DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/09/2014 - 09/18/2014* FEI NUMBER 3006014626

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark D. Acker, Co-Owner

FIRM NAME	STREET ADDRESS
Medistat RX L.L.C.	110 E. Azalea Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Foley, AL 36535	Producer of Sterile Products

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) Certification of laminar flow hoods, buffer rooms and ante rooms are not conducted under dynamic conditions.

b) You have no scientific rational or written specifications(air exchange rates, particle counts, pressure differential) for the classified rooms (air exchange rates, particle counts, pressure differential) where sterile compounding continues.

c) You also do not perform personnel and environmental monitoring each day sterile products are made.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, you have not qualified the (b) (4) demonstrate (b) (4) to sterilize drug products made from non-sterile drug components. The (b) (4) is labeled, "it was designed for laboratory use only." The (b) (4) is labeled for sterile "(b) (4)

In addition, media fills do not simulate actual production quantities and different size vials.

OBSERVATION 3

Drug products failing to meet established specifications are not rejected.

Specifically, you did not take corrective action for two lots of Progesterone capsules that failed potency and were distributed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Claire M Minden, Investigator Claire M. Minden	09/18/2014

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."

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OBSERVATION 4

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

Specifically, endotoxin testing is not conducted on each batch of injectable drug products made from non-sterile drug products.

In addition, you do not perform any growth promotion testing of the agar and media you use for sterility analysis.

OBSERVATION 5

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 test each lot/batch of drug product for potency for each active ingredient prior to release for distribution.

OBSERVATION 6

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, you have not validated your production process to demonstrate each batch of drug product meets the identity, strength, quality and purity it purports to be.

OBSERVATION 7

Written procedures describing the handling of complaints do not include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications, a determination as to the need for an investigation of any unexplained discrepancy, and explaining the reasons for the failure of the batch or any of its components to meet specifications.

Specifically, you do not fully investigate complaints to determine if the complaint extended to other batches of the same drug product and other drug products that may have been associated with the use of the same components.

In addition, complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse drug experiences which are required to be reported to FDA.

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OBSERVATION 8

Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, you do not document and have a written procedure to investigate unexplained discrepancies. (b) (4) samples sent to (b) (4) as part of the Quality Improvement Program did not meet specifications. The investigation into these out of specifications did not include documentation that extended to other drug products that may have been associated with the potency failures.

OBSERVATION 9

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

Specifically, employees were observed to use non-sterile cloth face masks while producing sterile drug products.

OBSERVATION 10

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, you have not calibrated the incubator thermometers.

*** DATES OF INSPECTION:**
09/09/2014(Tue), 09/10/2014(Wed), 09/11/2014(Thu), 09/12/2014(Fri), 09/18/2014(Thu)

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