DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U. S. Food & Drug Administration, NOL-DO 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 Ph. # 615-366-7801 Industry Information: www.fda.gov/oc/industry	06/03/2016 - 07/07/2016
	FEI NUMBER 3010241801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ronald D. Edwards / Owner

FIRM NAME	STREET ADDRESS
Vital Care Compounder, LLC	115 South 40th Avenue
CITY, STATE AND ZIP CODE Hattiesburg, MS 39402	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

There is no quality control unit.

Specifically,

1) Your firm has not established a quality control unit with the responsibility to approve or reject all components, containers, closures, packing material, labeling, and drug products. For example:

Your firm produced/distributed a non-patient specific non-sterile oral liquid. This product was identified as C-Chloral Hydrate 100mg/mL, RX#(b) (6) Per review of the batch record, 10 times the amount of required active ingredient was used, creating a super-potent drug product. This drug product was not rejected by your firm. Also, your firm does not perform potency testing on finished drug products and no retain samples are maintained.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

1) On 06/07/2016, we observed an employee aseptically processing patient specific C-VANCOMYCIN SUPER DROPS RX# (b) (6) (eye drops). During the processing we observed the employee, in non-sterile gowning, exiting the clean room and then re-entering without changing gowning materials, including gloves. Also, the employee obtained a bottle containing sterile (b) (4) from the prep room. The employee did not wipe down the bottle upon re-entering the clean room, nor did the employee re-sterilize the gloves.

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2) On 06/07/2016, we observed a scale, located in the firm's prep room (ISO 8), to contain a white powder residue from previous processing. Also, noted were active ingredients from previous processing in the firm's prep room.

3) On 06/07/2016, the firm's owner gowned in non-sterile gowning items and failed to wipe non-sterile goggles with (b) (4) before entering the firm's ISO 8 prep room.

4) Open trash receptacles were observed in all of the firm's classified areas. Specifically, an open trash receptacle was in close proximity to your ISO 5 Glove Box and your ISO 5 hood located in the clean room.

5) Your firm has not validated the sterilization process (b) (4) autoclave) used for sterilization of rubber stoppers and terminally sterilized finished drug products, such as, low configurations and capacities. According to your firm, (b) (4) are only used (b) (4)

6) Your firm has not validated your (b) (4) sterilization process using (b) (4) to aseptically fill injectable drugs purporting to be sterile.

7) Your firm has not validated your process for the depyrogenation (Dry Heat (b) (4) of glass vials/glassware used for processing drug products intending to be sterile, such as low configurations and capacities. According to your firm, (b) (4) are only used (b) (4) This Dry Heat (b) (4) is also used for the (b) (4) sterilization of injectable drug products.

8) Your firm does not perform positive/negative controls on media which is used for sterility testing on finished drug products. The firm's incubators used to incubate media for finished product testing have not been verified. For example, temperatures are not continuously monitored in these incubators.

9) Your firm's media fills do not stimulate ((b) (4) b) (4) the entire aseptic drug process. Also, the firm's largest batch size would be (b) (4) and the media fills performed by your firm are just for filling (b) (4)

10) Your firm has not performed preservative assay and antimicrobial effectiveness tests on injectable finished

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drug products contained in multiple dose vials.

OBSERVATION 3

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

Specifically,

1) Your firm does not monitor viable microbiological contamination in your ISO 7 (clean room) and ISO 5 Hoods during processing.

2) Your firm does not monitor non-viable particulates in your ISO 7 (clean room) and ISO 5 Hoods during processing.

3) Your firm does not monitor microbial contamination on product work surfaces in your ISO 7 (clean room) and ISO 5 Hoods during processing.

4) Your firm does not monitor personnel for microbial contamination during processing.

5) Your firm does not monitor pressure differentials in your ISO 5 Glove Box. Also, your ISO 5 Glove Box does not contain any type of pressure monitoring device.

OBSERVATION 4

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

Specifically,

1) Your firm does not use a sporicidal cleaning agent in your ISO 5 hood and ISO 5 Glove Box where aseptic processing is performed.

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2) Your firm uses non-sterile and low lint wipes to clean in your classified areas. On 06/07/2016, an employee was observed to use these non-sterile wipes in the firm's classified areas (ante room, prep room, clean room, and hood).

