DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE 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	7/7/2021-7/27/2021* FEI NUMBER 3002835459

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jennifer D. Yoakum, Pharmacist-in-Charge and Owner

FIRM NAME	STREET ADDRESS
Med Shop Total Care Inc.	470 E Loop 281
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Longview, TX 75605-7939	Producer 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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, you had several environmental monitoring results in the ISO 5 environment where you did not identify the microorganism and continued to produce and distribute sterile drug products without a complete investigation and corrective action taken.

Surface EM- Human			
6/3/2021	2 cfu	ISO 5 ((b) (4))	center of LFH

Fingertips- Vet			
5/25/2021	4 cfu	Left hand	(b) (6)
6/18/2021	1 cfu	Right hand	
6/21/2021	1 cfu	Left hand	

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Claire M. Minden Digitally signed by Claire M. Minden -S Date: 2021.07.27 08:07:55 -05'00'	Claire M. Minden, Investigator	07/27/2021

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1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2 RESPONSES@fda.hhs.gov	7/7/2021-7/27/2021* FEI NUMBER 3002835459

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Fingertips -Human			
3/19/2021	1 cfu	Left hand	(b) (6)
4/16/2021	1 cfu	Right hand	
4/16/2021	1 cfu	Left hand	
4/16/2021	2 cfu	Right hand	
4/19/2021	1 cfu	Left hand	
4/19/2021	1 cfu	Right hand	
4/20/2021	3 cfu	Left hand	
4/20/2021	1 cfu	Right hand	
5/10/2021	3 cfu	Left hand	
5/10/2021	2 cfu	Right hand	
5/17/2021	1 cfu	Left hand	
5/19/2021	2 cfu	Left hand	
5/20/2021	1 cfu	Left hand	
6/9/2021	3 cfu	Right hand	
6/10/2021	1 cfu	Right hand	
6/15/2021	1 cfu	Left hand	
6/16/2021	2 cfu	Left hand	
6/16/2021	1 cfu	Left hand	
6/18/2021	1 cfu	Left hand	
6/18/2021	1 cfu	Right hand	
6/21/2021	3 cfu	Left hand	
6/23/2021	1 cfu	Left hand	
6/23/2021	1 cfu	Left hand	

This is a repeat observation.

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	Claire M. Minden Digitally signed by Claire M. Minden -S Date: 2021.07.27 08:11:14 -05'00'	Claire M. Minden, Investigator	07/27/2021

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1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	7/7/2021-7/27/2021*
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OBSERVATION 2

Your facility design allowed the influx of poor-quality air into a higher classified area.

Specifically,

a) You replaced the condenser and air handler to the sterile suite on the human side on June 25, 2021 and loss pressure beginning Friday, 6/25/21 in (b) (4) room at 11:38 am until 06/27/21 at 14:00. You performed cleaning with (b) (4) on Monday, 6/28/21 after the installation but did not recertify the human side and continued to produce and distribute sterile drugs.

b) Doors between rooms are not fully closed to prevent air flow between classified areas.

OBSERVATION 3

Non-microbial contamination was observed in your production area.

Specifically, the metal screen in front of the HEPA filter for hood, identified as (b) (4), has brownish residue on the lower left portion.

OBSERVATION 4

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, during the (b) (4) cleaning of the clean room I observed on July 9, 2021, the dwell time for (b) (4) solution made with (b) (4) does not stay wet for the recommended labeled time of (b) (4) on LFHs (ISO 5), carts, walls and floors and other items located in the ISO 7 area allowing a dwell time of less than (b) (4).

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OBSERVATION 5

Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically, on July 6, 2021, I observed personnel touch the keyboard or other surfaces multiple times located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

OBSERVATION 6

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

Specifically,

a) 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. You do not include the largest batch size and different container types (vials).
b) The employee who produces the bulk intermediate sterile vials of Baclofen, Bupivacaine, Clonidine, Fentanyl, Hydromorphone and Morphine Sulfate last performed a media fill of this type on February 21, 2020.

This is a repeat observation.

OBSERVATION 7

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

Specifically, after notification from your contract laboratory of a sterility failure for bulk intermediate vial of Bupivacaine (b) (4), lot (b) (4), you recalled drug products that contained this lot.

*DATES OF INSPECTION

7/07/2021(Wed), 7/08/2021(Thu), 7/09/2021(Fri), 7/12/2021(Mon), 7/13/2021(Tue), 7/27/2021(Tue)

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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 judgement, 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."