DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	05/12/2015 - 05/21/2015
	FEI NUMBER 3011504027

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Vincent Matthew Poteet, Owner/Pharmacist

FIRM NAME	STREET ADDRESS
The Compounding Pharmacy of America	6216 Highland Place Way Ste 101-A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Knoxville, TN 37919-4068	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

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

Specifically,

1. Microbial testing is not performed for each lot of drug product purporting to be sterile. Your firm's lots range in volume from 1 mL to 2400 mL. Furthermore, you have not validated your microbial testing method.

2. No endotoxin testing is performed on finished product and vials and stoppers are not depyrogenated before use. All drug products your firm produces are made from non-sterile components.

OBSERVATION 2

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

Specifically,

Your firm does not depyrogenate any containers or closures used in the aseptic filling/terminal sterilization of drugs products intending to be sterile.

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OBSERVATION 3

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

Specifically,

1. Your firm has not validated your sterilization process for autoclaving glass vials to be used for drugs products intending to be sterile.

2. Your firm has not validated your filter sterilization process using a 0.2µm filter to aseptically fill injectable drugs purporting to be sterile. Furthermore, the user manual for the filter your firm is using states "this filter is not intended for intrathecal drug administration." Your firm has been using this filter since 2012 to aseptically fill injectable drugs purporting to be sterile, including intrathecal solutions.

3. Your firm has not validated your process of depyrogenating glassware used in the mixing of drug products to be aseptically filled or terminally sterilized.

4. Your firm's SOP 7.011, "Gowning and Gloving," states that gloves will be disposed of upon leaving the Clean Room and a new pair donned to return. On 05/12/15, we observed a technician leave the Clean Room to retrieve a syringe from the Ante Room. The firm's owner, who was not wearing gloves, had placed the syringe in the Ante Room for the technician without wiping down the syringe. The technician did not change gloves before beginning aseptic filling.

5. Your firm's SOP 8.012, "Compounding Sterile Solutions," states to produce all injectables in a Class 100 environment. On 05/12/15, we observed Lidocaine 2% gel, lot #05122015@15 to be used in an intrathecal pump, Morphine 10 mg/ml Intrathecal Solution, lot #05122015@6, Morphine 20 mg/ml Intrathecal Solution, lot #05122015@17 and Methylcobalamin 1,000 mcg/ml injection, lot #05122015@14 being compounded in the Lab Room , which is an unclassified room that does not have HEPA filtration.

6. Your firm's SOP 7.007.3, "Media Fill for High Risk Compounding," states that media-fill tests are to be performed semi-annually for each technician in an ISO class 5 area; however, this does not simulate your firm's actual process because all drug products are produce in the Lab Room which is an unclassified area with no HEPA filtration.

7. Your firm's SOP 7.011, "Gowning and Gloving," does not have requirements for complete covering of the facial area. On 05/12/15, we observed an employee aseptically filling Morphine 10 mg/ml Intrathecal Solution, lot #05122015@6, Morphine 20 mg/ml Intrathecal Solution, lot #05122015@17 and Methylcobalamin 1,000 mcg/ml injection, lot #05122015@14 with exposed forehead and eyes.

8. Your firm's SOP 7.011, "Gowning and Gloving," states the technician will spray gloves with sterile IPA 70% when needed throughout the filling process and allow to dry. On 05/12/15, a technician was observed spraying her gloves

with sterile IPA 70%, but not allowing the alcohol to dry before processing. The technician was aseptically filling Morphine 10 mg/ml Intrathecal Solution, lot #05122015@6, Morphine 20 mg/ml Intrathecal Solution, lot #05122015@17 and Methylcobalamin 1,000 mcg/ml injection, lot #05122015@14.

9. Your firm's SOP 7.011, "Gowning and Gloving," states technicians will wash forearms and hands from the elbows down before gowning to enter the clean room. On 05/12/15, we observed a technician washing only her hands and did not wash past the wrist before gowning and entering the Clean Room to aseptically fill Morphine 10 mg/ml Intrathecal Solution, lot #05122015@6, Morphine 20 mg/ml Intrathecal Solution, lot #05122015@17 and Methylcobalamin 1,000 mcg/ml injection, lot #05122015@14.

10. Your firm's SOP 4.004, "Incubator Temperature Monitoring," does not establish continuous monitoring or give procedures for investigating out of range temperatures. This incubator is used to incubate media fills, environmental monitoring samples, and finished product microbial testing. Temperature of the incubator is recorded once daily. During a record review for the past year of the Incubator Temperature log, it was noted the temperature went out of range approximately 30% of the time. No investigations were performed.

11. Your firm does not perform positive or negative controls on media which is used for sterility testing on products and environmental monitoring.

