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 Baltimore, MD 21215 Ph (410) 779-5455 Fax (410) 779-5707 Industry Information: www.fda.gov/oc/industry	01/09/2017; 01/11/2017; 01/24/2017; 03/09/2017; 03/10/2017
	FEI NUMBER 3012299349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: (b) (6)

FIRM NAME	STREET ADDRESS
MedPark Pharmacy, LLC	2002 Medical Parkway, Sajak Pavilion Suite 170
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Annapolis, MD 21401	Producer of sterile and non-sterile drug products

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

OBSERVATION 1

There is a lack of assurance of the sterility of prepared sterile human drugs and sterile veterinary drugs including injectable and ophthalmic drug products.

Specifically, some of the drug products and (b) (4) used to prepare drug products are made from non-sterile components and are sterilized by (b) (4). However,

(i) (b) (4) performed after (b) (4) of drug products and (b) (4) is not adequate to ensure (b) (4). (b) (4) is conducted by (b) (4). No (b) (4) is used during (b) (4) and no (b) (4) is recorded. (b) (4) is qualitative and recorded as "pass" or "fail" on the formulation sheet. Examples of (b) (4) and drug products (b) (4) include but are not limited to:

(b) (4) (b) (4) Chlorobutanol (b) (4) (Rx (b) (6) prepared (b) (4); BUD (b) (4)
2.Alprostadil (b) (4) (b) (4) (Rx (b) (6) prepared (b) (4); BUD (b) (4)
3.Tri-Mix Super20 30/2/20 (Rx (b) (6) prepared 12/26/16; BUD 02/24/17 - 60 days).
4.Quad-Mix Super 30/2/20/0.1 (Rx (b) (6) prepared 12/21/16; BUD 02/20/2017 - 60 days).

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stacie Woods Djamila Harouaka	Stacie Woods, Consumer Safety Officer Djamila Harouaka, Consumer Safety Officer	03/10/2017

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(ii) (b) (4) vial packs were opened in an unclassified room and were handled with and without gloves. (b) (4) plastic container closures for eye drops containing (b) (4) bottles are opened (b) (4) (b) (4) but if the (b) (4) bottle is not used, it is (b) (4) (b) (4) and then stored in an unclassified environment for (b) (4) before being discarded if it is not used.

This is a repeat observation.

OBSERVATION 2

The system for maintaining environmental conditions in the aseptic processing areas was deficient.

Specifically, sterile drug preparation is conducted (b) (4) (b) (4) by an (b) (4), which is also (b) (4). However, the (b) (4) is located inside of an unclassified room that opens to the general pharmacy area. The (b) (4) when the (b) (4) Furthermore, there are (b) (4) and are open to the air in the unclassified room.

In addition, a pair of sterile gloves are placed (b) (4) The sterile gloves are used to perform (b) (4) to prepare sterile drug products. These (b) (4) approximately (b) (4). In order to (b) (4) of the unclassified room. A (b) (4)

This is a repeat observation.

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OBSERVATION 3

The system for cleaning and disinfection of the critical areas used to prepare sterile drug products is deficient.

Specifically,

(1) The (b) (4) of the unclassified room during the (b) (4) cleaning and disinfection. The (b) (4) is cleaned with a (b) (4) disinfectant and sterile (b) (4).

(2) The disinfectant used to clean the (b) (4) is non-sterile.

(3) The wipes used to clean the (b) (4) are not stored or handled in a manner that maintains sterility. The wipes are purchased sterile in a multi-pack but the pack is opened in an unclassified room.

This is a repeat observation.

OBSERVATION 4

The aseptic technique used to prevent microbiological contamination of drug products purporting to be sterile was deficient.

Specifically, on 01/24/2017 during the preparation of 0.01% atropine eye drops pursuant to Rx (b) (6) (BUD 02/23/17 - 30 days), the operator who prepared the drug passed the (b) (4) over the open sterile finished product container that was holding the (b) (4) sodium chloride (b) (4) interrupting the flow of first air to the container. Furthermore, the (b) (4) sodium chloride (b) (4) The (b) (4) The (b) (4)

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