DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	10/15/2013 - 10/23/2013* FEI NUMBER 3010433194

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Wendy L. Haun, R.Ph., Owner

FIRM NAME	STREET ADDRESS
Blue Ridge Pharmacy and Compounding Center	2601 Blue Ridge Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Raleigh, NC 27607	Producer of Sterile Drug 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 air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

Your firm failed to establish an adequate air supply filtered through high-efficiency particulate air filters under positive pressure in the aseptic processing areas. For example,

1. The [redacted] (b) (4) that provides ISO 5 conditions where aseptic processing operations occurs, is located in an unclassified carpeted room where the room air is not HEPA filtered.

2. There is no pressure differential between the unclassified room where the [redacted] (b) (4) is located and the rest of the facility. Additionally, there is no measurement device to display the pressure differential between the [redacted] (b) (4) and the unclassified carpeted room.

3. The unclassified carpeted room where the [redacted] (b) (4) is located does not have covered walls or caulked ceilings to promote cleanability. The surfaces of the ceiling and walls appear pourous, with the ceiling having crevices between each of the drop ceiling panels and it appears hard to clean. The carpet has stains and ridges.

OBSERVATION 2

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

Specifically,

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	Viviana Matta, Investigator Viviana Matta	10/23/2013

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1. There are no records documenting (b) (4) cleaning and replacement performed in the ISO 5 (b) (4)

2. There are no sporicidal cleaning agents used inside the ISO 5 (b) (4)

3. The firm uses (b) (4) to disinfect inside the ISO 5 (b) (4).

4. There are no cleaning/maintenance records documenting cleaning/sanitization performed in the ISO 5 (b) (4).

OBSERVATION 3

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

Specifically,

1. There are no media fills conducted by the firm to ensure that the procedures used can produce a sterile product.

2. The unidirectional flow of air in the ISO 5 (b) (4) area has not been confirmed through visual mechanisms (such as smoke studies) under dynamic conditions to ensure adequacy for use.

3. The firm has not performed (b) (4) on any of the (b) (4) utilized for (b) (4) filling sterile injectable products. For example, the firm uses (b) (4) to (b) (4) all sterile products. The firm has not ever conducted an (b) (4) test after aseptic (b) (4).

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OBSERVATION 4

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

Specifically,

1. There is no record documenting the aseptic processing of sterile drug products. For example, Papaverine HCl 30mg/ml and Phentolamine 10mg/2ml injectable stock solution components are prepared in the pharmacy from non-sterile components and there is no written procedure or documentation detailing that these prodcuts are [redacted] (b) (4) to create Trimix and QuadMix injectable finished products.

2. There is no environmental monitoring conducted by the firm to ensure that the environment inside the ISO 5 area consistently maintains acceptable viable and non viable particle levels. Additionally, there is no personnel monitoring conducted by the firm to assess the operator's work practices.

3. There was no sampling conducted of viable particles in the ISO 5 [redacted] (b) (4) space during the semi-annual recertifications of this area conducted 04/10/12, 10/23/12, and 05/07/13.

4. Instruments and packaging of components are not disinfected prior to introduction into the [redacted] (b) (4) ISO 5.

OBSERVATION 5

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

Specifically,

For example, samples were sent to [redacted] (b) (4) for potency testing and results were as follows:

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Sample Number	Chemical	Potency
(b) (4)	Alprostadil	137%
(b) (4)	Papaverine Hydrochloride	120%
(b) (4)	Phentolamine Mesylate	87.3%
(b) (4)	Papaverine Hydrochloride	66.7%

No investigation was conducted to determine the root cause of these out of specification results and all sampled lots were distributed.

OBSERVATION 6

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

Specifically,

The firm does not routinely perform sterility or endotoxin testing on their sterile injectable products.

1. The firm has not performed sterility or endotoxin testing for any of the QuadMix (papaverine, phentolamine, alprostadil and atropine) injectable, PGE (prostaglandin E-1) injectable and cyclosporin ophthalmic eye drug products produced by the firm. For example, from 07/15/13 to 08/23/13, approximately (b) (4) lots of PGE injectables were released and no sterility or endotoxin testing was conducted prior to release.

2. The firm has not conducted endotoxin testing for any of the Trimix (papaverine, phentolamine and alprostadil) injections produced and only three of the lots produced have been tested for sterility. For example, from 07/15/13 to 08/23/13, approximately (b) (4) lots of Trimix injectables were released and no sterility or endotoxin testing was conducted prior to release.

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OBSERVATION 7

Written production and process control procedures are not documented at the time of performance.

Specifically,

1. Lot numbers for drug components utilized in the compounding of Dr. Leatherman's Triple Rx Injectable, with lot number 06242013@4 and expiration date 09/22/13, were not documented at the time of performance in the pertinent Logged Formula Worksheets as confirmed by the firm's owner. According to the owner, drug component lot number data documented on the logged formula worksheets does not reflect the actual lots used for the finished drug product, but rather the lot numbers of drug components on hand during a recent audit.

2. Drug product compounding steps are not delineated in the logged formula worksheets and documented at the time of performance.

OBSERVATION 8

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

Specifically,

The firm has not established a stability program. In addition, there is no stability data including sterility data to support the current expiration dates of up to 90 days assigned to sterile injectable products. For example, beyond use dates are established in the logged formula worksheets as: "60 days after compounding date" or "90 days after compounding date".

OBSERVATION 9

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

Specifically,

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The compounding pharmacist engaged in aseptic processing operations utilizing the [redacted] (b) (4) ISO 5 space stated a single pair of non-sterile vinyl gloves and a face mask are the only garments utilized during aseptic processing.

/* **DATES OF INSPECTION:**
10/15/2013(Tue), 10/16/2013(Wed), 10/17/2013(Thu), 10/21/2013(Mon), 10/23/2013(Wed)

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