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	04/11/2016 - 04/28/2016* FEI NUMBER 3011624368

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Steven D. Weeks, Executive Vice President & COO

FIRM NAME	STREET ADDRESS
Baptist Health Medical Towers Pharmacy and Infusion Services	9601 Baptist Health Dr Ste 109
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Little Rock, AR 72205-6323	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 OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, the ISO 8 Ante Room does not have a HEPA filter. Per your Clinical Pharmacy Manager the HEPA filter, (b) (4) and box were removed the morning of 1-7-16. The room was last certified as ISO 8 on (b) (4) Approximately (b) (4) orders (b) (4) units) were dispensed from January 2016 to April 15, 2016.

OBSERVATION 2

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

Specifically, the following deficiencies were observed during the current inspection

1) Your clean room facility design is insufficient in that:

   a. The ISO 7 Buffer Room floor is uneven and contains too numerous to count areas filled in with clear epoxy ranging in size from a penny to a credit card.

   b. On 4-11-16, hood (b) (4) contained a whitish-yellowish build up in the lip of the workbench which comes in direct contact with operator gowning; white residue-like build up on the perforated metal diffuser and a HEPA filter which appeared to have rust colored spots.

   c. On 4-11-16, hood (b) (4) which houses the (b) (4), had a white residue-like build up on the perforated metal diffusers and the HEPA filter appeared to have rust colored spots.

   d. The HEPA Filter located in the NW corner of the ISO 7 Buffer Room (closest to the gift shop and retail pharmacy counter) contained two blackish areas approximately the size of a golf ball and a quarter.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Latorie S Jones, Investigator	04/28/2016

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2) Your firm continued to produce drug products purporting to be sterile when positive growths were observed during viable air testing performed by your contractor on the following dates (b) (4) (b) (4). The growth results can be seen summarized in the table below:

Date	CFU count	Positive Growth	Use of Area with Positive Growth
(b) (4)		(b) (4)	
	18	Microbacterium saperdae, other bacteria, Phylobacterium rubiacearum, staphylococcus epidermis	Yes, approximately (b) (4) sterile drug orders (b) (4)
	20	Gram negative rods, other fungi bacillus, gram positive rods, micrococcus, Staph. Coagulase (-)	Yes, approximately (b) (4) sterile drug orders (b) (4) (b) (4)
	18	Other fungi, gram positive rods, micrococcus, Staph. Coagulase (-)	Yes, approximately (b) (4) sterile drug orders (b) (4)
	250	Gram negative rods, other fungi, yeasts, bacillus, gram (+) rods, micrococcus, Staph. Coagulase (-)	Yes, approximately (b) (4) sterile drug orders (b) (4)
	2	Curtobacterium	Yes, approximately (b) (4) sterile drug orders (b) (4) (b) (4)
		(b) (4)	
	2	Not identified;(b) (4) positive 250 CFU on same date	Yes, approximately (b) (4) sterile drug orders (b) (4) (b) (4)
	1	Micrococcus	Yes, approximately 4,500 sterile drug orders (b) (4) (b) (4)
		(b) (4)	

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(b) (4)	1	Bacillus	Yes, approximately (b) (4) sterile drug orders (b) (4)

*Note: (b) (4) were only tested (b) (4)

3) Your operators failed to clean the rubber (b) (4) of the (b) (4) located inside of Hood (b) (4) on 4/12/16. The (b) (4) of the (b) (4) were moved back and forth through whitish substance on the workbench.

4) Empty (b) (4) housed inside of the ISO 7 Buffer Room contained a build-up of lint in the grooves of the (b) (4) (b) (4) after being sprayed with (b) (4) and subsequently wiped with a sterile lint free cloth.

5) On 4-12-16 I observed non-sterile, non-sporicidal (b) (4) was (b) (4) per the manufacturing instructions in a spray bottle then subsequently sprayed on equipment inside of the Buffer Room to include ISO 5 work benches, (b) (4) and (b) (4). The instructions for use state (b) (4) .

Furthermore, the (b) (4) was (b) (4) beyond the manufacturer's instructions prior to mopping the Buffer Room.

In addition, the firm also (b) (4) the following non-sterile cleaning agents for the ISO 5, ISO 7 and ISO 8 areas:

- (b) (4) [a non-sporicidal agent]
- (b) (4) [a non-sporicidal agent]
- (b) (4)

OBSERVATION 3

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

Specifically,

1. Improper donning of sterile gloves in which the operator touched the critical surface of the glove with their bare hand. This practice was observed repeatedly during production of RX (b) (6) - TPN (b) (4) on 4/11/16. In addition, operators were observed moving between the ISO 7 Buffer Room and the ISO 8 Ante Room without sanitizing or changing their sterile gloves prior to placing them back inside of the ISO 5 zone during compounding of RX (b) (6) TPN (b) (4) on 4-11-16 and during cleaning of the ISO 5 zones on 4-12-16.
2. Sterile sleeve donned by operator was used to move (b) (4) closer to hood, then sleeve was placed back inside of ISO 5 zone and observed resting inside of the ISO 5 workbench while compounding RX (b) (6)-Remicade 600mg in 250mL 0.9% NS on 4/11/16.
3. All items moving from Ante Room to Buffer Room are not always disinfected prior to being introduced to ISO 5

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zone. Specifically, I observed the bags used to make TPN were not disinfected after coming into the Buffer Room and then being opened inside of the ISO 5 zone during the production of RX (b) (6) - TPN (b) (4) on 4/11/16.

