

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

DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	DATE(S) OF INSPECTION 6/6/2016-6/17/2016* FEI NUMBER 3012360920
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen G. Anderson , Owner

FIRM NAME W & C dba The Apothecary	STREET ADDRESS 165 19th St S, Suite 102
CITY, STATE, ZIP CODE, COUNTRY Sartell, MN 56377-2567	TYPE ESTABLISHMENT INSPECTED Producer of sterile drug product

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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

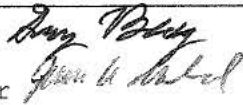
- On 02/11/2015, air and surface samples were collected and analyzed by (b) (4). The results indicated the HEPA Filter (b) (4) in Anteroom (b) (4) (ISO 7) failed due to un-repairable leaks and recommended replacement and re-test of the filter. Your firm failed to replace the filter for approximately 6 months.
- Surface and air monitoring within the ISO 5 area is not performed each day sterile drug products are aseptically produced. The current practice is to perform this monitoring every (b) (4).
- Personnel monitoring is not performed each day sterile drug products are produced. The current practice is to perform this monitoring every (b) (4), and prior to December of 2015, no personnel monitoring was being conducted.
- Differential pressure within the ISO 5 area is not monitored regularly during aseptic operations. The current practice is to perform and document this monitoring, (b) (4).

OBSERVATION 2

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

Specifically,

- A sporicidal disinfectant has not been used to clean the ISO 5 hood.
- A non-sterile disinfecting agent, (b) (4), was used in the aseptic processing (ISO 5) area and on floors, walls and ceiling within the ISO 7 clean room and ISO 8 anteroom.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Gregory A Berg, Investigator James K Ireland, Investigator Anthony J Ladner, Investigator	 <input checked="" type="checkbox"/> Gregory A Berg <small>Gregory A Berg Investigator Signed by: Gregory A. Berg-S</small>	DATE ISSUED 6/17/2016 6/17/2016

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-Contact time for cleaners is approximately (b) (4), and was described as being (b) (4). The directions for general disinfection on the (b) (4) label require (b) (4).
-Only non-sterile wipes are used within the aseptic processing area.

OBSERVATION 3

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

Specifically,

- Smoke studies are not completed during HEPA filter and hood certification testing. Smoke study of the ISO 5 hood used for all of the firm's aseptic processing has not been done within approximately the last 10 years.
- The (b) (4) (b) (4) is used to sterilize a (b) (4) and metal ointment tubes for Vitamin A ophthalmic ointment, Lot#: 17201603@18, aseptically processed on 03/23/2016, has not been validated. The (b) (4) is used during aseptic processing and the ointment tubes are dispensed containing the finished product.
- The (b) (4) within the pharmacy's compounding lab used to (b) (4) sterilize Vitamin A ophthalmic ointment, Lot#: 17201603@18, aseptically processed on 03/23/2016, has not been validated.

OBSERVATION 4

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

Specifically,

- Stability testing for the 6 month Beyond Use Date (at both refrigerated and frozen conditions) being assigned to the Papaverine/Phentolamine/Prostaglandin injectable product is not being conducted for all aseptically produced strengths, and does not always utilize a stability-indicating method.
- Stability testing provided only documented (b) (4) for prostaglandin and papaverine/phentolamine components, and not (b) (4). The current practice is to store the (b) (4). The

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Papaverine/Phentolamine/Prostaglandin injectable product is dispensed for patient use with directions to be refrigerated.

OBSERVATION 5

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

-On 02/12/2016, air and surface samples were collected and analyzed by (b) (4). The results indicated at location (b) (4) the (b) (4) sampled within the (b) (4), the "Total CFU Per Air Sample = (b) (4) An investigation into the source of the colony growth was not initiated.

-The temperature log for (b) (4) different refrigerators and freezers used for storage of Papaverine/Phentolamine/Prostaglandin 75mg/2.5mg/25mcg/4.2ml Lot#: 06201604@15 and Prostaglandin (b) (4) (b) (4) Lot# (b) (4) among other (b) (4) and patient specific, aseptically processed products, showed a combined 26 excursions outside of the defined range or (b) (4) degrees Fahrenheit to (b) (4) degrees during the previous 6 months. Investigations into the excursions were not initiated.

OBSERVATION 6

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification as a condition for their approval and release.

Specifically,

-Papaverine/Phentolamine/Prostaglandin (b) (4) lot#: (b) (4) aseptically produced on (b) (4) reported potency for prostaglandin of 136%. Prostaglandin (b) (4) lot#: (b) (4) aseptically produced on (b) (4) had initial potency test results of 63.5%. Both (b) (4) were out of the defined range for potency (b) (4)%, and were released for further aseptic processing into patient specific orders and dispensed.

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OBSERVATION 7

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are not written or followed.

Specifically,

-The calibration for the (b) (4) scale, model: (b) (4) used to measure all (b) (4) drug ingredients for sterile products, is deficient in that it is only calibrated (b) (4) with (b) (4) The operational range of the scale is (b) (4) (b) (4)

-The thermometers used in monitoring (b) (4) different refrigerators and freezers used for storage of Papaverine/Phentolamine/Prostaglandin (b) (4) Lot#: (b) (4) and Prostaglandin (b) (4) (b) (4) Lot# (b) (4), among other (b) (4) and patient specific, aseptically processed products have never been calibrated.

***DATES OF INSPECTION**

6/06/2016(Mon),6/07/2016(Tue),6/08/2016(Wed),6/09/2016(Thu),6/10/2016(Fri),6/17/2016(Fri)
6/17/2016

James K Ireland

James K Ireland
Investigator
Signed by: James K. Ireland -5

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