately (b) (4) prescriptions including Rx (b) (6) (IV-CUBICIN 800MG/100ML NACL) and Rx (b) (6) (IV-TOBRAMYCIN 240MG/

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	LKrueger TBernard	Liatte Krueger, CSO Tonia Bernard, CSO	10/24/2016

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NACL 100ML) were produced and dispensed on 7/30/16 and 7/31/16, respectively.
iii. On 7/04/2016, the reading of the (b) (4) was recorded as 0.14 inWc and the reading of the (b) (6) (b) (4) was recorded as 0.12 inWc. No investigation was conducted into this loss in positive pressure and approximately (b) (4) products were produced on 7/04/16 including: Rx (b) (6) (IV-TEFLARO 300MG/250ML NACL) and Rx (b) (6) (IV-PIPER-TAZO 3.375GM/50ML NS).

OBSERVATION 2
Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Garbing and hand washing is inconsistently and incorrectly performed by IV technicians. IV technicians were observed to not wash forearms (to the elbows), not use sanitizer prior to placing gloves on, and don shoe covers last. Gloves donned for aseptic processing and cleaning are not sterile and do not properly overlap with non-sterile, open-backed gowns. An IV technician engaged in cleaning of the ISO 5 (b) (4) was observed with exposed wrists, facial hair, and clothing (b) (4)

OBSERVATION 3
The ISO 5 (b) (4) was not certified under dynamic conditions. Specifically, your vendor did not perform active smoke studies during certification to verify uni-directional airflow under operational conditions.

OBSERVATION 4
A HEPA filter in the (b) (4) of the ISO 5 (b) (4) failed airflow testing on 10/24/16 (b) (4) during certification. Your firm did not investigate from the date of your latest passing result, (b) (4) to determine if product had been affected.

OBSERVATION 5
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. Specifically, one of the steps in the production of ophthalmic eye drops such as vancomycin and tobramycin is (b) (4) (b) (4) (one of the ingredients in the final sterile preparation) by an IV technician using the (b) (4) (b) (4) There is no assurance that IV technicians are properly (b) (4) without contamination. For

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example, Vancomycin ophthalmic eye drops Rx (b) (6) was prepared on September 2, 2016 by (b) (4) (b) (4) and dispensed on September 3, 2016.

OBSERVATION 6

Cleaning and disinfecting of the ISO 5 (b) (4) is inadequate. For example,

a. Disinfecting agents and cleaning wipes used are not sterile.

b. Sporicidal agents are not used.

c. Non-sterile cleaning wipes, inadequately saturated with cleaning agent, were used to clean the (b) (4) of the (b) (4) Additionally, personnel observed did not clean from back to front.

OBSERVATION 7

Your firm produced non-sterile drugs while (b) (4) without adequate controls to prevent contamination of the production environment and product. Examples include:

Rx#	FacState	DispDt	Drug	PackagedOn
(b) (6)	NJ	10/6/2016	C-SANTYL/MUPIROCIN OINT 1:1	10/6/16 9:10 AM
	NY	10/9/2016	C-VANCOMYCIN 250MG/5ML SUSP	10/9/16 10:17 AM

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