3) Your hood in the clean room was observed to have a shattered plastic shield located on the front of the hood, which is unable to be properly cleaned or sanitized.

4) Your hood in the clean room was observed to have a flaking plastic material glued to the bottom of the hood.

5) Your hood in the clean room was observed to have debris on the top of the unit.

OBSERVATION 5

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

1) During this inspection, we observed three injectable drug products to be improperly sealed (crooked metal crimps). Per the firm, the rubber stoppers used for these lots were oversized. These products included Trypan Blue Lot# 391462, Testosterone Cypionate Lot# 382331, and Methylcobalamin Lot# 389279.
Containers and closures are not examined upon receipt to ensure they meet specifications for use.

2) During this inspection, we noted finished drug products containing active drug ingredients that are light sensitive being stored in clear glass and plastic containers. Products observed in this condition included Moxifloxacin Lot# 395123 and Betamethasone L/A Lot# 387562.

OBSERVATION 6

Clothing of personnel engaged in the manufacturing, processing, and packing of drug products is not appropriate

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for the duties they perform.

Specifically,

1) Non-sterile bunny suits, face masks, shoe covers, and hair covers are used during the production of drug products intended to be sterile.

OBSERVATION 7

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

1) Your firm's ISO 5 glove box, which is used for aseptic processing, is located in a non-classified multipurpose area. This area does not have HEPA filtration.

2) Stains were observed on the HEPA filter located inside the ISO 5 glove box.

OBSERVATION 8

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

Specifically,

There are no records to demonstrate the following equipment has been calibrated for use:

1) The (b) (4) used for (b) (4) for aseptic filling. During this inspection, we noted that the viewing glass on the (b) (4) was damaged in such a way as to block the reading of numerical values.

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2) All scales used to weigh ingredients used in processing sterile and non-sterile drug products. Per the firm, a (b) (4) calibration of the scales is carried out with a (b) (4) This (b) (4) had no certification records. This is the only method used by the firm for calibration of the scales (linearity, accuracy, and repeatability are not tested).

3) The thermometers in the incubators used to test environmental and finished product samples.

4) The thermometer used in the depyrogenation (b) (4) used for glass vials/glassware and the terminal sterilization of injectable drug products.

5) The thermometer/pressure gauge in the autoclave used to sterilize rubber stoppers and terminally sterilize injectable drug products.

OBSERVATION 9

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

1) We observed that the firm's only HEPA filter for the clean room was located directly above the ISO 5 hood.

2) On 06/08/2016, it was demonstrated to the firm's primary aseptic processing employee and the firm's owner, using a sheet of paper, how the ISO 7 clean room air was being pulled into the ISO 5 (b) (4) Hood. Also, it was demonstrated with a sheet of paper that in the hood area, where the employee performs aseptic processing, there was no air movement to ensure proper air quality.

3) On 06/07/2016, we observed plastic storage compartments in front of the return HEPA air vent in the firm's ante room.

4) Your firm has no documented diagram or video smoke studies to determine airflow patterns in the firm's classified areas (ISO 8, ISO 7, & ISO 5 Hoods). Also, your firm has no documented evidence that smoke studies

were performed under dynamic conditions.

OBSERVATION 10

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

Specifically,

1) Microbial testing is not performed for each lot of drug product purporting to be sterile. Your firm's lots range in volume from (b) (4) Furthermore, you have not validated your microbial testing methods that are performed by your firm.

2) Endotoxin testing is not performed on every lot of injectable finished drug products.

OBSERVATION 11

Results of stability testing are not used in determining expiration dates.

1) Specifically, your firm has not conducted any stability testing. Some multiple dose vial products are assigned expiration dates of 18 months to drug products intended to be sterile. Also, your firm produces preservative free products without stability testing. For example, your Methylcobalamin 5,000 mcg/ml has an assigned six month beyond use date.

OBSERVATION 12

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

Specifically,

1) Your firm has no written protocols for finished drug products and no lots of drug products have been tested for

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stability.

OBSERVATION 13

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

Specifically,

1) Your firm has not established any (b) (4) for the sterilized glass vials and rubber stoppers used in processing injectable drug products. Additionally these items, (b) (4)

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