DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	10/15/2018-11/1/2018* FEI NUMBER 3002835459

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

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) You had several environmental monitoring results where you did not identify the microorganism and continued to produce and distribute sterile drug products without a complete investigation and corrective action taken.

Human	Class		
(b) (4)A	ISO 7	2 cfu (fungal)	5/21/2018
(b) (4)S	ISO 7	1 cfu (fungi)	6/26/2018
(b) (4)S	ISO 7	5 cfu (counted)	7/31/2018
(b) (4)S	ISO 7	TNTC	8/1/2018
(b) (4)S	ISO 7	1 cfu ((b) (4))	8/21/2018
Veterinary			
(b) (4)S	ISO 5	1 cfu	5/22/2018
(b) (4)S	ISO 7	TNTC	5/29/2018

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EMPLOYEE(S) SIGNATURE
Claire M Minden, Investigator

X Claire M Minden
Investigator
Signed By: Claire M. Minden -S
Date Signed: 11-01-2018 12:55:36

DATE ISSUED
11/1/2018

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(b) (4)			
S	ISO 7	1 cfu (fuzzy white)	8/21/2018

A: Air

S: Surface

b) Employees had positive results multiple times for fingertip testing after producing sterile drug products. You did not identify the microorganism and continued to produce and distribute sterile drug products without a complete investigation and corrective action taken.

Human Fingertip		
(b) (6)	3 cfu (L)	4/19/2018
	7 cfu (Rt)	5/29/2018
	3 cfu (L & Rt)	6/5/2018
	1 cfu (L) asperg	6/25/2018
Veterinary Fingertip		
(b) (6)	9 cfu (Rt)	7/19/2018
	12 cfu (L)	7/12/2018
	7 cfu (Rt)	7/12/2018

c) Your written procedure does not address how microorganisms can affect the sterile drug product nor does it define the specific location of the sampling points.

d) You only monitor viable particulates (b) (4) and non-viable particulates every (b) (4).

e) You do not have a qualified individual to read the (b) (4) plates for environmental monitoring.

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OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, you do not conduct sterility testing on any finished sterile drug products.

OBSERVATION 3

Each batch of drug product purporting to be pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

a) You do not have endotoxin analysis for any of the sterile stock solutions of veterinary drug products you produce.
b) The endotoxin test method used for human sterile stock solution is not a compendial method.
c) You do not conduct any endotoxin testing for any finished sterile drug products including intrathecal products that contain Morphine Sulfate, Bupivacaine, Fentanyl, Clonidine, Baclofen or Hydromorphone.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, you do not conduct any potency testing for finished sterile drug products.

OBSERVATION 5

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

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 smallest or largest batch size and different container types (vials).
b) Smoke studies have not been performed under dynamic conditions in ISO 5 areas. The smoke study you performed during the inspection only included the hoods and biosafety cabinets only demonstrated pulling drug product from a vial into a syringe.
c) (b) (4) testing performed on finished products is not (b) (4). In addition, the results of (b) (4) testing for veterinary products is not documented.

OBSERVATION 6

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

a) I observed a brownish residue on top of the return air vent in the human clean room (ISO 7) where the laminar flow hoods and biosafety cabinet are located, and aseptic operations occur.
b) The seam on the floors for all rooms in the classified area is raised and not smooth.
c) All the (b) (4) are scratched and cloudy in appearance.

OBSERVATION 7

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

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Specifically, you do not have any hold time studies to support storing preservative free stock solutions held in glass and plastic vials and assigning beyond-use-dates of more than three months.

OBSERVATION 8

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically, the gown and mask worn by personnel on the veterinary side during sterile compounding is not sterile.

OBSERVATION 9

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, your formulation worksheets do not include specific instructions. For example, you do not have specifications/parameters putting the Morphine Sulfate Stock (b) (4) (time and temperature).

OBSERVATION 10

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a) You do not use a hood to prepare non-sterile hormonal products. The capsule equipment is only cleaned with (b) (4) after use. You have no further documentation to show prevention of contamination from one lot to another lot.
b) You also only use non-sterile (b) (4) to clean the cabinet area where non-sterile operations occur.

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***DATES OF INSPECTION**

10/15/2018(Mon), 10/16/2018(Tue), 10/17/2018(Wed), 10/18/2018(Thu), 10/19/2018(Fri), 10/23/2018(Tue), 10/24/2018(Wed), 10/31/2018(Wed), 11/01/2018(Thu)

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