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	10/06/2014 - 10/10/2014 FEI NUMBER 3010078549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Craig Chalmas Stewart, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Stewart Compounding Pharmacy	101 Broadfoot Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28305-5001	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

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

Specifically,

Your firm failed to establish a standard operating procedure delineating sterility and/or endotoxin testing requirements for all sterile produced drug products.

A. The following formulations, purported to be sterile, were produced; nonetheless, no sterility testing was conducted:

1. Mupirocin Nasal Irrigation, labeled as sterile, 22gms(2%)/L Nasal Soln with lot number 07102014+20729@17 and beyond use date 07/24/14. In addition, the (b) (4) utilized for the formulation is not sterile and the finished solution is not sterilized.
2. Mupirocin Nasal Irrigation, labeled as sterile, 22gms(2%)/L Nasal Soln with lot number 06272014+20430@15 and beyond use date 07/11/14. In addition, the (b) (4) utilized for the formulation is not sterile and the finished solution is not sterilized.
3. Tobramycin (Bladder) Irrigation 240mg/500mL Solution with lot number 06062014+19959@15 and beyond use date 06/20/14.
4. Verapamil 2.5mg/mL (5mg/2mL) Injectable with lot number 06042014+19887@5 and beyond use date 06/07/14.
5. Verapamil 2.5mg/mL (5mg/2mL) Injectable with lot number 05072014+19280@9 and beyond use date 05/10/14.

B. No endotoxin testing is currently conducted for any drug products purported to be sterile and pyrogen free.

This is a recurrent observation.

OBSERVATION 2

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written, and followed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Viviana Matta, Investigator	10/10/2014

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	10/06/2014 - 10/10/2014 FEI NUMBER 3010078549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Craig Chalmas Stewart, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Stewart Compounding Pharmacy	101 Broadfoot Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28305-5001	Producer of Sterile Drug Products

1. Verification studies performed on the (b) (4) are not scientifically justified.

A. The verification study was not conducted under the same (b) (4) currently used for the depyrogenation of utensils.

B. The verification study, for utensils, was not conducted utilizing a NIST traceable thermometer.

C. The number of verification study runs were not justified or established prior to the conduct of the study.

D. Endotoxin challenge vials are not utilized during verifications studies.

2. Environmental monitoring conducted during media fills executed on 05/13/14 and 05/14/14 show positive results for growth in contact plates; nontheless, the specific number of colony forming units were not documented to demonstrate these were below the action level established in standard operating procedure 3.030: Environmental Monitoring of the Clean Room Facility, effective 05/06/13, and to validate the passing classification for the media fills.

3. Verification studies performed on the (b) (4) are not scientifically justified.

A. The number of verification study runs were not justified or established prior to the conduct of the study.

B. The (b) (4) has not been evaluated for adequacy of intended use.

4. Your firm has failed to established a standard operating procedure delineating the visual inspection of finished drug products to identify particulate matter, appearance or seal issues.

5. Your firm has failed to monitor non-viable particulate during sterile drug production as delineated in standard operating procedure 3.030: Environmental Monitoring of the Clean Room Facility, effective 05/06/13.

6. Non-sterile towels are utilized to clean inside the ISO-5 hood area as delineated in standard operating procedure 3.020: Cleaning and Maintenance of the Clean Room Facility, effective 04/25/13.

This is a recurrent observation.

OBSERVATION 3

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Viviana Matta, Investigator	10/10/2014

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	10/06/2014 - 10/10/2014 FEI NUMBER 3010078549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Craig Chalmas Stewart, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Stewart Compounding Pharmacy	101 Broadfoot Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28305-5001	Producer of Sterile Drug Products

The firm's written and established standard operating procedure for gowning, 9.100: Required Garb for Clean Room Facility Access, effective 05/02/13, does not require the donning of a sterile gowning suit when engaged in sterile compounding operations in the ISO 5 area.

This is a recurrent observation.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Cleanroom testing and certification reports are not reviewed by the Pharmacist-in-charge as delineated in standard operating procedure 9.010: The Quality Assurance Program, effective 08/05/13. Mr. Stewart, Pharmacist and Owner, confirmed he had not read the most recent cleanroom testing and certification report, dated 05/29/14.

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,

Your firm failed to establish a standard operating procedure delineating potency testing requirements for all sterile produced drugs. The following formulations were produced and distributed; nonetheless, no potency testing was conducted for finished products:

1. Human Chorionic Gonadotropin with B12 250IU/0.1mL Solution, with lot number 05302014+19782@1 and beyond use date 06/29/14. The (b) (4) utilized for this formulation was tested for potency on 05/28/14 and a result of 122% was obtained. Calculations were conducted to determine the quantity of the trituration to use in the formulation to achieve the desired potency in the finished drug product solution; nonetheless, the finished drug product was not tested for potency. Approximately (b) (4) prescriptions have been produced with the aforementioned super-potent trituration.
2. The (b) (4) (b) (4) with lot number (b) (4) was sent for potency testing and a potency of 128% was reported on 04/17/14. Calculations were conducted to determine the quantity of the trituration to use in the finished product formulation; nonetheless, all finished drug products produced utilizing this trituration were not tested for potency. Approximately (b) (4) prescriptions have been produced with the aforementioned super-potent trituration.
3. The (b) (4)) with lot number (b) (4) was sent for potency testing and a potency of 71.7% was reported on 09/12/14. Calculations were conducted to determine the quantity of the trituration to use in the finished product formulation; nonetheless, all finished drug products produced utilizing this

