

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

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 12/08/2014 - 12/12/2014
	FEI NUMBER 3011193301

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jeffrey A. Fenerty R. Ph., Executive Director of Sterile Compounding

FIRM NAME PharmaLogic CSP, Inc.	STREET ADDRESS 9 W Benedum Industrial Park Drive
CITY, STATE, ZIP CODE, COUNTRY Bridgeport, WV 26330	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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:

Facilities and Equipment System

OBSERVATION 1

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

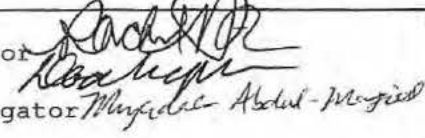
Specifically,

- a) (b) (4), is used to make the disinfectants, (b) (4). The disinfectants are used to clean the ISO 7 "Manufacturing Room" and ISO 8 "Anteroom". No sporicidal agents are used to clean either of these rooms.
- b) The (b) (4) ISO 5 Laminar Air Flow Hoods, which are used to produce sterile drugs, and the (b) (4) pass-through boxes, which are used to bring supplies into the ISO 7 Cleanroom, are only cleaned using sterile (b) (4). No disinfectants or sporicidal agents are used in cleaning.
- c) A sponge mop is used to clean the floors, walls, and ceilings in the ISO 7 Cleanroom and ISO 8 Anteroom with non-sterile (b) (4). The mop is stored in an unclassified area between cleanings for up to a week.
- d) Buckets used to bring (b) (4) from an unclassified common area into the ISO 7 Cleanroom are not wiped or sanitized after contacting multiple non-sterile surfaces including the inside of a sink, the floor of the unclassified common area, and the floor of the ISO 8 Anteroom.

OBSERVATION 2

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

Specifically, there is no written procedure describing the requirements for environmental monitoring in aseptic processing areas, including the frequency of sampling or the action and alert limits for personnel, surface, and air samples. In addition, personnel monitoring is not performed during routine production.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rachel C. Harrington, Investigator Doan T. Nguyen, Investigator Mujadala M. Abdul-Majid, Investigator	DATE ISSUED 12/12/2014
		

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OBSERVATION 3

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

Specifically, there is no documentation showing that pressure gauges are reviewed during production of sterile drugs to demonstrate that appropriate pressure differentials are maintained between classified areas. The pressure differentials are not alarmed or continuously monitored by an electronic system.

Production System

OBSERVATION 4

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

Specifically, the Media Fills/Process Validations for Syringes (2mL, 5mL, 60mL) and PCAs (Patient Controlled Analgesia) ((b) (4)) do not document the actual steps performed during the validation, including the time started and stopped, number of employees involved, interventions, and/or deviations. Furthermore, personnel monitoring is not conducted after completion of media fills. Finally, the firm does not include positive or negative controls when incubating the media filled units.

OBSERVATION 5

Results of stability testing are not used in determining expiration dates.

Specifically, stability studies have not been completed to support the ninety (90) day expiry period on the following released lots of sterile drug products: Fentanyl 10mcg/mL Lot# 11181401, 11181402, 11181403, 11181404, 11181405, 11241401, and 11251401; and Calcium Gluconate 2g in 100mL Lot# 11171401, 11171402, 12031402, 12091401, and 12091402. The studies were initiated in September 2014 for Fentanyl and October 2014 for Calcium Gluconate.

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OF THIS PAGE**

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Rachel C. Harrington, Investigator
Doan T. Nguyen, Investigator
Mujadala M. Abdul-Majid, Investigator

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Materials System

OBSERVATION 6

Each lot of drug product containers and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, Certificate of Analysis reports are not received for each lot of sterile containers and closures, which are used for finished sterile drug products.

Labeling

OBSERVATION 7

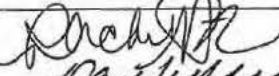
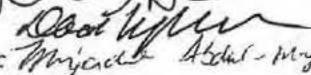

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A).

Specifically, the labels for midazolam 1mg/ml, morphine 1mg/ml, and Pitocin 20 units do not have the statement "This is a compounded drug". Also, none of the labels have the statement "Office Use Only" or the date the drug was compounded.

OBSERVATION 8

The container of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B).

Specifically, the labels for Levophed 4mg, Calcium Gluconate 2g, Morphine 1 mg/ml, Pitocin 20 units, Succinylcholine 20mg/ml, Ketamine 10mg/ml, and Rocuronium 10 mg/ml do not contain administration information.

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