DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/21/2015 - 10/07/2015* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Thomas J. Wilson PharmD., Owner

FIRM NAME	STREET ADDRESS
Cape Apothecary, Inc.	1384 Cape Saint Claire Rd
CITY, STATE, ZIP CODE, COUNTRY Annapolis, MD 21401	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and non-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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

On 09/22/2015, during the production of Glutathione 200mg/ml Injection, lot # 88208, the following aseptic techniques were observed in the cleanroom:

A) An aseptic operator was observed placing an (b) (4) with (b) (6) bare hands; (b) (6) then proceeded to disinfect (with (b) (4) the bench top inside the ISO 5 LAFH without any gloves. The operator proceeded to exit the cleanroom fully gowned and walked into the adjacent unclassified gowning area to wash (b) (6) hands and dry (b) (6) hands with a paper towel before returning back into the unclassified "clean room". The pharmacist was then observed putting on sterile gloves. However, (b) (6) was observed adjusting the glove with (b) (6) bare left hand to fit into the glove.

B) An aseptic operator was observed introducing material, such as sterile (b) (4), into the hood without disinfecting these materials. The operator did not disinfect (b) (6) hand every time (b) (6) reached out of the hood to grab material from shelves that are located in the cleanroom.

C) Another aseptic operator was also observed introducing material into the hood without disinfecting the surface and also not disinfecting (b) (6) gloves when going back into the hood. This pharmacist was producing ALFA-2B 1million unit/ml ophthalmic.

D) An aseptic operator was observed walking multiple times into and out of the unclassified "clean room" without putting on any appropriate gowning. Additionally, there is no procedure in place for gowning and no gowning instruction in the gowning area.

E) The ISO 5 LAFH is housed in an unclassified room.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nebil A. Oumer, Investigator Qin Xu, Investigator	10/07/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/21/2015 - 10/07/2015* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Thomas J. Wilson PharmD., Owner

FIRM NAME	STREET ADDRESS
Cape Apothecary, Inc.	1384 Cape Saint Claire Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annapolis, MD 21401	Producer of Sterile and non-sterile drug products

OBSERVATION 2

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

Specifically,

A) The (b) (4) of the (b) (4) for the (b) (4) (b) (4) after the sterilization of Triamcinolone diacetate Injection (on 11/19/14, 1/28/15 and 8/5/15) and Dexamethasone acetate Injection (on 3/10/15) is not appropriate. The firm uses a (b) (4) (b) (4) which has (b) (4) (b) (4) The firm uses the (b) (4) incorrectly by only (b) (4) (b) (4) to the sterilization process and no (b) (4) The firm incubates the unit without (b) (4) (b) (4) (b) (4) Furthermore, there are no procedures in place for how to conduct sterilization (b) (4)

B) Sterile drug product and drug products produced from non-sterile components are (b) (4) However the (b) (4) that's performed after the production of the drug products is inadequate. No (b) (4) is performed for (b) (4); however, according to Mr. TJW, he takes a (b) (4) (b) (4), which would indicate a failing result. Furthermore, the (b) (4) is not always documented and there is no procedure in place for how to conduct (b) (4). Products such as TriMix Injection, HCG Injection, Methylcobalamin Injection, and Hydroxyprogesterone Injection are (b) (4) at this site.

C) The most (b) (4) of Triamcinolone diacetate Injection (b) (4) (b) (4) states that the product should be (b) (4) However, the current method of sterilization of this product is (b) (4) (b) (4) Mr. TJW stated that in the past the (b) (4) (b) (4); however, he has not checked the (b) (4). The stability of the product after (b) (4) is currently unknown.

D) No media fill has been conducted that simulates routine aseptic operation.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/21/2015 - 10/07/2015* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Mr. Thomas J. Wilson PharmD., Owner	
FIRM NAME Cape Apothecary, Inc.	STREET ADDRESS 1384 Cape Saint Claire Rd
CITY, STATE, ZIP CODE, COUNTRY Annapolis, MD 21401	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and non-sterile drug products

OBSERVATION 3

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

Specifically,

A) Mr. TJW stated that sterility and endotoxin testing of sterile products are conducted (b) (4) basis. However, endotoxin test result certificates of recently manufactured products could not be produced by the firm. Mr. TJW stated that endotoxin samples have not been sent to their contract laboratory for the past 9 months.

B) Your firm does not conduct sterility and, endotoxin testing on all sterile drug products produced by your firm. Instead (b) (4) for testing.

C) Sterility samples are incubated in (b) (4) medium in-house; however, the firm did not evaluate the sterility samples using media (b) (4) intended to support anaerobic microbes. Furthermore, sterility samples are only incubated at (b) (4) days. There is no data that supports the validation of the sterility test.