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE: Viviana Matta, Investigator — DATE ISSUED: 10/10/2014

trituration were not tested for potency. Approximately (b)(4) prescriptions have been produced with the aforementioned sub-potent trituration.
4. Papaverine/Phentolamine/Alprostadil (Standard Strength) 30mg/1mg/20mcg/mL Solution, with lot number 07022014+20510@2 and beyond use date 07/05/14.
5. Cyanocobalamin 1000mcg/mL Injectable, with lot number 07072014+20592@3 and beyond use date 10/05/14.
6.Verapamil 2.5mg/mL (5mg/2mL) Injectable with lot number 06042014+19887@5 and beyond use date 06/07/14.
7.Verapamil 2.5mg/mL (5mg/2mL) Injectable with lot number 05072014+19280@9 and beyond use date 05/10/14.
8. Cyanocobalamin (B12) / Pyridoxine (B6) 0.5mg / 50m/mL (0.1mg/0.2mL) Solution with lot number 06302014+20546@8 and beyond use date 12/27/14.
9. Mupirocin Nasal Irrigation (Sterile) 22gms(2%)/L Nasal Soln with lot number 07102014+20729@17 and beyond use date 07/24/14.
10. Mupirocin Nasal Irrigation (Sterile) 22gms(2%)/L Nasal Soln with lot number 06272014+20430@15 and beyond use date 07/11/14.
11. Tobramycin Irrigation 240mg/500mL Solution with lot number 06062014+19959@15 and beyond use date 06/20/14.

OBSERVATION 6

Records are not made concurrently with the performance of each step in the manufacture of products.

Specifically,

1. The Logged Formula Worksheet for Cyanocobalamin (B12) / Pyridoxine (B6) 0.5mg / 50m/mL (0.1mg/0.2mL) Solution with lot number 06302014+20546@8 and beyond use date 12/27/14, was logged and checked on 06/30/14; nonetheless, the product was not produced until 07/01/14 according to a note in the worksheet. There is no concurrent documentation of the performance of each step in the formulation. The date made was documented as 06/30/14, nonetheless, this is the date the worksheet was logged into the system and not when drug products are actually made.

2. The Logged Formula Worksheet for Benzocaine/Lidocaine/Tetracaine 20%/8%/4% Gel, with lot number 08222014+21623@2 and best use by date 11/20/14, shows a date made of 08/22/14, a formula verified date of 08/14/13 and no dated signatures in the "checked by" sections of the worksheet to validate review of the worksheet after production and prior to release of the drug product.

3. The Logged Formula Worksheet for Papaverine/Phentolamine/Alprostadil (Standard Strength) 30mg/1mg/20mcg/mL

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	10/06/2014 - 10/10/2014 FEI NUMBER 3010078549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Craig Chalmas Stewart, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Stewart Compounding Pharmacy	101 Broadfoot Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28305-5001	Producer of Sterile Drug Products

Solution, with lot number 07022014+20510@2 and beyond use date 07/05/14, and Cyanocobalamin 1000cg/mL Injectable, with lot number 07072014+20592@3 and beyond use date 10/05/14, do not have dated signatures in the "checked by" sections of the worksheets to validate review of the worksheet after production and prior to release of the drug product.

4. The Logged Formula Worksheet for Medroxyprogesterone Acetate 1% (10mg/mL) OPH SUSP, with lot number 06172014+20188@15 and beyond use date 08/01/14, shows the technician listed as (b) (6) [redacted]; nonetheless, (b) (6) [redacted] confimed the initials that appear next to her name are not her own.

5. The hard-copy and checked Logged Formula Worksheet for Methylcobalamin (PF) 25mg/mL (25,000mcg/mL) Injectable, with lot number 06182014+20208@8 and beyond use date 12/15/14, could not be located at the firm.

OBSERVATION 7

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

Specifically,

The firm's established and written procedure delineating beyond use dates, 9.050: Beyond-Use Dating (BUD) of Compounded Preparations, effective 05/08/13, allows beyond use dates (b) (4) [redacted]. Your firm failed to establish a testing program designed to support the currently assigned beyond use dates.

For example,

A. The Logged Formula Worksheet for Cyanocobalamin (B12) / Pyridoxine (B6) 0.5mg / 50m/mL (0.1mg/0.2mL) Solution with lot number 06302014+20546@8 and beyond use date 12/27/14,shows a preservative formula and a beyond use date of 180 days after production, refrigerated.

B. The Logged Formula Worksheet for Methylcobalamin (PF) 25mg/mL (25,000mcg/mL) Injectable, with lot number 06182014+20208@8 and beyond use date 12/15/14, shows a preservative free formula with beyond use date of 180 days after production, refrigerated.

C. The Logged Formula Worksheets for Cyanocobalamin 1000mcg/mL Injectable, with lot number 07072014+20592@3 and beyond use date 10/05/14, shows a preservative formula with beyond use date of 90 days after production, at room

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	10/06/2014 - 10/10/2014 FEI NUMBER 3010078549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Craig Chalmas Stewart, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Stewart Compounding Pharmacy	101 Broadfoot Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28305-5001	Producer of Sterile Drug Products

temperature.

D. The Logged Formula Worksheet for Medroxyprogesterone Acetate 1% (10mg/mL) OPH SUSP, with lot number 06172014+20188@15 and beyond use date 08/01/14, shows a preservative free formula with beyond use date of 45 days after production, refrigerated.

This is a recurrent observation.

OBSERVATION 8

The calibration of instruments is not done at suitable intervals in accordance with an established written program.

Specifically,

Your firm failed to conduct verifications of (b) (4) balances with (b) (4) as established in standard operating procedure 4.070: Use, Calibration and Maintenance of The (b) (4) Balances, effective 07/08/13.

OBSERVATION 9

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

Exhaust vents inside hoods for the weighing of chemicals have substantial amounts of chemical residues which may contain hormones and hazardous chemicals. There is no documented evidence to support these exhaust vents have ever been cleaned.