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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 6000 Metro Drive, Suite 101<br>Baltimore, MD 21215<br>(410) 779-5454 Fax: (410) 779-5707<br>Industry Information: www.fda.gov/oc/industry | 05/09-10/2016, 05/23/2016 |
| | FEI NUMBER<br>3012299349 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joan M. Phillips, Pharmacist

| FIRM NAME | STREET ADDRESS |
|---|---|
| MedPark Pharmacy | 2002 Medical Parkway, Suite 170, Sajak Pavillion |
| CITY, STATE AND ZIP CODE<br>Annapolis, MD 21401 | TYPE OF ESTABLISHMENT INSPECTED<br>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) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, the firm does not consistently test batches of produced sterile and non-sterile drugs to ensure consistency and potency before products are released. (b) (4) drug products, consisting of (b) (4) sterile and (b) (4) non-sterile drug products, are produced by the firm. Final specification tests (sterility and potency) have only been conducted (b) (4). One such test for Trimix resulted in a recall on May 3, 2016, when the results demonstrated that the component Alprostadil (b) (4) (Lot# (b) (4)) failed potency test.

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, the firm does not consistently test every batch of (b) (4) drug product. All sterile drug products are rendered sterile by (b) (4); however these drug products are not consistently checked prior to distribution. The pharmacy does not perform (b) (4) to ensure that the product obtain (b) (4) is free from contamination. Since sterile compounding started in March 2016, sterility has only been tested on the (b) (4) Since 03/15/2016, (b) (4) Trimix prescriptions, containing Alprostadil, have been administered.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE *(Print or Type)* | DATE ISSUED |
|---|---|---|---|
| | Jai Prakash Singh | Tajah L. Blackburn, Investigator<br>Jai P. Singh, Investigator | 05/23/2016 |

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OBSERVATION 3

Drug product containers shall be clean, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated.

Specifically, the firm does not use depyrogenated glassware for the preparation of the sterile drug product prior to (b) (4). Additionally, the firm also does not have the equipment for depyrogenation or a validated process demonstrating that glassware is pyrogen-free. The current practice for cleaning glassware is to (b) (4).

OBSERVATION 4

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

Specifically, the firm rotates between (b) (4) for firm defined "heavy" ((b) (4)) and "light" ((b) (4) when sterile compounding activities are performed) cleaning/disinfecting. None of the currently used disinfectants are sporicidal for disinfecting the ISO 5 area and environment. The firm has not determined disinfectant effectiveness for the (b) (4) products and concentrations that are used for disinfecting. Further, the (b) (4), used during sterile drug production (b) (4) are not sterilized prior to use.

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OBSERVATION 5

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

Specifically, the differential pressure monitoring of the room, normally opened to the retail pharmacy area, is not monitored during manufacture of sterile drug products. Further, when sterile drug manufacturing is conducted, the retail pharmacy is separated from the sterile manufacturing area by a wooden door, and the sterile manufacturing room lacks a HEPA filteration system.

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