

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	DATE(S) OF INSPECTION 7/30/2019-8/9/2019*
	FET NUMBER 3015316526

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tushar Palan, MS, RPh, Partial Owner & Pharmacist in Charge

FIRM NAME Medoz Pharmacy of Polk Inc	STREET ADDRESS 40230 Highway 27 Ste 100
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CITY, STATE, ZIP CODE, COUNTRY Davenport, FL 33837-7807	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drugs
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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

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of personnel to prevent cross-contamination.

Specifically, on 10/31/18, according to formulation worksheets, your firm produced (b) (4) of Chorionic Gonadotropin (HCG) 1,000U/mL Injection, lot #10312018@7, BUD: 3 Days and (b) (4) of Cyclosporin (Corn Oil) New 2% Ophthalmic Solution, lot #10312018@10, BUD: 3 Days on the same production day without evidence that cleaning was conducted between batches of hazardous drug products. Both lots were released and dispensed. In addition, your firm failed to identify on the formulation worksheets which ISO 5 BSC (b) (4) (b) (4) was used for these hazardous drug products.

OBSERVATION 2

Vermin was observed in your production area.

Specifically,

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- a) Numerous dead ants were observed (7/30/19 and 7/31/19) on the (b) (4) clean room (where sterile drug products are produced) floors (corners of the room closest to the anteroom door).
- b) Numerous dead ants were observed (7/30/19) along the corners of the walls within the non-sterile suite (where non-sterile drug products are produced). According to your firm's Pharmacist, house hold (b) (4) was used to spray these areas.

Your firm's Pharmacist stated he noticed the pest problem approximately three years ago when construction was occurring within close proximity of his facility. During the current FDA Inspection your firm failed to provide pest control records.

OBSERVATION 3

Vermin was observed in an area immediately adjacent to your production area.

Specifically,

- a) A small dead spider and small dead cockroach were observed (7/30/19) on the anteroom floor (closest to the bench where gowning occurs).
- b) A colony of dead ants were observed (7/30/19) on (b) (4) bag containing sterile stoppers located in the unclassified area (adjacent to the anteroom but separated by a door).
- c) Colonies of small dead ants and living spiders were observed (7/30/19) on the hallway floors and dead insects observed within the light fixtures leading into the non-sterile suite (where non-sterile drugs are produced).

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OBSERVATION 4

The ISO 5 classified aseptic processing areas had visibly dirty equipment or surface.

Specifically,

- a) Your firm's Bio-Safety Cabinet (b) (4) ISO 5 work surface contained blue stains (resembling stamped ink). On 7/31/19, the blue stains were observed on your Pharmacist's gloves and crimping handle during the production of Methylcobalamin, 5mg/mL injection, lot #07312019@1, BUD: 3 Days (b) (4) (b) (4) (b) (4) clean room) and Chorionic Gonadotropin (HCG) 1,000U/mL Injection, lot #07312019@3, BUD: 3 Days (b) (4) (b) (4) clean room) which can potentially cause product contamination.
- b) Your firm's (b) (4) clean room (where sterile drug products are produced) contained cracks within the flooring in front of the Biosafety Cabinet (b) (4) which appear difficult to clean and sanitize.

OBSERVATION 5

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

- a) Your firm stores all gowning components in an unclassified area (non-sterile hair net, sterile gloves, non-sterile gown, non-sterile shoe covers, non-sterile sleeve protectors and non-sterile face mask). Your Pharmacist was observed donning the non-sterile hair net, non-sterile shoe covers, and non-sterile face mask within the unclassified area.

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- b) Within the ISO 8 anteroom your firm's Pharmacist was observed (7/31/19) donning his non-sterile gown (which came into contact with the anteroom floor) and non-sterile sleeve protectors with his bare hands.
- c) Within the ISO 7 (b) (4) clean room your firm's Pharmacist was observed with his bare hands inside the ISO 5 BSC donning his sterile gloves.
- d) Your firm's Pharmacist was observed moving from the ISO 7 (b) (4) clean room, through the ISO 8 anteroom and into the ISO 7 (b) (4) clean room without changing his garb. Prior to conducting aseptic operations within the ISO 5 (b) (4) BSC your Pharmacist changed his gloves, exposing his hands again to the ISO 5 environment (sleeve protectors were never changed).

OBSERVATION 6

Personnel manually contacted the inner surface of the container or closure.

Specifically, your firm's Pharmacist was observed (7/31/19) manually stoppering and touching the inner surface of the stoppers with his gloved hands to the vials of Methylcobalamin, 5mg/mL injection, lot #07312019@1, BUD: 3 Days (b) (4) (b) (4) clean room). On 8/2/19, Rx (b) (6) for (b) (4) of Methylcobalamin, 5mg/mL injection, lot #07312019@1 was released and shipped.

OBSERVATION 7

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

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Specifically, your firm's Pharmacist was observed (7/31/19) carrying the components into each clean room and touching door handles potentially contaminating his garb and components used during aseptic operations.

OBSERVATION 8

HEPA filters were not sealed around each perimeter to the support frame.

Specifically,

- a) On 7/30/19, your firm's ISO 7 (b) (4) clean room contained 1 HEPA filter (b) (4) (b) (4) to be visually un-clean (HEPA and ceiling around the HEPA appeared stained) and not properly sealed.
- b) On 7/30/19, your firm's ISO 7 (b) (4) clean room contained 1 HEPA filter (b) (4) (b) (4) to contain gaps between the ceiling and HEPA frame making it difficult to properly clean and sanitize and chipping paint surrounding the ceiling frame. In addition, your firm's Pharmacist stated the chipping of paint surrounding the ceiling frame is monitored during his daily cleaning checklist.

OBSERVATION 9

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically, your firm's Pharmacist stated he cleans the ISO 5 BSC's with only (b) (4). This practice was observed on 7/31/19. Your firm's Pharmacist stated he does not use a sporicidal agent within the ISO 5 BSC's.

OBSERVATION 10

Environmental monitoring was not performed in your aseptic processing areas.

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Specifically, according to your firm's Pharmacist, Environmental Monitoring (EM) is conducted by your vendor every (b) (4), but after cleaning has occurred therefore making the results unreliable.

OBSERVATION 11

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, uni-directional airflow was not verified under operational conditions within your firm's (b) (4) clean rooms where sterile products are produced.

OBSERVATION 12

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's Media fill dated, 6/12/19 fails to closely simulate current aseptic operations. In addition, no environmental and personnel monitoring was conducted during the media fill.

OBSERVATION 13

Your firm exposed stock solutions, intended to be sterile, to lower than ISO 5 quality air.

Specifically, I observed (7/30/19) the storage of Tacrolimus 10mg/ML Base C Stock, lot #04262019@3, exp.: 7/25/19 and Alprostadil 500 MCG/mL Alcohol Stock, lot #05012019@2, exp.: 10/28/19 solutions in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period.

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OBSERVATION 14

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, your firm is utilizing a non-calibrated AND, Model: (b) (4) balance to weigh active ingredients designated for your firm's non-sterile drug products, therefore lacking assurance if the required amounts are being added to a particular batch.

***DATES OF INSPECTION**

7/30/2019(Tue), 7/31/2019(Wed), 8/01/2019(Thu), 8/09/2019(Fri)

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