DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	12/9/2019-12/17/2019* FEI NUMBER 3011123993

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey S. Steele, Owner and PIC

FIRM NAME	STREET ADDRESS
Infusion Systems of SW Florida Inc. dba Myerlee Pharmacy	1826 Boy Scout Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Myers, FL 33907-2113	Producer of Sterile and Non-sterile Drugs

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 WE OBSERVED:

OBSERVATION 1

Personnel manually contacted the inner surface of the container or closure.

Specifically, on 12/10/19, during the production of Papaverine/Alprostadil/Phentolamine 30MG/2MG/20MCG/mL solution (Trimix), Lot 12-09-2019@36, BUD 01/24/20, we observed the operator using her gloved fingers to (b) (4) the ISO 5 laminar airflow workbench (LAFW). This was also observed during review of your firm's dynamic smoke studies performed 09/30/19 for the (LAFW) and BSC hoods.

OBSERVATION 2

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Specifically, on 09/30/19, your firm's Environmental Monitoring (EM) testing vendor returned 1 cfu/m³ of the actionable microorganism, Aspergillus versicolor, from active air sampling in the LAB (b) (4) Compounding Room. On 11/11/19, your firm returned 1 cfu of the actionable microorganism, Aspergillus versicolor, on settle plate sampling in the LAB (b) (4) AnteRoom. Your firm failed to retest the LAB (b) (4) AnteRoom after cleaning was performed on 11/19/19 and to assess the impact on drug products produced between 09/30/19 to 11/18/19 in the LAB (b) (4) Compounding Room.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Huntington, Investigator Saundrea A Munroe, Investigator	X Jennifer L Huntington Investigator Signed By Jennifer L. Huntington Date Signed 12-17-2019 08:46:26	12/17/2019

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Procedures designed to prevent insanitary conditions are not established or followed.

Specifically,

A) Your firm does not perform endotoxin testing for intrathecal drug products prepared. For example, your firm did not perform endotoxin testing on I-MORPHINE (PF-NS) (40ML) 30 MG/ML SOLUTION, Lot 11-19-2019@4.

B) On 12/10/19, we observed the operator introduce the non-sterile API (b) (4) Papaverine and Phentolamine, into the ISO 5 LAFW during the production of Papaverine/Phentolamine/Alprostadil (Trimix) 30mg/2mg/20mcg/mL, Lot 12-09-2019@36, BUD 01/24/20.

C) Your firm does not (b) (4) Alprostadil 1000mcg/mL multi-dose vial stock solution prior to use in the production of drug products. For example, Alprostadil 1000mcg/mL stock solution, Lot 11-26-2019@32, BUD 04/24/20, was not (b) (4) prior to use in the compounding of Papaverine/Phentolamine/Alprostadil (Trimix) 30mg/2mg/20mcg/mL, Lot 12-09-2019@36, BUD 01/24/20.

D) Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. For example, your firm has a maximum batch size of (b) (4) units with up to (b) (4) mL/vial for high risk drug products however your firm's media fill practice is to (b) (4) (b) (4) vials with (b) (4) /vial.

E) On 12/10/19, we observed the pressure differentials between areas with different air classifications were not monitored and recorded prior to performing the sterile drug production of Papaverine/Phentolamine/Alprostadil (Trimix) 30mg/2mg/20mcg/mL, Lot 12-09-2019@36, BUD 01/24/20.

***DATES OF INSPECTION**

12/09/2019(Mon), 12/10/2019(Tue), 12/11/2019(Wed), 12/12/2019(Thu), 12/13/2019(Fri), 12/16/2019(Mon), 12/17/2019(Tue)

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X Saundrea A Munroe
Investigator
Signed By: Saundrea A. Munroe -S
Date Signed: 12-17-2019 08:47:12

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Jennifer L Huntington, Investigator
Saundrea A Munroe, Investigator

X Jennifer L Huntington
Investigator
Signed By: Jennifer L. Huntington -S
Date Signed: 12-17-2019 08:46:26

DATE ISSUED
12/17/2019

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."