

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION  7/11-7/15; 7/20; 7/22; 7/27; 8/4/2016
	FEI NUMBER  3012562031

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Shabir M. Somani, MS, MBA, RPh, Chief Pharmacy Officer

FIRM NAME  University of Washington Medical Center Inpatient Pharmacy	STREET ADDRESS  1959 NE Pacific St, Box 356015
CITY, STATE AND ZIP CODE  Seattle, WA 98195	TYPE OF ESTABLISHMENT INSPECTED  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 (I) (WE) OBSERVED:

**OBSERVATION 1**

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

Specifically,

A) On July 11, 2016 during the production of Epinephrine 5 mg in D5W 250 mL (20 mcg/mL), Lot: OG1116A and Nicardipine 25 mg in NS 250 mL (0.1 mg/mL), Lot: OG1116B inside the Small Clean Room:

1) Non-sterile TX 612 TechniCloth Nonwoven Wipers sprayed with sterile 70% isopropyl alcohol were used to clean and wipe down the surface of the Baker ISO 5 horizontal laminar flow hood (LFH), S/N 107347.

B) On July 11, 2016 apparent white debris was observed on the metal filter grate of the Baker ISO 5 horizontal LFH, S/N 116386 located inside the Small Clean Room.


**OBSERVATION 2**

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A) Apparent pitting was observed on the main workbench and apparent pitting and black scratches were observed on the bottom of the metal filter grate of the Baker ISO 5 horizontal LFH, S/N 107347 located in the Small Clean Room.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type)  Gerard P. De Leon, Investigator Gloria J. Baca, Investigator Erica D. Butler, Consumer Safety Officer	DATE ISSUED  8/4/2016
-----------------------------------	--	---	-----------------------------

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION 7/11-7/15; 7/20; 7/22; 7/27; 8/4/2016
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED <b>TO:</b> Shabir M. Somani, MS, MBA, RPh, Chief Pharmacy Officer		FEI NUMBER 3012562031
FIRM NAME University of Washington Medical Center Inpatient Pharmacy	STREET ADDRESS 1959 NE Pacific St, Box 356015	
CITY, STATE AND ZIP CODE Seattle, WA 98195	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products	

B) A door installed in the Small Clean Room, between the ISO 8 anteroom and ISO 7 buffer room, is composed of a sealed, wooden material.

**OBSERVATION 3**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

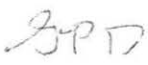
A) Sterilized containers, closures, and utensils that are used in sterile drug production are stored in their original sterilization pouch on a cart in the unclassified Drug Services Laboratory and they are used within three to six months of sterilization. This hold time has not been validated to ensure the sterility of the containers, closures, and utensils.

B) Your practice to "depyrogenate" glass beakers and stir bars used in sterile drug production is inadequate in that they are rinsed with sterile water-for-injection and wiped with a non-sterile TX 612 TechniCloth Nonwoven Wipers prior to use. The outside of the glass beaker is also not wiped with a sterile wipe and sterile 70% isopropyl alcohol prior to introduction into the ISO 5 LFH.

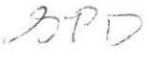
C) Your practice of wiping down components, containers and closures prior to introduction into the ISO 7 buffer room and the ISO 5 LFH is inadequate in that it is performed with a non-sterile TX 612 TechniCloth Nonwoven Wiper sprayed with sterile 70% isopropyl alcohol.

D) On May 26, 2016, the Baker S/N # 118435 ISO 5 horizontal LFH and the Baker S/N # 118436 ISO 5 horizontal LFH in the Large Clean Room were certified under at rest/static conditions. The Baker S/N # 118435 ISO 5 horizontal LFH was observed in use during the production of Magnesium Sulfate/Dextrose 5% 8 mEq/52 mL IVPB Once 208 mL/hr on July 11, 2016.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE ( <i>Print or Type</i> ) Gerard P. De Leon, Investigator Gloria J. Baca, Investigator Erica D. Butler, Consumer Safety Officer	DATE ISSUED 8/4/2016
-----------------------------------	--	--	-------------------------

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION  7/11-7/15; 7/20; 7/22; 7/27; 8/4/2016	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  TO: Shabir M. Somani, MS, MBA, RPh, Chief Pharmacy Officer		FEI NUMBER  3012562031	
FIRM NAME  University of Washington Medical Center Inpatient Pharmacy	STREET ADDRESS  1959 NE Pacific St, Box 356015		
CITY, STATE AND ZIP CODE  Seattle, WA 98195	TYPE OF ESTABLISHMENT INSPECTED  Producer of Sterile Drug Products		
<p>E) An in situ air pattern analysis (smoke study) of the following has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions:</p> <p>1) The Baker S/N # 116386 ISO 5 horizontal LFH, Baker S/N # 107347 ISO 5 horizontal LFH, and ISO 7 buffer room in the Small Clean Room.</p> <p>2) The Baker S/N # 165579101014 ISO 5 compounding aseptic isolator, Baker S/N # 118435 ISO 5 horizontal LFH, Baker S/N # 118436 ISO 5 horizontal LFH, and ISO 7 buffer room in the Large Clean Room.</p>			
<p><b>OBSERVATION 4</b></p> <p>Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed.</p> <p>Specifically, on July 11, 2016 the side of an operator's non-sterile gown was observed coming into direct contact with the inner liner of a receptacle container that was stored adjacent to the ISO 5 horizontal LFH in the Large Clean Room. The operator then proceeded to work in the Baker S/N # 118435 ISO 5 horizontal LFH with the front parts of the non-sterile gown exposed inside and in direct contact with the ISO 5 LFH work surface.</p>			
<p><b>OBSERVATION 5</b></p> <p>Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.</p> <p>On June 25, 2016 an air handling unit that supplied air to the ISO 7 buffer room and ISO 8 anteroom located in the Small Clean Room was shut off for approximately five hours. The air supplied to the ISO 7 buffer room and ISO 8 anteroom was not recertified to verify the classification of the room and environmental monitoring of the room was not performed prior to resuming sterile drug production on June 25, 2016.</p>			
Add Continuation Page			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE ( <i>Print or Type</i> )  Gerard P. De Leon, Investigator Gloria J. Baca, Investigator Erica D. Butler, Consumer Safety Officer	DATE ISSUED  8/4/2016

