

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION  07/14/2021-08/11/2021*
	FEI NUMBER  3015235235

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Dawn T. Hoang, PharmD. & Co-Owner

FIRM NAME  First Royal Care Co. LLC, dba Red Mountain Compounding	STREET ADDRESS  6828 E Brown Rd Ste 101
CITY, STATE AND ZIP CODE  Mesa, AZ 85207-3761	TYPE OF 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) (WE) OBSERVED:

**OBSERVATION 1**

The (b) (4) intended to render final product sterile was not pharmaceutical grade.

Specifically, the (b) (4) used to produce finished drug products are not pharmaceutical grade. For example, the following dispensed finished sterile drug products were produced using laboratory grade (b) (4)

A) Rx (b) (6), S-Dexpanthenol 250MG/ML MDV INJ SOLN, Lot 03172021DH@13, was produced using (b) (4) Part number (b) (4)

B) Rx (b) (6) S-MIC/B12A 25/50/50MG/ML 1MG/ML MDV, Lot S06042021JL@12, was produced using (b) (4), Part number (b) (4)

C) Rx (b) (6) S-Methylcobalamin 10,000MCG/ML MDV INJ, lot S0302021DH@01, was produced using (b) (4) Part number (b) (4)

**OBSERVATION 2**

(b) (4) testing to the (b) (4) was not performed.

Specifically, your firm does not perform the (b) (4) test per the (b) (4) manufacturers' specifications. For example:

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A) The specification for the (b) (4), Part number (b) (4) (b) (4) is  $\geq$  (b) (4) psi with (b) (4). You firm used this type (b) (4) to produce the sub-compounds:

- i. (b) (4), lot (b) (4)
- ii. (b) (4) lot (b) (4)

The batch records for the above sub-compounds indicate 13 psi on the records; however, you stated only (b) (4) was used instead of (b) (4) for the (b) (4) test. Your procedure states an (b) (4) (b) (4) mixture can be used but this changes the specification to at least (b) (4) psi for the (b) (4)

The above sub-compounds, (b) (4) and (b) (4) were used to produce S-Cyclosporine 0.2% OPTH OINTMENT, lot S07152021DH@01, and S-Tacrolimus 0.03% OPTH IN MCT OIL, lot S06302021JL@08, respectively. No further sterilization steps were performed after producing the above finished ophthalmic drug products and no finished product testing has ever been conducted for these products.

B) The specification for the (b) (4), Part number (b) (4) (b) (4) is  $\geq$  (b) (4) psi in water. Your firm used this type of (b) (4) for (b) (4), lot (b) (4), and 43 psi was recorded on the batch record. No sterility testing was performed on this lot and it was subsequently used to produce Rx (b) (6) S-Myer's Cocktail (250ML), lot S04232021DC@04.

**OBSERVATION 3**

The cycle parameters (temperature, pressure and time) used for (b) (4) of product intended to be sterile are not lethal to heat-resistant microorganisms.

Specifically, load mapping studies have never been conducted to qualify the (b) (4) process for the sub-compound, (b) (4). For example, this sub-compound is subsequently used to produce

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finished drug products:

- a) S-Cyclosporine 0.2% OPTH OINTMENT, lot S07152021DH@01, Rx (b) (6) and (b) (6)
- b) S-Tacrolimus 0.03% OPTH IN MCT OIL, lot S06302021JL@08, Rx (b) (6)

No further sterilization steps are performed after producing the above finished ophthalmic drug products and no finished product testing has ever been conducted for these products.

**OBSERVATION 4**

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.

Specifically, media fills do not include the most challenging process performed. For example, your media fill records indicate filling (b) (4) ml vials; however, I reviewed sterile production records that demonstrate more challenging operations such as filling (b) (4) ml vials for S-Ascorbic Acid (NON-CORN) 500MG/ML MDV, lot S03042021DH@09 and/or filling (b) (4) ml syringes for S-Glutathione 200MG/3ML (PF) INHALATION, lot S03172021DH@04.

**OBSERVATION 5**

Lack of adequate routine environmental monitoring.

Specifically, environmental monitoring of ISO classified zones for viable (surface and air) microorganisms and non-viable particles is conducted on a (b) (4) basis only. Your firm produces sterile drug products on a (b) (4) basis and dispenses approximately (b) (4) sterile drug products per day.

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**OBSERVATION 6**

Lack of adequate personnel sampling.

Specifically, personnel monitoring is conducted using samples taken from the gloved hands of employees following sterile drug production on a (b) (4) basis only. Your firm produces sterile drug products on a (b) (4) basis and dispenses approximately (b) (4) sterile drug products per day.