OBSERVATION 4

Drug product containers were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

On 09/22/2015, a (b) (4) used for manufacturing a sterile drug product: Glutathione 200 mg/ml Injection (lot # 88208). Mr. TJW stated that all glassware / beakers are washed with (b) (4) and disinfected with (b) (4) prior to use. Endotoxin testing is conducted on a (b) (4) basis whereby (b) (4) to be tested.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nebil A. Oumer, Investigator Qin Xu, Investigator	DATE ISSUED 10/07/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/21/2015 - 10/07/2015* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Mr. Thomas J. Wilson PharmD., Owner	
FIRM NAME Cape Apothecary, Inc.	STREET ADDRESS 1384 Cape Saint Claire Rd
CITY, STATE, ZIP CODE, COUNTRY Annapolis, MD 21401	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and non-sterile drug products

OBSERVATION 5

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

Specifically,

The following non-sterile disinfectants are used for sanitizing the ISO 5 LAFH and the surrounding unclassified "clean room" (b) (4) [redacted]. No efficacy study was performed to determine if these disinfectants are capable of reducing the microbial load to an acceptable level in the ISO 5 LAFH and other surfaces (i.e. benchtop, walls and floor). Furthermore, none of these disinfectants have sporicidal properties.

OBSERVATION 6

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

Specifically,

On 09/22/2015, two aseptic operators were observed performing aseptic operations in the ISO 5 LAFH wearing non-sterile gowning. Specifically, their coat, face mask, shoe covers and pants were not sterile. Additionally, their face mask did not fully cover their faces, leaving skin around their forehead exposed.

OBSERVATION 7

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

Specifically,

There are no calibration and qualification records for the following equipment:

A) (b) (4) [redacted] used for the sterilization of Triamcinolone diacetate Injection and Dexamethasone acetate Injection. A (b) (4) [redacted] however, no documentation was provided that showed what was conducted.

B) The (b) (4) incubator (b) (4) [redacted] Incubator) used for incubating passive air samples, sterility samples and (b) (4) [redacted].

Additionally, there is no procedure in place for calibration and qualification of the above listed equipment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nebil A. Oumer, Investigator Qin Xu, Investigator	DATE ISSUED 10/07/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/21/2015 - 10/07/2015* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Thomas J. Wilson PharmD., Owner

FIRM NAME	STREET ADDRESS
Cape Apothecary, Inc.	1384 Cape Saint Claire Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annapolis, MD 21401	Producer of Sterile and non-sterile drug products

OBSERVATION 8

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

Specifically,

A) No passive, active and non-viable air is always monitored in the ISO5 LAFH during aseptic operations.

B) Personnel monitoring is conducted on (b) (4) whereby (b) (4) . Passive air sampling is conducted on the (b) (4) in the unclassified "clean room" with LAFH, (b) (4) .

C) An expired sampling mediu(b) (4) , Exp. Date 04/09/2015) used for fingertip testing was observed on 09/21/2015 during the facility tour.

OBSERVATION 9

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

Specifically,

The last qualification of the ISO 5 LAFH used for aseptic operations was conducted on (b) (4) . The qualification did not challenge the hood during the smoke study under dynamic conditions. According to Mr. TJW, (b) (4)

OBSERVATION 10

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

No investigation was initiated to determine the root cause for several potency failure results for products produced in 2013, 2012 and 2011. For example, Diethysltilbestrol 1mg (lot # 49011, dated 10/10/13), "Bactroban, Sporonox, Triam, Xylitol" (lot # 20085, dated 5/31/12), and Bactroban Nasal Spray 0.2% (lot # 2040103, dated 6/6/12) had the following potency results: 80%, 80.5%, and 53.5% respectively, against a specification of (b) (4) Furthermore, there is no procedure in place for conducting investigations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nebil A. Oumer, Investigator Qin Xu, Investigator	10/07/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/21/2015 - 10/07/2015* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Thomas J. Wilson PharmD., Owner

FIRM NAME	STREET ADDRESS
Cape Apothecary, Inc.	1384 Cape Saint Claire Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Annapolis, MD 21401	Producer of Sterile and non-sterile drug products

OBSERVATION 11

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

Specifically,

The firm does not have a stability program for sterile and non-sterile drug products manufactured at this site. Hydroxocobalamin (B12) 3000 MCG/ml injection, Tobramycin (Ophth) 15mg/ml Drops and Cisapride 5mg/ml suspension have an expiration date of 6 months, 1 month, and 2 months respectively.

*** DATES OF INSPECTION:**
09/21/2015(Mon), 09/22/2015(Tue), 09/28/2015(Mon), 09/29/2015(Tue), 10/06/2015(Tue), 10/07/2015(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nebil A. Oumer, Investigator Qin Xu, Investigator	10/07/2015