DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313)-393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	06/26-28/2017; 07/11/2017
	FEI NUMBER 3011357279

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William C. Drake, President

FIRM NAME	STREET ADDRESS
Tri-Med Inc. dba Advanced Care Infusion - Shelby	39011 Harper Ave.
CITY, STATE AND ZIP CODE Clinton Township, MI 48036	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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

OBSERVATION 1

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

Specifically,

Prior to processing Lioresal 2000MCG/ML (2X20ML) SYRINGE for (b) (6), (b) (7)(C) on 6/27/17, the (b) (4) box containing the Lioresal ampules was sanitized using non-sterile (b) (4) and a non-sterile wipe in the (b) (4) transfered on a cart into the (b) (4) and placed into the ISO 5 hood without any additional sanitization. Additionally, these same non-sterile wipes are used in the ISO 5 hood (b) (4) (b) (4)

This is a repeat observation of that written on the FDA 483 dated 2/23/2015.

OBSERVATION 2

Personnel engaged in aseptic processing did not use adequate aseptic techniques to ensure drug products remain sterile.

Specifically,

The following was observed prior to and during the processing of Lioresal 2000MCG/ML (2X20ML) SYRINGE for (b) (6), (b) (7)(C) on 6/27/17:

- The technician was wearing non-sterile gloves during sanitization of the ISO 5 hood prior to processing.
- The technician left the ISO 5 hood to retrieve additional materials needed during processing from a cart in the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Emily J. Orban Bei Y. He	Emily J. Orban, Investigator Bei Y. He, Investigator	07/11/2017

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(b) (4) and returned to work in the ISO 5 hood without sanitizing their gloves.
-The technician was observed donning sterile gloves in the ISO 5 hood over a pair of non-sterile gloves, however, the sterile gloves were not donned aseptically.
-While sanitizing the ISO 5 hood with sterile (b) (4) before and after processing, the technician's non-sterile gown sleeve was observed to be in direct contact with the ISO 5 hood surface.
- The technician's movements in the ISO 5 hood or the (b) (4) were not observed to be slow and deliberate, for example, after sanitizing their hands with (b) (4) prior to performing activities, the technician waved their hands around in the ISO 5 hood.

This is a repeat observation of that written on the FDA 483 dated 2/23/2015.

OBSERVATION 3

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

Specifically,

Inadequate aseptic practices were observed while transferring materials for the processing of Lioresal 2000MCG/ML (2X20ML) SYRINGE for (b) (6), (b) (7)(C) on 6/27/17:

- Components were wiped down with non-sterile (b) (4) in the (b) (4) by the technician wearing non-sterile gloves. The components were brought into the (b) (4) and then placed into the ISO 5 hood without disinfecting the components prior to entering the ISO 5 hood.

- The paper box containing the Lioresal ampule resting on a piece of foam was wiped with non-sterile (b) (4) in the (b) (4) The box was opened in the ISO 5 hood and the ampule was removed exposing items that were not sanitized, including the piece of foam and the ampule, to the ISO 5 environment.

This is a repeat observation of that written on the FDA 483 dated 2/23/2015.

OBSERVATION 4

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Pressure differentials are not monitored at least daily in areas where aseptic processing occurs.

Specifically,

Pressure differentials between the (b) (4) and anteroom and the anteroom and unclassified space are not monitored at least daily. The pressure differentials were monitored during the initial qualification of the rooms in 3/2017 and have not been monitored since. Several products have been processed since this initial room qualification, including Lioresal 2000MCG/ML (2X20ML) SYRINGE for (b) (6), (b) (7)(C) on 6/27/17.

This is a repeat observation of that written on the FDA 483 dated 2/23/2015.

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