In addition, your program for monitoring personnel is deficient in that:

- A) Monitoring does not include samples taken from the gowns of employees.
- B) Monitoring only includes samples taken from fingertips and does not include the broader surface of the operators' fingers which are used during sterile vial assembly.

**OBSERVATION 7 (Repeat Observation)**

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

Specifically, your firm produces sterile drug products on a (b) (4) basis and dispenses approximately (b) (4) sterile drug products per day. Sterility and pyrogen testing are not routinely conducted on finished sterile drug products.

For example, Rx (b) (6) S-Sod Citrate 4% INJ SOLN MDV, lot S06182021DC@02 and Rx (b) (6) S-Myer's Cocktail (250ML), lot S04232021DC@04.

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**OBSERVATION 8 (Repeat Observation)**

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

Specifically, extended beyond-use-date (BUD) was used for a high-risk product without the appropriate stability data or required sterility testing. For example, Rx (b) (6) S-Sod Citrate 4% INJ SOLN MDV, lot S06182021DC@02, was labeled with a BUD of approximately 30 days and to store at room temperature.

**OBSERVATION 9 (Repeat Observation)**

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

Specifically, potency testing is not routinely conducted on finished drug products prior to release. For example, Rx (b) (6) S-Sod Citrate 4% INJ SOLN MDV, lot S06182021DC@02 and Rx (b) (6) S-Myer's Cocktail (250ML), lot S04232021DC@04.

**OBSERVATION 10 (Repeat Observation)**

Sporicidal agents were not adequately used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically, the cleaning agent, (b) (4) is being used as a sporicidal in the ISO 5 BSC; however, it is not labeled as a sporicidal and the approximate contact time observed on 07/15/21 was (b) (4) before wiping.

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**OBSERVATION 11**

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

Specifically, I observed the cleaning practices in the firm's classified areas on 07/15/21. During cleaning of the ISO 7 areas, the operator did not allow the appropriate (b) (4) dwell time for the (b) (4) cleaning agent before wiping. The operators use this cleaning agent for all classified areas outside of the ISO 5 BSC.

**OBSERVATION 12**

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, the following conditions were observed on 07/14/21 during the production of H-Fluconazole 40MG/ML OIL SUSPENSION, lot 07142021DLJ@03:

- 1) There were multiple damaged and discolored (b) (4) spatulas that were designated clean. One of the (b) (4) spatulas had a glossy unknown material on it.
- 2) There were multiple glass mortars with dust build-up that were designated clean.
- 3) The scale used to weigh (b) (4) had a large crack across the front panel with tape holding it together.

The above non-sterile equipment and utensils are used to produce hazardous and non-hazardous drug products such as capsules, ointments, gels, creams, suspensions, solutions, suppositories, troches, and sprays.

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**OBSERVATION 13**

Personnel engaged in aseptic processing were observed wearing non-sterile gown components.

Specifically, on 07/16/21, during sterile production Rx (b) (6) S-Acetylcysteine 5% ophthalmic solution, lot S07162021DH@02, the operator donned a non-sterile coverall that was past the expiry date, "EXP: 2020-01", listed on the packaging. The operator's sleeves entered the ISO 5 BSC while producing the sterile drug product.

**OBSERVATION 14**

Routine checking of scales used for production is not performed to assure proper performance.

Specifically, the (b) (4) scales used by your firm to produce hazardous and non-hazardous sterile and non-sterile drug products are not routinely checked for accuracy.

Example batches requiring small quantities:

- a) Rx (b) (6) H-BIEST/P4/TEST 1.5/100/2MG TROCHE, lot 07082021DLJ@41, requires a quantity of (b) (4) grams for (b) (4).
- b) Rx (b) (6) S-Acetylcysteine 5% OPTHALMIC SOLN, lot S07162021DH@02, requires a quantity of (b) (4) grams for (b) (4).

The scales are calibrated (b) (4) but you do not have suitable weights to verify accuracy down to 0.001 grams before use.

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**OBSERVATION 15**

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, Rx (b) (6) C-BLT 20/10/6% IN DMSO 10% LIPO, lot 04162021DLJ@07 and Rx (b) (6) C-BLT 20/10/10% IN DMSO 10% LIPO, lot 06092021DJ@05 used (b) (4) which do not indicate USP/NF standards on respective COAs.

**\*DATES OF INSPECTION**

7/14/2021(Wed), 7/15/2021(Thu), 7/16/2021(Fri), 7/19/2021(Mon), 7/20/2021(Tue), 7/29/2021(Thu), 7/30/2021(Fri), 8/02/2021(Mon), 8/11/2021(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."