DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	5/16/2023-6/8/2023*
	FEI NUMBER 3002835459

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jennifer D. Yoakum , Pharmacist in Charge and Owner

FIRM NAME	STREET ADDRESS
Med Shop Total Care Inc.	470 E Loop 281
CITY, STATE, ZIP CODE, COUNTRY Longview, TX 75605-7939	TYPE ESTABLISHMENT INSPECTED Produce of Sterile and 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

Lack of routine environmental monitoring in the classified areas.

Specifically, your firm does not perform routine environmental monitoring, of the laptop, located adjacent to the Laminar Flow Hood (ISO5), (b) (4), used to enter data into the logged formula worksheet during sterile human drug production. The surface of the laptop is frequently touched in-between filling sterile human drug products.

For example,

1)During the production of Hydromorphone HCl PF 4MG/ML Injectable 21ml, Lot 05162023@(b) (4), BUD 6/13/2023, I observed the sterile compounding technician touching the keyboard of the laptop to enter data between filling sterile syringes of finished drug product. Your firm does not perform environmental monitoring on the frequently touched surfaces of the laptop. The finished sterile drug product was released by your firm's pharmacist and distributed to the patient.

2)During the production of Morphine Sulfate- Baclofen PF 10/MG/100MCG, Lot 05162023@(b) (4), BUD 6/14/2023, I observed the sterile compounding technician touching the keyboard of the laptop to enter data between filling sterile syringes of finished drug product. Your firm does not perform environmental monitoring on the frequently touched surfaces of the laptop. The finished sterile drug product was released by your firm's pharmacist and distributed to the patient.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Demario L Walls, Investigator	X Demario L Walls Investigator Signed By: Demario L. Walls -S Date Signed: 06-08-2023 11:51:26	6/8/2023

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*DATES OF INSPECTION

5/16/2023(Tue), 5/17/2023(Wed), 5/18/2023(Thu), 6/06/2023(Tue), 6/07/2023(Wed), 6/08/2023(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Demario L Walls, Investigator	X Demario L Walls Investigator Signed By: Demario L. Walls -S Date Signed: 06-08-2023 11:51:26	DATE ISSUED 6/8/2023

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."