12. Your firm does not perform growth promotion testing on media used for microbial testing.

13. On 05/12/15, we observed one of the firm's owners/pharmacists chewing gum in the Lab Room while Lidocaine 2% gel, lot #05122015@15, for intrathecal use was being produced.

14. On 05/12/15, a technician was observed placing her hands between the product and air flow during processing. This obstruction could cause turbulent air flow around the product being aseptically filled.

OBSERVATION 4

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

Specifically,

1. No environmental monitoring is conducted in the Lab Room where weighing and mixing take place. The HVAC unit for

this room is shared with other uncontrolled areas in the building and a supply vent is located directly above the space on the counter where compounding takes place. Weighing and mixing processes are not performed under a hood, the room is not classified, and does not have HEPA filtration.

2. We observed the door to the Lab Room to remain open during weighing and mixing of non-sterile components to be used to produce drug products intended to be sterile. This door opens into a hallway that leads to the exit door and is adjacent to a door leading into the neighboring office.

3. Your firm shares the building with an infusion office. The door into their office is adjacent to the door into your Lab Room . We observed employees from the infusion office coming into the Lab Room to retrieve product they have stored in your Lab Room .

4. Viable air and personnel monitoring is not conducted for every production of injectable drug product. Currently your firm uses settling plates for viable air and finger-tip swabs for personnel monitoring only once per week and for only one technician.

OBSERVATION 5

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

Specifically,

1. A review of your firm's Air Pressure Differential Log from the past year found the pressure from the Clean Room into the Ante Room and the Ante Room into the Lab Room to be equal in measurement. This indicates there is no positive pressure to direct air supply away from the clean room.

2. Air pressure is not continuously monitored in the laminar flow hoods, Clean Room, or Ante Room.

3. There is no HEPA filtration in the Lab room where components are weighed and mixed for producing drug products intended to be sterile. Weighing and mixing does not take place in an ISO classified area.

4. Smoke studies for qualification of the ISO 5 area where injectable drug products are processed were not documented with diagram or video.

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OBSERVATION 6

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

Specifically,

1. Your firm's daily cleaning of the Clean Room and Ante Room consists of wiping the walls and floors with a non-sterile Swiffer brand mop. On a monthly basis, your firm cleans with Lysol IC and Clorox Hydrogen Peroxide in the Clean Room and Ante Room. Your firm does not use any sporicide while cleaning in the Clean Room. This cleaning method and schedule is inadequate for cleaning and disinfecting a room for aseptic processing. Also, cleaning products used are not documented on cleaning logs.

2. You do not use a sporicide in your ISO 5 hood where aseptic filling takes place. The only product used to clean the ISO 5 hood is sterile 70% Isopropyl Alcohol.

3. On 05/12/15, we observed stacked, plastic baskets containing in-process drug product and aseptic filling equipment (pre-packaged syringes and filters). The technician took these stacked baskets into the Ante Room and did not wipe the baskets or materials down before entering. Once the technician completed gowning, she carried the baskets into the Clean Room for aseptic processing. The materials were wiped with a non-sterile, pre-wetted alcohol wipe before being placed in the ISO 5 hood. These wipes are in a re-sealable container via sticky flap located on the top.

4. During the inspection, visible dirt and debris was observed on the return vent in the clean room and Swiffer mops used in the Clean Room and Ante Room were propped up against the walls in each room, with the mop end leaning against the wall. Also, it was noted the Clean Room, Ante Room, and Lab Room all had open trash receptacles.

5. The lighting in the Clean Room is not recessed into the ceiling and there is a visible gap between the light fixture and the ceiling that would allow for a build-up of dirt and debris.

OBSERVATION 7

There is a failure to thoroughly review 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,

A review of records from the past year found Sufentanil 50mcg/ml Intrathecal Solution, lot #01102014@24, Morphine 50 mg/ml Intrathecal Solution, lot #06252014@6, and Morphine 40 mg/ml + Fentanyl 2,000 mcg/ml Intrathecal solution, lot 08062014@19 all tested positive for microbial contamination. No investigations were performed and the lots were

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distributed.

OBSERVATION 8

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

Specifically,

1. Non-sterile gowns, face masks, and hair covers are used during the production of drug products intended to be sterile. These garments are stored in open containers in the Ante Room.

2. On 05/12/15, we observed the processing of Morphine 10 mg/ml Intrathecal Solution, lot #05122015@6, Morphine 20 mg/ml Intrathecal Solution, lot #05122015@17 and Methylcobalamin 1,000 mcg/ml injection, lot #05122015@14, all purporting to be sterile. The technician's gown did not adequately cover the technician, leaving the collar of her shirt and her neck area exposed. Also, the technicians forehead and eyes were not covered and her hair was loose from her hair cover around the back of her neck.

