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.

<table>
<thead>
<tr>
<th>Class</th>
<th>ISO</th>
<th>2 cfu (fungal)</th>
<th>5/21/2018</th>
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<thead>
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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.

<table>
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<th>b) Location</th>
<th>4 cfu (fuzzy white)</th>
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<tr>
<td>Air</td>
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<td>Surface</td>
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- **Human Fingertip**
  - 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**
  - 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.
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
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) Testing performed on finished products is not documented. In addition, the results of 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 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.
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 \((\text{b} (4))\) (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 \((\text{b} (4))\) 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 \((\text{b} (4))\) to clean the cabinet area where non-sterile operations occur.

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Claire M Minden, Investigator

11/1/2018
NAME AND TITLE OF INDIVIDUAL ISSUING REPORT
Jennifer D. Yoakum, Pharmacist-in-Charge/Owner

FIRM NAME
Med Shop Total Care Inc.

STREET ADDRESS
470 E Loop 281

CITY, STATE, ZIP CODE, COUNTY
Longview, TX 75605-7939

TYPE ESTABLISHMENT INSPECTED
Producer of Sterile and Non-sterile Drugs

*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)

SEE REVERSE OF THIS PAGE
Claire M Minden, Investigator

DATE ISSUED
11/1/2018