DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	12/29/2015-1/8/2016* FEI NUMBER 3005529620

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John Garcia , Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Abbott's Compounding Pharmacy, Inc.	2320 Woolsey St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Berkeley, CA 94705-1973	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 WE OBSERVED:

OBSERVATION 1

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, your firm's clean room where your ISO 5 laminar air flow workbenches (LAFW) are located has not been maintained in a good state of repair. For example, the clean room walls are (b) (4) [redacted] that are attached using Velcro. There are multiple areas around the edges of the (b) (4) [redacted] where the Velcro has become detached or does not provide a seal, which allows air to pass to the non-classified environment.

In addition, your ISO 5 LAFW work surface appears to be made of a wood like material covered with a laminate material. We observed scratches on this surface. Your firm also uses wooden cabinets in the ISO 7 clean room to (b) (4) [redacted] The ISO 5 LAFW is (b) (4) [redacted] of these cabinets. Your firm also uses these cabinets to (b) (4) [redacted] in cardboard boxes.

We also observed a hole in the wall behind the ISO 5 LAFW. This hole is approximately ½ inch x 4 inches and is located on the far left side of the wall, to the left of the ISO 5 LAFW, approximately 3 feet from the floor.

OBSERVATION 2

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

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Specifically, your firm has not performed smoke studies in dynamic conditions to demonstrate the air flow patterns in the ISO 5 LAFW and ISO 7 clean room where injectable drug products are produced. According to the reports provided by the contract vendor who performs re-certification of the ISO 5 LAFW and ISO 7 clean room, smoke studies are performed; however, the firm does not have any documentation (i.e. video) to demonstrate the air flow patterns of the ISO 5 LAFW and ISO 7 clean room.

Also, the positive pressure of airflow out of your clean room is not constant as we observed the room's air handling system was turned off the morning of 12/31/2015. According to your firm's PIC, the room's air handling system must have been turned off the(b) (4) [redacted] Your firm does not have a procedure to describe how the air handling system of your ISO classified areas should be turned back on for situations when it has been turned off.

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, the garments and protective apparel worn by your sterile drug technicians is inadequate. Your clean room gowning consists of non-sterile shoe covers, non-sterile hair net, non-sterile face mask, non-sterile lab coat, and sterile gloves. On 12/29/2015, we observed your technicians wearing the above non-sterile clean room garb while performing aseptic filling of Koate 7700 Inj Lot # 12292015@42, and on 12/30/2015, filling Antihemophillic Factor (Alphanate) 5220 Units Injection Lot # 12302015@41 and Koate 7700 Inj Lot # 12302015@7 in the ISO 5 LAFW. The technician did not wear eye goggles or have eye protection. The non-sterile mask did not provide adequate coverage to the forehead, neck or face areas. We observed most of the technician's forehead, face around his eyes, and both cheek areas exposed. The technician's neck also had strands of hair exposed.

OBSERVATION 4

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

Specifically,

A. On 12/29/2015, we observed the aseptic preparation of Koate 7700 Inj Lot # 12292015@42. We observed the technician move components and materials (b) (4) without disinfecting them. These components and materials were placed inside the ISO 5 LAFW without being wiped down with any disinfectant. Once inside the ISO 5 LAFW, only the bottoms of the glass vials were wiped on a non-sterile lint-free cloth dampened with non-sterile (b) (4) SOP 1.060 v1.0 entitled, "GENERAL ASEPTIC TECHNIQUE", section 9.4.5 states, "(b) (4) (b) (4) (b) (4)." We also noted the same non-sterile lint-free cloth sprayed with non-sterile (b) (4) was used earlier to clean all sides of the inside of the ISO 5 LAFW prior to filling sterile drug product. The same cloth was used to clean the ISO 5 LAFW after sterile filling operations were completed.

B. On 12/29/2015, we observed the aseptic preparation of Koate 7700 Inj Lot # 12292015@42. We observed the technician, on numerous occasions, touched the clean room cabinet drawer handles with sterile gloves and returned to work in the ISO 5 hood without disinfecting (b) (6) gloves with disinfectant. SOP 1.060 v1.0 entitled, "GENERAL ASEPTIC TECHNIQUE", section 9.4.6 states, (b) (4) The same technician later disinfected (b) (6) gloves toward the end of sterile filling but (b) (6) used non-sterile (b) (4)

C. On 12/30/2015, we observed a technician spray (b) (6) gloves with sterile (b) (4), but (b) (6) did not allow the (b) (4) to dry before returning to work in the ISO 5 LAFW. The technician was preparing sterile injectable drug product, Antihemophillic Factor (Alphanate) 5220 Units Inj Lot # 12302015@41. SOP 1.060 v1.0 entitled, "GENERAL ASEPTIC TECHNIQUE", section 9.4.6

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states, (b) (4)
(b) (4)

D. Your firm's ISO 7 ante room lacks separation between the clean and dirty sides of the room. On 12/29/2015 and 12/30/2015, we observed a technician walking into the ante room with street shoes. (b) (6) put on shoe covers but stepped in the same area where (b) (6) previously traversed with (b) (6) street shoes. The technician later entered into the ISO 7 clean room buffer area wearing the same shoe covers.

OBSERVATION 5

Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed .

Specifically, your firm's testing of sterile drug products is inadequate for the following reasons:

AP 1/8/2016
A ~~E.~~ All of your firm's "for office use" sterile drug products are tested for sterility by a contract laboratory. However, sterility testing by the contract laboratory does not meet all the requirements for sampling and method suitability specified in relevant compendial methods. For example, finished drug product of Sodium Tetradecyl Sulfate 3% Injectable, Lot # 12152015@24 contains 30 mL of the product in a (b) (4) glass vial. The compendial method requires a minimum of 4 vials and 15 mL from each vial (half the contents of each vial) to be tested for sterility. Your firm submitted (b) (4) of the product in a (b) (4) for sterility testing. Not only were insufficient quantities of samples tested, samples also did not represent the actual finished drug products compounded (a different container and closure system was used in sample submission). The certificate of analysis provided by your contract laboratory indicates your sample "Does not meet all the requirements for sampling and/or method suitability specified in USP <71>."

