DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/28/2015 - 10/13/2015* FEI NUMBER 3010536120

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joe S. Moore, Owner

FIRM NAME	STREET ADDRESS
Medical Center Pharmacy, Inc.	2401 N Ocoee St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, TN 37311-3853	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

a) Media fills performed for injectable drug products do not simulate the entire production process including but not limited to all process steps and manipulations, (b) (4) performed under ISO 5 classified areas, and all container/closure systems used. Also, media fills performed do not include a challenge of worst case conditions including but not limited to duration of aseptic processing and representative batch sizes. Additionally, positive controls are not used to demonstrate the media is growth promoting.

b) Sterilization (b)(4) (b) (4) (b)(4) (b) (4) have not been validated for (b) (4) (b) (4) finished drug products. (b) (4) have not been evaluated to ensure (b) (4) of finished drug products. Additionally, (b) (4) are not used for (b) (4) or at (b) (4) intervals in accordance with your firm's procedures titled "9.180 Verification of Sterility by (b) (4)" and "8.185 (b) (4) Validation."

c) Depyrogenation (b)(4) using the (b) (4) with serial number (b) (4) have not been validated for depyrogenation of glassware used in the production of sterile drug products. (b) (4) have not been evaluated to ensure the depyrogenation of glassware. Additionally, your firm has not performed an endotoxin challenge for the glassware depyrogenation (b)(4). Furthermore, glassware processed in the (b) (4) (b) (4) is not dated or otherwise tracked to determine acceptability for later use.

OBSERVATION 2

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

Specifically,

a) (b) (4) used for aseptic processing in the Laminar Air Flow Hoods (LAFHs) (ISO 5 areas)

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are not sterile.

b) The frock used for aseptic processing in the LAFHs (ISO 5 areas) is not low linting.

c) Gowning used for processing in the LAFHs (ISO 5 areas) does not provide for adequate coverage of the operator. The gowning components used do not cover the operator's skin on the face and neck and it does not completely cover the operator's clothing. Portions of lower legs are left uncovered by the frock.

d) On 09/28/2015, a previously donned frock and shoe covers were observed to be stored on the door handle of the cleanroom on the anteroom side. A technician with initials (b) (4), was observed to reuse the previously donned frock and shoe covers during (b) (4) of Morphine/Clonidine Injectable lot 09282015@5 in the (b) (4) LAFH (ISO 5 area).

e) (b) (4) are stored uncovered on a shelf in a non-classified area outside the anteroom prior to use in the LAFHs (ISO 5 areas).

OBSERVATION 3

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

Specifically,

a) (b) (4) used to clean the LAFHs (ISO 5 areas) are not sterile. Also, disinfection efficacy studies have not been performed using these cleaning solutions on all materials represented in the LAFHs (ISO 5 areas).

b) (b) (4) used to clean the LAFHs (ISO 5 areas) are not sterile and low linting.

c) On 09/28/2015, a technician with initials (b) (4), (b) was observed to move syringes, (b)(4), caps, and connectors into the (b) (4) LAFH (ISO 5 area) placing them directly on the surface of the bench (inside the ISO 5 area) and then later spraying them with sterile (b) (4).

OBSERVATION 4

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

Specifically,

a) On 09/28/2015, the bulk drug substance for Morphine/ Clonidine Injectable lot 09282015@5 was transported in an (b)(4) (b) (4) and then (b) (4) and set on the work surface of the (b) (4) LAFH (ISO 5).

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b) Full washing and sanitizing of hands, forearms, and fingernails is not required with each entry into the cleanroom according to your firm's procedure titled "4.110 Hand Hygiene Procedures." Instead (b) (4) is only required (b) (4). On 09/28/2015, a technician with initials (b) (4), (b) was observed to leave the cleanroom and anteroom after (b) (4) and then re-enter the cleanroom without (b) (4) prior to the production of Morphine/ Clonidine Injectable lot 09282015@5.

OBSERVATION 5

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

Specifically,

a) Environmental monitoring of the LAFHs (ISO 5 areas) including surface, air, and personnel is not performed each day drug products are produced using the LAFHs. Currently, surface and personnel monitoring is only performed (b) (4). Viable air is not monitored in accordance with your firm's procedure titled "8.173 Laminar Flow Hood (LFH) Environmental Monitoring." Also, (b) (4) samples taken from the (b) (4) (b)(4) on 09/28/2015 were taken (b) (4) (b) (4) instead of (b)(4). Additionally, non-viable particulate monitoring is only performed every (b) (4) the LAFHs.

b) Raw data for smoke studies performed in the LAFHs (ISO 5 areas) were not documented and retained. Also, the test conditions for the smoke studies were not documented.

