

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax: (973)331-4969		DATE(S) OF INSPECTION 7/30/2018-8/7/2018* FEI NUMBER 3012837733
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED John F. Walker, RPh, Chief Operating Officer		
FIRM NAME PharmScript, LLC	STREET ADDRESS 150 Pierce St	
CITY, STATE, ZIP CODE, COUNTRY Somerset, NJ 08873-4185	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: For the processing of all sterile intravenous (IV) drug solutions such as: Vancomycin 1.25 gm/250 ml Normal Saline; Cefazolin 2 gram/100 ml D5W; Rifampin 300 mg/100 ml Normal Saline; and Meropenem 2 gram/100 ml Normal Saline (e.g. RX (b) (6)), processed 7/30/2018 and shipped to NY):</p>		
<p>OBSERVATION 1 You produced beta-lactam drugs without providing adequate containment, segregation and cleaning of work surfaces to prevent cross-contamination.</p> <p>Specifically, your firm is processing beta-lactams in the same ISO 5 hood as non-beta-lactam sterile injectable IV products, without adequate cleaning of work surfaces.</p> <p>Additionally, on 8/2/2018 we observed a sterile beta-lactam drug product, Meropenem IV solution, 2 grams/100 ml (RX (b) (6)), being processed, in the "left" ISO 5 hood. During that processing, a small quantity of the beta-lactam drug product sprayed on the interior back side of the ISO 5 hood, when the (b) (4) This surface supplies the (b) (4) flow of HEPA filtered air across the critical ISO 5 area. That surface of the ISO 5 hood was not cleaned and sanitized before a non-beta-lactam drug product, Methylpredisone IV solution 40 mg /100 ml 0.9% NaCl (RX (b) (6)), was processed.</p>		
<p>OBSERVATION 2 The use of sporicidal agents in the ISO 5 classified aseptic processing area was inadequate.</p>		
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		Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 08-07-2018 10:11:02 X

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<p>Specifically, your firm was not using a sporicide to periodically sanitize your ISO 5 hoods. Your ISO 5 hoods were only being sanitized with (b) (4) Sporicide use was limited to other cleanroom surfaces.</p>		
<p>OBSERVATION 3</p> <p>Personnel engaged in aseptic processing were observed with exposed hands, exposed wrists and exposed hair.</p> <p>Specifically,</p> <p>A. Your cleanroom operators exposed their bare hands and wrists inside the ISO 5 area, as part of your gowning procedure for donning sterile gloves. Sterile injectable drug products were then aseptically processed in this area.</p> <p>B. Your cleanroom operators exposed their facial skin and the hair around their eyes and forehead to the ISO 5 area. This occurred while aseptically processing sterile injectable drug products and during sanitization of the ISO 5 hood between drug products. On 7/30/2018, we observed on two occasions that your cleanroom operators processed sterile injectable drug products, while not wearing the sterile gown hood over their hairnet.</p>		
<p>OBSERVATION 4</p> <p>Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.</p> <p>Specifically, we observed some poor aseptic practices, such as:</p> <p>A. On 7/31/2018, your cleanroom pharmacy technician used a bottle of (b) (4) that fell from the cart to the floor of the ISO 7 buffer room three (3) times. That bottle was used without wiping the bottle itself, which then became a potential source of contamination to the technician's gloves and the other surfaces upon which that bottle was rested.</p>		
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<p>B. On 7/31/2018, your cleanroom pharmacy technician touched the base of a chair in the ISO 7 buffer room immediately before processing in the ISO 5 area without sanitizing his gloves.</p> <p>C. On 7/31/2018 and 8/2/2018, individually packaged (b) (4) wipes, stored immediately beneath the ISO 5 processing hood in the ISO 7 area, were not sanitized prior to them being introduced into the ISO 5 area.</p> <p>D. On 8/2/2018 a cleanroom operator allowed the sleeves of the gown to touch the floor of the ISO 8 ante room during the gowning process. That operator then proceeded with that same gown to aseptically process sterile drug products, a process that requires them to extend their gloved hands and gowned arms into the ISO 5 hood.</p> <p>E. Materials, such as the loose IV bag port seals stored in bins on a (b) (4) cart in the ISO 7 area, were not being adequately sanitized before moving them from the ISO 7 area to the ISO 5 hood. Additionally, the solid structure of the cart and the bins do not facilitate the continuous flow of HEPA filtered air across these items.</p>			
<p>*DATES OF INSPECTION 7/30/2018(Mon), 7/31/2018(Tue), 8/01/2018(Wed), 8/02/2018(Thu), 8/07/2018(Tue)</p>			
<p>Russell J Glapion Investigator Signed By: Russell J. Glapion -S Date Signed: 08-07-2018 10:11:38</p> <p>X _____</p>			
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