

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 6/5/2019-6/14/2019*
	FEI NUMBER 3015235235

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dawn Hoang, RPh, Owner

FIRM NAME First Royal Care Co. LLC, dba Red Mountain Compounding Pharmacy	STREET ADDRESS 6828 E Brown Rd Ste 101
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CITY, STATE, ZIP CODE, COUNTRY Mesa, AZ 85207-3761	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products
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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

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

Specifically,

- A) Your firm failed to validate equipment used to sterilize and depyrogenate equipment used in the production of sterile drug products.
- B) Your firm does not verify (b) (4) through an endotoxin challenge. Therefore, there is no assurance that the (b) (4) for glassware used to prepare sterile injectable drug products achieves an appropriate reduction of endotoxin levels.
- C) Equipment used in (b) (4) sterilization has never been qualified or calibrated.
- D) (b) (4) studies have never been conducted to qualify the (b) (4) sterilization process; a biological indicator is not used.
- E) (b) (4) equipment and process used in the (b) (4) sterilization of product has not been qualified or proceduralized.
- F) Media fills are conducted (b) (4) but do not include the most challenging process performed.
- G) Dynamic smoke studies have been conducted but do not adequately demonstrate actual aseptic filling operations performed.

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bryan L Mcguckin, Investigator	Bryan L. Mcguckin Investigator Signed By: Bryan L. Mcguckin -S Date Signed: 12-12-2019 09:49:39 X _____	DATE ISSUED 12/12/2019

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OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- A) Sterile (b) (4) is used to disinfect gloves, but equipment and supplies introduced into the ISO5 classified zone are wiped down with non-sterile wipes left open throughout the ISO classified zones. Sterile Prepackaged (b) (4) wipes are also used but for unspecified periods of time after breaking seal, rendering the wipes "non-sterile". Non-sterile (b) (4)-based antiseptic hand wash was applied to sterile gloves during production.
- B) Disinfectants being used either do not provide sporicidal activity or have not been verified to provide sporicidal activity in the manner they are currently being used.
- C) Container totes used to transfer supplies into the ISO7 classified buffer area are disinfected with non-sterile (b) (4) wipes.
- D) Mixing bars used in sterile drug production are washed but not sterilized prior to use.

OBSERVATION 3

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

Specifically,

- A) Environmental monitoring of ISO classified zones is conducted on a (b) (4) basis only.
- B) Pressure differentials of classified areas are not monitored daily but on (b) (4) only.

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C) Personnel monitoring is conducted using samples taken from the gloved hands of employees following sterile drug production on a **(b) (4)** basis only.
D) Alarm systems to monitor for potential breaches in air quality are currently not employed.

OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.
Specifically, on 06/05/2019 and 6/7/2019 during the production of sterile product I observed the following:
The curtain used to demarcate the ISO5 classified zone and control airflow was swaying therefore allowing disruptions in airflow. The curtain was observed to be too high to prevent the sterile drug tech from breaching the ISO5 classified zone with exposed skin, while reaching for equipment.

OBSERVATION 5

Written records are not made of investigations into unexplained discrepancies.
Specifically,
On 02/04/2019 viable air samples exceeded bacterial and fungal limits in the ISO7 classified zones. No investigation was made to determine cause or source of contamination or to ensure patient safety was not compromised.
On 02/19/~~2019~~ **2018** viable air samples exceeded bacterial limits in the hazardous drug room. No investigation was made to determine cause or source of contamination or to ensure patient safety was not compromised.

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OBSERVATION 6

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

Specifically, on 06/05/2019 and 06/07/2019 during production of sterile product I observed the following:

A) Non-Sterile clothing (head cover, mask, gown and booties) were used during production. Per the sterile drug tech and owner, this is the mandatory uniform employed during sterile drug production.

The sterile tech was observed leaning against the bench and into the ISO5 classified zone repeatedly throughout production with exposed skin (neck, forehead and eyes).

B) During donning of production clothing, the sterile tech was observed allowing copious amounts of water to run from the elbows onto the floor of the anti-chamber. Booties were then donned on the wrong side of the demarcation line allowing for water to be tracked into the ISO7 classified buffer area.

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Extended BUD's are established for high-risk products without the appropriate stability data or required sterility testing. For example:

1. S-Lidocaine HCL 1% MDV; BUD of 90 days.
2. S-Glutathione 200MG/ML MDV; BUD of 90 days.
3. S-Methylcobalamin 5000MCG/ML MDV INJ; BUD of 90 days.

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OBSERVATION 8

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

Specifically, sterility and pyrogen testing are not conducted on finished sterile drug products. For example:

1. Rx (b) (6) S-Lidocaine HCL 1% MDV for Injection 1000ml, Lot S05012019DH@05.
2. Rx (b) (6) S-Glutathione 200MG/ML MDV for Injection 500ml, Lot ~~S05082019DH@07~~ **S05082019DT@07**.
3. Rx (b) (6) S-Methylcobalamin 5000MCG/ML MDV for Injection 600ml, Lot S04112019DT@08.

OBSERVATION 9

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, potency testing is not conducted on finished drug products prior to release. For example:

1. Rx (b) (6) S-Lidocaine HCL 1% MDV for Injection 1000ml, Lot S05012019DH@05.
2. Rx (b) (6) S-Glutathione 200MG/ML MDV for Injection 500ml, Lot ~~S05082019DH@07~~ **S05082019DT@07**.
3. Rx (b) (6) S-Methylcobalamin 5000MCG/ML MDV for Injection 600ml, Lot S04112019DT@08.

OBSERVATION 10

Written procedures for cleaning and maintenance fail to include assignment of responsibility, description in sufficient detail of methods, equipment and materials used, description in sufficient detail

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of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance and instructions for protection of clean equipment from contamination prior to use.

Specifically,

There were no cleaning SOP's to review which demonstrate actual procedures utilized at the facility. A generic, commercially available template SOP was provided but lacked any supporting information or detail that would reflect actual practices at your firm.

Cleaning practices observed on 06/07/2019 prior to sterile drug production are not reflected in SOP #: 3.020 "Cleaning and Maintenance of The Clean Room Facility". Multiple cleaning products utilized are not reflected in SOP #: 3.020 or lack procedural information such as frequency, location, dwell time and concentration.

There are no procedures to review that reflects how equipment is broken down, cleaned or reassembled to prevent microbial contamination.

OBSERVATION 11

Batch production and control records for each batch of drug product produced do not include an accurate reproduction of the appropriate master production or control record which was checked for accuracy, dated and signed.

Specifically,

During sterile drug product review, the batch record for Rx ^{(b) (6)} S-Glutathione 200MG/ML MDV for Injection 500ml, Lot ~~S05082019DH@07~~ **S05082019DT@07**, the API manufacturer in the formulation was incorrect but had been signed off as accurate by the Pharmacist. The correct API manufacturer was identified only because of the API still being on hand at that time.

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OBSERVATION 12

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

Specifically,

Non-sterile products are not tested for the presence of objectionable organisms at any time. For example:

1. Rx (b) (6) C-Kids Cocktail oral solution 480ml, Lot 03272019AT@25.
2. Rx (b) (6) C-Tretinoin 0.3% Topical Solution, Lot 05312019AT@29.

***DATES OF INSPECTION**

6/05/2019(Wed), 6/06/2019(Thu), 6/07/2019(Fri), 6/10/2019(Mon), 6/11/2019(Tue), 6/14/2019(Fri)

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