

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Detroit District Office 300 River Place Dr., Suite 5900 Detroit, MI 48207 313-393-8100 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 2/6-9/17, 2/21/17, 2/23/17
	FEI NUMBER 3009215346

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Mr. Robert Kulak, R.Ph. Director of Pharmacy

FIRM NAME PharMerica LLC	STREET ADDRESS 6330 E. 75th St. Suite 322
CITY, STATE AND ZIP CODE Indianapolis, IN 46250	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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

**Observation 1**

Personnel engaged in aseptic processing were observed with exposed hands, wrists, hair, or mouth.

Specifically,

During the production of prescription numbers (b) (6) performed on 2/6/17 as well as the production of ondansetron 2mg/ml batch number B:36222 performed on 2/7/17, the technician was observed donning sterile gloves in the ISO5 hood. While donning the sterile gloves the technician's bare hands were exposed to the ISO5 environment.

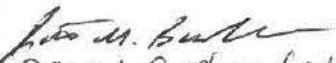

Additionally, during the production of prescription numbers (b) (6) performed on 2/6/17 as well as the production of ondansetron 2mg/ml batch number B:36222 performed on 2/7/17, the technician was observed wearing a non-sterile gown while working in the ISO5 hoods. The sleeve portion of this gown was observed to be exposed to the ISO5 environment during production.

**Observation 2**

Personnel were observed manipulating sterile components outside of the ISO 5 area.

Specifically,

During the production of ondansetron 2mg/ml batch number B:36222 performed on 2/7/17, the technician opened a container of sterile syringe caps in the ISO7 area and then placed them in the ISO5 hood. The technician then completed the filling of the final two syringes from this lot.

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**Observation 3**

Disinfecting agents and cleaning pads or wipes used in the aseptic processing areas are not sterile.

Specifically,

The (b) (4) solution used to sanitize the ISO7 and ISO8 clean rooms, as well as the (b) (4) used to sanitize surfaces of materials transported into the ISO7 cleanroom, are not labeled as sterile.

Additionally, the wipes currently used in the ISO7, ISO8, and the ISO5 LFUs are not labeled as sterile or low lint/shedding wipes. A technician was observed using these wipes to sanitize the interior ISO5 hood surfaces. This technician was also observed using these wipes to clean up a product spill during the filling of ondansetron 2mg/ml batch number B:36222 on 2/7/17. The wipes were observed making contact with the sterile (b) (4)

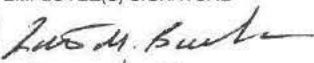
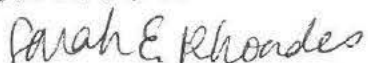
**Observation 4**

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically,

During the production of prescription numbers (b) (6) performed on 2/6/17 as well as the production of ondansetron 2mg/ml batch number B:36222 performed on 2/7/17, the technician was observed leaving the ISO5 hood to retrieve additional materials needed during compounding. However, the technician did not sanitize their hands again each time prior to performing work in the ISO5 hoods.

**Observation 5**

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Equipment, materials and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,

While observing the sanitization of your ISO7 clean room performed on 2/7/17 the technician was observed placing a bottle of (b) (4) a bottle of sanitizing solution, and empty biohazard bags into the ISO5 C1 hood. None of these items were sanitized prior to placement on the ISO5 hood working surface.

Additionally, one of the biohazard bags was observed to fall on the floor. The technician then picked the biohazard bag up and placed it back into the ISO5 hood without sanitizing the surface of the bag. The technician was also observed to have cleaned the floor of the clean room with a tacky mop. The technician changed the mop head but did not change their sterile gloves or sanitize their hands prior to sanitizing the two remaining hoods or returning the fallen biohazard bag back into the ISO5 hood.

ISO5 hoods are used for performing all sterile production of your firm's sterile products.

**Observation 6**

Surfaces in the classified areas are not disinfected.

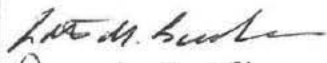
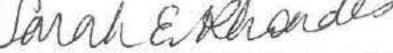
Specifically,

The (b) (4) located on the rear interior wall of the ISO5 hoods are not sanitized during routine daily sanitization of the hoods.

The ISO5 hoods are used for performing all sterile production of your firm's sterile products.

**Observation 7**

Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 areas.

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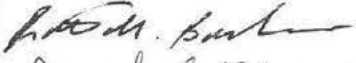
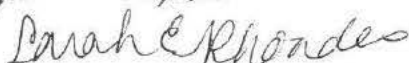
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Specifically,  
 The cleaning procedure for the ISO5 hoods includes the use of (b) (4)  
 (b) (4). There is currently no requirement for using a sporicidal agent for cleaning these hoods.  
 The ISO5 hoods are used for performing all sterile production of your firm's sterile products.

Observation 8  
 The media fill program does not represent all aseptic activities performed.  
 Specifically,  
 Your firm's current media fill program requires that (b) (4)  
 (b) (4). However this process does not represent the production process for  
 the ondansetron 2mg/ml and metoclopramide 5mg/ml as your current media fill process does not include the  
 (b) (4) using a system similar to  
 the one used during the filling of ondansetron 2mg/ml and metoclopramide 5mg/ml products.

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