AP 1/8/2016
B ~~F.~~ All of your firm's "for office use" sterile drug products are tested for endotoxin by a contract

laboratory. We observed the endotoxin specification or EL (endotoxin limit) was not always provided in the results C of A (certificate of analysis). For example, the contract laboratory did not provide specification in the results C of A for Glycerin 72% Injectable, Lot # 09222015@64, Lot # 05122015@58, and Lot # 01052015@43. SOP 9.060 v1.0, entitled, "PRODUCT QUARANTINE, STORAGE AND RELEASE" section 9.3.1.6 specifies (b) (4) (b) (4) Without specification, your firm is not able to ensure endotoxin results meet release criteria. Also the correct MVD (Maximum Valid Dilution) cannot be calculated for sample preparation in order to obtain valid test results per USP <85>. For example, samples diluted beyond the MVD can lead to false negative endotoxin results.

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, the release testing for your sterile drug products is inadequate for the following reasons:

A. Your firm does not routinely perform potency testing for either patient specific or "for office use" sterile drug products prior to release. According to your PIC, (b) (4) (b) (4)

B. 100% visual inspection for (b) (4) batch of compounded sterile injectable is not documented by your firm. SOP 9.060 v1.0 entitled, "PRODUCT QUARANTINE, STORAGE AND RELEASE", section 9.3.1.7 provides requirement for (b) (4) (b) (4) On 12/29/15, we observed what appeared to be floating particulates in Sodium Tetradecyl Sulfate

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3% Injectable, Lot #12152015@24.

OBSERVATION 7

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

Specifically, your firm's environmental monitoring operations are inadequate due to the following:

A AP 1/8/2016 G. Non-viable particular counts, viable air and surface monitoring of the (b) (4) (b) (4) are performed every (b) (4) (b) (4) (b) (4) (b) (4) SOP 3.030 v1.0 entitled, "ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITY", section 6.2 states, '(b) (4) (b) (4) (b) (4) "

B AP 1/8/2016 H. Personnel monitoring of operators gloves are not sampled daily upon completion of sterile compounding. Instead, they are performed every (b) (4) According to SOP 3.030 v1.0, entitled, "ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITY", section 6.1, '(b) (4) (b) (4) '

OBSERVATION 8

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

Specifically, your firm's cleaning agents are not adequate for use in your ISO 5 LAFW and ISO 7 clean room. On 12/30/2015, we observed a bottle of expired (b) (4) (sporicidal agent) in the clean room ISO 7 clean room. The (b) (4) was expired as of 9/27/2015. According to your technician (b) (6) it is

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used to clean the (b) (4), (b) (4) (b) (4); however, the use of (b) (4) is not documented on your cleaning records.

Also, according to your technician (b) (6), (b) (7)(C), non-sterile (b) (4) is used to clean the floors and walls of the ISO 7 clean room. In addition, your cleaning procedures are deficient as they do not describe how to clean and sanitize the stool and (b) (4) located in your ISO 7 clean room. Your cleaning records do not document the cleaning of the stool or (b) (4). According to the PIC, the (b) (4) is used (b) (4) (b) (4). An example of a product which the (b) (4) is used for is cyclosporin eye drops used meant for veterinary use.

OBSERVATION 9

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, your firm has not established and does not follow procedures for cleaning, sterilizing, and depyrogenation of glassware used to produce sterile drug products. We observed your technician (b) (6), (b) (7)(C) use (b) (4) used to produce your Papaverine, Phentolamine, and Edetate combination sterile drug product.

OBSERVATION 10

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, your firm does not bear appropriate expiration dates on your sterile drug products. Your firm has not performed any stability studies to justify assigning expiration dates. Your firm produces sterile drug products based on (b) (4) (b) (4) and assigns a beyond use date (BUD) based on the (b) (4) (b) (4)

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On 12/29/2015, we observed Sodium Tetradecyl Sulfate 3% Injectable Lot 12152015@24 ("For office use") was assigned a 30 day beyond use date. A 90 day expiration date was on the master formula worksheet; however a 30 day expiration date was handwritten on the product label. After your firm had discussions with (b) (4) (b) (4) on 12/29/2015 and while reviewing the most recent (b) (4) (b) (4) it was discovered the (b) (4) (b) (4) firm failed to follow (b) (4) (b) (4) (b) (4) in assigning the correct beyond use date.

Other "for office use" sterile injectable drug products with BUD's longer than the (b) (4) (b) (4) include but are not limited to the following:

AP 1/8/2016
A. Sodium Tetradecyl Sulfate 3% Injectable Lot 05122015@59
B. Epinephrine 0.05%, Lidocaine 4%, Tetracaine 0.5% Injectable (pediatrics) Lot # 09222015@40.
AP 1/8/2016

OBSERVATION 11

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

Specifically, your firm failed to calibrate equipment used in the production of sterile drug products. For example, your firm has not calibrated the scales used to weigh ingredients used to produce sterile drug products. In addition, your firm has not calibrated the (b) (4) (b) (4) (b) (4) (b) (4) or the (b) (4) (b) (4) used in the refrigerator that stores finished drug product.

***DATES OF INSPECTION**

12/29/2015(Tue),12/30/2015(Wed),12/31/2015(Thu),1/06/2016(Wed),1/07/2016(Thu),1/08/2016(Fri)

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