4. Your firm's media fills are not performed under the most challenging conditions and do not simulate actual production. Your media fill SOP states to use (b) (4) and (b) (4). On 4/11/16, I observed RX (b) (6) TPN (b) (4) being compounded which used (b) (4) and (b) (4).

   In addition, no positive or negative controls were tested during the media fill. Furthermore, the (b) (4) Media (b) (4) were observed in the storage cage adjacent to the general pharmacy area which contains a (b) (4) near the ambient temperature monitor, per your Director of Pharmacy, because the cage area gets really hot. The (b) (4) (b) (4) states the media should be stored between (b) (4) °C.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. Your firm does not perform viable and non-viable environmental monitoring each day that sterile drug products are produced. Your pharmacy director stated viable air sampling is (b) (4) performed, but you do not document the location or results. Furthermore, SOP Pharmacy 4.4 states "***Air sampling must not be performed (b) (4) (b) (4) ***".
2. Your firm does not perform gloved finger-tip testing each day drugs purporting to be sterile are produced. Your Inventory Specialist stated operators are tested (b) (4) without use of positive and negative controls. Furthermore, your firm uses (b) (4) plates incubated for (b) (4) hours at (b) (4), however, the package insert states the agar should be incubated for (b) (4) hours at (b) (4) then read.
3. Your firm did not monitor the pressure differentials from all areas the entire month of August 2015 and produced approximately (b) (4) sterile orders between August 1-31, 2015.

OBSERVATION 5

Test procedures relative to appropriate laboratory testing for sterility are not followed.

Specifically, your firm failed to follow the instructions for use of the (b) (4) used to (b) (4) test the sterility of TPN. The instructions state to incubate a (b) (4) however, your firm incubators are set at (b) (4) and your inventory specialist stated you incubate at (b) (4) for (b) (4). Your firm has tested approximately (b) (4) TPNs from January 2015 to April 2016.

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OBSERVATION 6

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically, your firm does not thoroughly investigate patient complaints and deviations from your production of sterile products. For example,

1. Incident report dated 3/3/16 states the pharmacist used NaCl (b) (4), lot (b) (4), expiry date 12/2015 while producing NaCl 0.9% with electrolytes 1000mL on 2/18/16 and subsequently dispensed on 2/18/16. No investigation was conducted to determine if the expired lot was used to produce additional sterile drug products.

2. Your firm was notified of 12 patients with hospital admissions or line infections subsequent to receiving drug product purporting to be sterile from your facility between 3-9-15 and 3-23-16. The adverse events were documented in (b) (4), your firm's (b) (4), by nurses, and reviewed Director of Nursing and Clinical Pharmacy Director. Your firm does not investigate to determine if the quality of the drug product is related to the adverse event. For example,

RX#	RX Date	Product	Event Date	Event	Blood Culture
(b) (6)	5/6/15	TPN	5/19/15	Line Infection	Enterococcus
	8/25/15	Milrinone	9/6/15	Line Infection	Stenotrophomonas maltophilia
	7/16/15	TPN	7/23/15	Line Infection	Staph. Coagulase (-)
	1/14/16	TPN	1/20/16	Line Infection	Enterococcus faecalis
	3/18/16	½NS+Sod. Acetate	3/25/16	Line Infection	Gram + Cocci
	9/17/15	Vancomycin	9/19/15	Line Infection	Candida Albicans + Staphylococcus

*Note: Your firm does not conduct any sterility or endotoxin testing on finished product other than (b) (4) testing approximately (b) (4) TPNs produced between January 2015 and April 2016.

OBSERVATION 7

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

Specifically, on 4/11/16, I observed operators donning non-sterile (b) (4) (b) (4) coveralls (item

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(b) (4)), non-sterile (b) (4) single use procedure masks, and non-sterile blue hair nets with exposed skin around the eyes and forehead inside of the ISO 5 zone during production of the following sterile drug products:

- RX (b) (6) Milrinone 200mcg/mL in D5W 600mL bag
- RX Remicade 600mg in 250mL 0.9% NS
- RX TPN (b) (4)
- RX Vancomycin 1gram in 250mL 0.9% NS
- RX Ceftriaxone 1gram AV in 500mL 0.45% NS

Furthermore, on 4-12-16, I observed two technicians don non-sterile (b) (4) (b) (4) coveralls (item (b) (4)) in which the suit continuously came in contact with the floor and tacky mat containing debris in front of the door leading from the ISO 8 Ante Room into the ISO 7 Buffer Room.

OBSERVATION 8

Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, your Clinical Pharmacy Manager stated the (b) (4) pressure gauges were installed approximately 2-3 years ago to monitor pressure differential between the (b) (4) room and (b) (4) room and (b) (4) room to general pharmacy area, but were not calibrated every (b) (4) as indicated by the manufacturing instructions. The first calibration of the pressure gauges was (b) (4) and no COA was provided to certify calibration was to NIST standards.

Furthermore, your firm did not have a pressure gauge measuring the pressure differential from the (b) (4) room to the general pharmacy area until September 2015. In addition, no pressure differentials were documented for the month of August 2015 in which approx. (b) (4) orders were compounded.

*** DATES OF INSPECTION:**
04/11/2016(Mon), 04/12/2016(Tue), 04/13/2016(Wed), 04/14/2016(Thu), 04/15/2016(Fri), 04/18/2016(Mon), 04/19/2016(Tue), 04/20/2016(Wed), 04/28/2016(Thu)

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