

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

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139		DATE(S) OF INSPECTION 12/3/2018-12/14/2018*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Stanley S. Kent, Chief Pharmacy Officer		FEI NUMBER 3003531601
FIRM NAME Michigan Medicine	STREET ADDRESS 1500 E Medical Center Dr	
CITY, STATE, ZIP CODE, COUNTRY Ann Arbor, MI 48109-5000	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

Product labels are printed in the unclassified area and transferred into the ISO 7 buffer room through the (b) (4). The labels are not sanitized or disinfected and are brought directly into the ISO 5 hood to label the product as was observed on 12/3/18 in (b) (4) for Leucovorin Dextrose 5% for Order (b) (6). On 12/6/18, I observed the labels that were printed in the unclassified area to touch the floor after they came out of the printer. These labels were brought into the ISO 7 buffer room without any sanitization.

On 12/3/18, I observed a Sharpie-type pen being used in the ISO 5 hood #1 in (b) (4) to write on the product labels. Your firm stated that these pens are sanitized prior to entering the hoods, however, the pens are opened inside the hood and the pen tip is exposed to the ISO 5 environment. These pens remain inside the ISO 5 hood until they run out of ink.

OBSERVATION 2

Personnel moved rapidly in the vicinity of instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Emily J Orban, Investigator	Emily J Orban Investigator Signed by 2000532336 Date Signed 12-14-2018 07:55:05 X _____	DATE ISSUED 12/14/2018

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Specifically,

On 12/6/18, I observed a technician exhibiting fast movements while working in hood #1 in (b) (4) processing Sodium Chloride Dextrose 15% for Order (b) (6). Additionally, items were wiped with sterile (b) (4) in the ISO 7 buffer room and were tossed into the ISO 5 hood. The items were tossed in so forcefully that many of the items slid across the hood work surface and hit the laminar airflow grate.

OBSERVATION 3

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

Specifically,

On 12/3/18, technicians working in (b) (4) were observed with exposed skin on their face, neck, and foreheads. Also, on 12/6/18, a technician working in hood #1 in (b) (4) had exposed skin on their forehead and was observed with their head inside the ISO 5 hood while processing Sodium Chloride Dextrose 15% for Order (b) (6). This same technician was also observed to rest their elbow of their non-sterile gown and have their sleeve touch the work surface.

OBSERVATION 4

Your facility was designed and/or operated in a way that permits poor flow of materials.

Specifically,

Materials, including sterile drug products and components, are brought into the ISO 7 buffer room directly from an unclassified area through a (b) (4) in both (b) (4) and (b) (4).

OBSERVATION 5

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The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

Specifically,

1. Your firm uses a (b) (4) non-sterile smoke to conduct smoke studies in the ISO 5 hoods. After performing the smoke study, the ISO 5 hood is not disinfected with a sporicidal agent.
2. Cleaning is not adequately documented on the Daily Cleaning Log. For example, the cleaning agent used to clean the ISO 5 hoods in B2 was not always documented in June 2018. Also, a sporicidal agent was not documented as being used to clean the ISO 5 hoods in B2 in July 2018 until the 20th day of the month. The cleaning log states that a sporicidal agent should be used (b) (4)

***DATES OF INSPECTION**

12/03/2018(Mon), 12/04/2018(Tue), 12/06/2018(Thu), 12/14/2018(Fri)

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