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION 7/11-7/15; 7/20; 7/22; 7/27; 8/4/2016
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED <b>TO:</b> Shabir M. Somani, MS, MBA, RPh, Chief Pharmacy Officer		FEI NUMBER 3012562031
FIRM NAME University of Washington Medical Center Inpatient Pharmacy	STREET ADDRESS 1959 NE Pacific St, Box 356015	
CITY, STATE AND ZIP CODE Seattle, WA 98195	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products	

**OBSERVATION 6**

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

A) The following sterile drug products that undergo sterility testing are not held under quarantine (pending sterility testing results) and are released for distribution:

- Fentanyl PCA 1250 mcg/25 mL, BUD 30 days refrigerated
- Hydromorphone PCA 25 mg/25 mL, BUD 30 days refrigerated
- Morphine PCA 125 mg/25 mL, BUD 30 days refrigerated

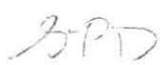
B) Endotoxin testing is not performed on each finished batch or representative finished batches of finished sterile drug products. For example, endotoxin testing is not performed on batches of the following sterile drug products:

- Fentanyl PCA 1250 mcg/25 mL, BUD 30 days refrigerated
- Hydromorphone PCA 25 mg/25 mL, BUD 30 days refrigerated
- Morphine PCA 125 mg/25 mL, BUD 30 days refrigerated

C) Samples submitted for testing to a third-party laboratory are pooled together and analyzed as one sample. For example,

- 1) 4 out of 42 vials (20 mL each) of PBS 0.05M Sterile Injection Solution 20 mL, DS Lot # 7105 were submitted for potency, sterility, endotoxin, and fungi testing.
- 2) 3 out of 25 vials (10 mL each) of Phenol Aqueous 5% Sterile Injection 10 mL, DS Lot # 7258 were submitted for potency, sterility, endotoxin, and fungi testing.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE ( <i>Print or Type</i> ) Gerard P. De Leon, Investigator Gloria J. Baca, Investigator Erica D. Butler, Consumer Safety Officer	DATE ISSUED 8/4/2016
-----------------------------------	--	--	-------------------------



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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  22215 26th Ave SE, Suite 210 Bothell, WA 98021 (425) 302-0340  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION 7/11-7/15; 7/20; 7/22; 7/27; 8/4/2016
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED <b>TO:</b> Shabir M. Somani, MS, MBA, RPh, Chief Pharmacy Officer		FEI NUMBER 3012562031
FIRM NAME University of Washington Medical Center Inpatient Pharmacy	STREET ADDRESS 1959 NE Pacific St, Box 356015	
CITY, STATE AND ZIP CODE Seattle, WA 98195	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products	

**OBSERVATION 7**

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a stability program or any stability data to support the beyond use date (BUD) assigned to the following sterile drug products that are produced in anticipation of use:

- Fentanyl PCA 1250 mcg/25 mL, BUD 30 days refrigerated
- Hydromorphone PCA 25 mg/25 mL, BUD 30 days refrigerated
- Morphine PCA 125 mg/25 mL, BUD 30 days refrigerated

**OBSERVATION 8**


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

Specifically, the non-sterile attire worn by the operators on July 11, 2016 during the production of Magnesium Sulfate/Dextrose 5% 8 mEq/52 mL IVPB Once 208 mL/hr in the Large Clean Room and during the production of Epinephrine 5 mg in D5W 250 mL (20 mcg/mL), Lot: OG1116A and Nicardipine 25 mg in NS 250 mL (0.1 mg/mL), Lot: OG1116B in the Small Clean Room was inadequate as follows:

A) Operators producing sterile drug products in the Baker S/N # 118435 ISO 5 horizontal LFH (Large Clean Room) and Baker S/N # 107347 ISO 5 horizontal LFH (Small Clean Room) were observed wearing a disposable non-sterile head cover, non-sterile surgical mask, non-sterile gown, and non-sterile shoe covers.

B) The disposable non-sterile surgical mask and non-sterile head cover worn by the operators in the Large Clean Room and Small Clean Room did not provide adequate coverage to the forehead, neck or face. Both operators were also not wearing protective eyewear and the operator in the Small Clean Room was observed to be wearing eye makeup.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE ( <i>Print or Type</i> ) Gerard P. De Leon, Investigator Gloria J. Baca, Investigator Erica D. Butler, Consumer Safety Officer	DATE ISSUED 8/4/2016
-----------------------------------	--	--	-------------------------