

**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 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 8/23/2021-8/27/2021*
	FEI NUMBER 3015316526

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tushar Palan, Pharmacist in Charge

FIRM NAME Medoz Pharmacy of Polk Inc	STREET ADDRESS 40230 Highway 27 Ste 100-110
---	--

CITY, STATE, ZIP CODE, COUNTRY Davenport, FL 33837-7807	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs
--	---

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

Vermin was observed in your production area.

Specifically, on 8/23/21 numerous dead ants were observed along the corners of the walls within your firm's non-sterile hazardous and non-hazardous production areas. Your firm has a (b) (4) pest control service (b) (4) with (b) (4) (Active Ingredient: (b) (4) and on 7/31/21, the service noted unsealed exterior cracks and crevices. Additionally, your non-sterile hazardous production area has a door leading directly to the outside that was observed to contain a (b) (4) gap at the bottom which can allow for the possible ingress of ants.

*****Repeated Observation from Previous 483 issued on 8/9/19**

***DATES OF INSPECTION**

8/23/2021(Mon), 8/24/2021(Tue), 8/27/2021(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator	<small>Jessca L Pressley Investigator Signed By: Jessica L Pressley -6 Date Signed: 08-27-2021 11: 0:36</small> X _____	DATE ISSUED 8/27/2021

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 judgment, 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."