OBSERVATION 6

Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

a) Air pressure differentials of the anteroom (ISO 7) and cleanroom (ISO 7) are not appropriate for the classification of the rooms:

- Air testing performed by a contractor on (b) (4) measured a pressure differential of .00 inches of water for the anteroom and .032 inches of water for the cleanroom.

- Air testing performed by a contractor on (b) (4) measured a pressure differential of .02 inches of water for the anteroom and .03 inches of water for the cleanroom.

- On (b) (4), air pressure of the anteroom was observed to be .023 inches of water prior to the production of

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Morphine/Clonidine Injectable lot 09282015@5 in the cleanroom.

b) Air pressure differentials of the anteroom (ISO 7) and clean room (ISO 7) are not continuously monitored during production of drug products.

c) The number of air changes per hour for the anteroom is not appropriate for the classification of the room (ISO 7):

- Air testing performed by a contractor on (b) (4) found the number of air changes per hour was 18.6 for the anteroom (ISO 7 area).

- Air testing performed by a contractor on (b) (4) found the number of air changes per hour was 16.2 for the anteroom (ISO 7 area).

OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

a) A (b) (4) Laminar Flow Clean (b)(4) (b) (4) located in the cleanroom is equipped with a (b) (4) work surface with irregular edges and corners, and (b) (4) . According to the Operation and Maintenance Manual for Model (b) (4) , (b)(4) should not be used to clean the (b) (4) due to possible crazing. However, (b) (4) is used in (b) (4) cleaning of the LAFHs.

b) A black chair observed in the cleanroom on 09/28/2015 is not constructed of materials that can be readily sanitized.

c) A (b) (4) mop used to clean the cleanroom floors is not constructed of materials that can be readily sanitized. Also, this (b) (4) mop was observed on 09/28/2015 to be temporarily stored in the hallway outside the anteroom in direct contact with the floor and wall.

d) There is no line of demarcation in the anteroom (ISO7) to separate the clean side from the dirty side.

OBSERVATION 8

The calibration of instruments and gauges is not done at suitable intervals .

Specifically,

An (b) (4) used to perform (b) (4) testing of all (b) (4) has not been calibrated.

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OBSERVATION 9

Drug products failing to meet established standards, specifications, and quality control criteria are not rejected.

Specifically,

A (b) (4) test for the (b) (4) used in the (b) (4) of Morphine/Clonidine Injectable lot 09282015@5 measured (b) (4), however the (b) (4)(b)(4) (b) (4) specification is greater than or equal to (b) (4) (b) (4) This drug product was subsequently released for distribution on 09/28/2015.

OBSERVATION 10

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

Sterility and endotoxin testing is not performed in accordance with your firm's procedures titled "9.130 End Product Sterility Testing" and "9.140 Bacterial Endotoxin (Pyrogen) Testing" which requires (b) (4). Also, sterility and endotoxin testing is not required for all other sterile drug products. According to your firm's procedure titled "9.160 Testing by an Independent Laboratory" sterility and endotoxin testing is only required for (b) (4). A review of your firm's testing records found that the last time sterility and endotoxin testing was performed on a finished injectable drug product was on 03/04/2015.

OBSERVATION 11

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

Potency testing is not performed on every lot of sterile drug product produced by your firm. Potency testing is performed (b) (4) every (b) (4) for sterile preparations according to your firm's procedure titled "9.150 Potency Testing." A review of your firm's testing records found that the last time potency testing was performed for a finished injectable drug product was on 03/11/2015. Additionally, testing performed did not include testing of antimicrobial preservatives for preservative containing drug products.

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OBSERVATION 12

The operations relating to the manufacture, processing, and packing of penicillin are not performed in facilities separate from those used for other drug products for human use.

Specifically,

Beta-lactam containing drug products and cytotoxic drug powders are not prepared in separate areas from non-beta lactam and non-cytotoxic drug products. Examples include but are not limited to the following processes:

- Amoxicillin tablets are (b) (4) in the non-sterile compounding area (lab area).

- Cephalexin capsules are (b) (4) in the non-sterile compounding area (lab area).

- Fluorouracil powder is (b) (4) in the non-sterile compounding area (lab area).

OBSERVATION 13

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Prostaglandin E1 and Tacrolimus (b)(4) are given a 30 day Beyond Use Date (BUD) and held refrigerated. No stability studies have been performed to support these BUDs.

OBSERVATION 14

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

Temperatures of the (b) (4) (b)(4) incubators are not continuously monitored or documented during incubation of media for media fills and environmental samples.

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*** DATES OF INSPECTION:**
09/28/2015(Mon), 09/29/2015(Tue), 09/30/2015(Wed), 10/01/2015(Thu), 10/13/2015(Tue)

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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 judgement, 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."