3. On 05/12/15, we observed a technician mixing and filling Lidocaine 2% gel, lot #05122015@15, for intrathecal use, into glass vials to be autoclaved. The technician was wearing gloves, but not wearing any gowning or head/face covers over her street clothes. This process was taking place in the Lab Room , which is an unclassified room with no HEPA filtration.

OBSERVATION 9

Results of stability testing are not used in determining expiration dates.

Specifically,

Your firm has not conducted any stability testing. Expiration dates of 2-3 months are assigned to drug products intended to be sterile that do not contain preservatives. You have no data to support your product expiration dates.

OBSERVATION 10

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

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1. Your firm's Clean Room contains two ISO 5 laminar flow hoods for aseptic filling; however, you only have one staging table for materials. When two technicians are filling in the Clean Room, they must share the table increasing the likelihood of a mix-up.

2. In the Lab Room, several different products can be weighed and staged for mixing on the same counter top. For example, on 05/12/15, we observed pre-printed worksheets and labeling for different products on the counter where production takes place. There is no separation for these materials, which can lead to a mix-up of labeling or components. Also, multiple products can be taken into the Clean Room, simultaneously, for aseptic filling.

3. On 05/12/15, 1 IV bag of 0.9% Sodium Chloride solution and 1 IV bag of Sterile Water for Injection were observed in the sink in the Ante Room. These bags had no additional labeling to determine if the firm had used them in processing or was going to use them, and no indication of what product these solutions would be used for.

OBSERVATION 11

There is no quality control unit.

Specifically,

Your firm has not established a quality control unit with the responsibility to approve or reject all components, containers, closures, packing material, labeling, and drug products. For example:

1. Containers and closures are not examined upon receipt to ensure they meet specifications for use.

2. No finished product testing is performed on drug products intending to be sterile before release for distribution.

3. Your firm has just recently established a complaint file. A review of your firm's Incident Report Forms found no investigations were performed for complaints to determine root cause. For example:

a. On 3/4/25, your firm received a complaint for Neurogenic XR + BAC + GAB cream being "sticky." No lot number was recorded on the Pharmacy Incident Report Form and you did not request that the product be returned for analysis. No investigation was performed and the corrective action was to remake the product and send the patient a new jar.

b. On 03/06/15, your firm received a complaint for Anti-Inflammatory Plus 10 pain gel that had separated upon the patient receiving the product. No lot number was recorded on the Pharmacy Incident Report Form and you did not request that the product be returned for analysis. No investigation was performed and the corrective action was to remake the product and send the patient a new jar.

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OBSERVATION 12

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

Your firm has not established any hold times for processing drug products intended to be sterile.

OBSERVATION 13

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

Specifically,

There are no records to demonstrate the following equipment has been calibrated for use:

1. The pressure gauge used for the filter integrity testing of the B. Braun 0.2µm filter used for aseptic filling.

2. The scale in the Lab Room used to weigh ingredients used in production of drug products.

3. The thermometer in the incubator used to test environmental samples and finished product.

4. The thermometer used in the depyrogenation oven used for glassware.

5. The thermometer in the autoclave used to sterilize glassware and terminally sterilize injectable drug products.

OBSERVATION 14

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically,

1. Your firm accepts incoming lots of non-sterile raw materials and components based on the Certificate of Analysis (CoA). You do not conduct any additional testing on incoming lots of raw materials and components. Also, the CoA's you receive from your supplier do not include microbial testing.

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2. You have not qualified the reliability of your suppliers.

OBSERVATION 15

Aseptic processing areas are deficient regarding temperature and humidity controls.

Specifically,

1. During a review of temperature and humidity logs from the past year (Jan. 2014-May. 2015), it was found the temperature was out of range for the Lab room approximately 70% of the time, the Clean Room approximately 18% of the time, and the Ante Room approximately 98% of the time. No investigations were performed into these discrepancies.

2. During a review of temperature and humidity logs from the past year (Jan. 2014-May. 2015), it was found the humidity was out of range for the Lab Room approximately 13% of the time, the Clean Room approximately 63% of the time, and the Ante Room approximately 14% of the time. No investigations were performed into these discrepancies.

3. Temperature and humidity in aseptic processing areas are not continuously monitored. The gauge readings are only documented once daily.

OBSERVATION 16

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

1. Your firm's Logged Formula Worksheets do not contain a representative label from the product that was produced.

2. Your firm's Logged Formula Worksheets do not indicate which containers and closures were used or what container the product was filled into.

3. Heating and mixing times during production are not documented in the Logged Formula Worksheets.

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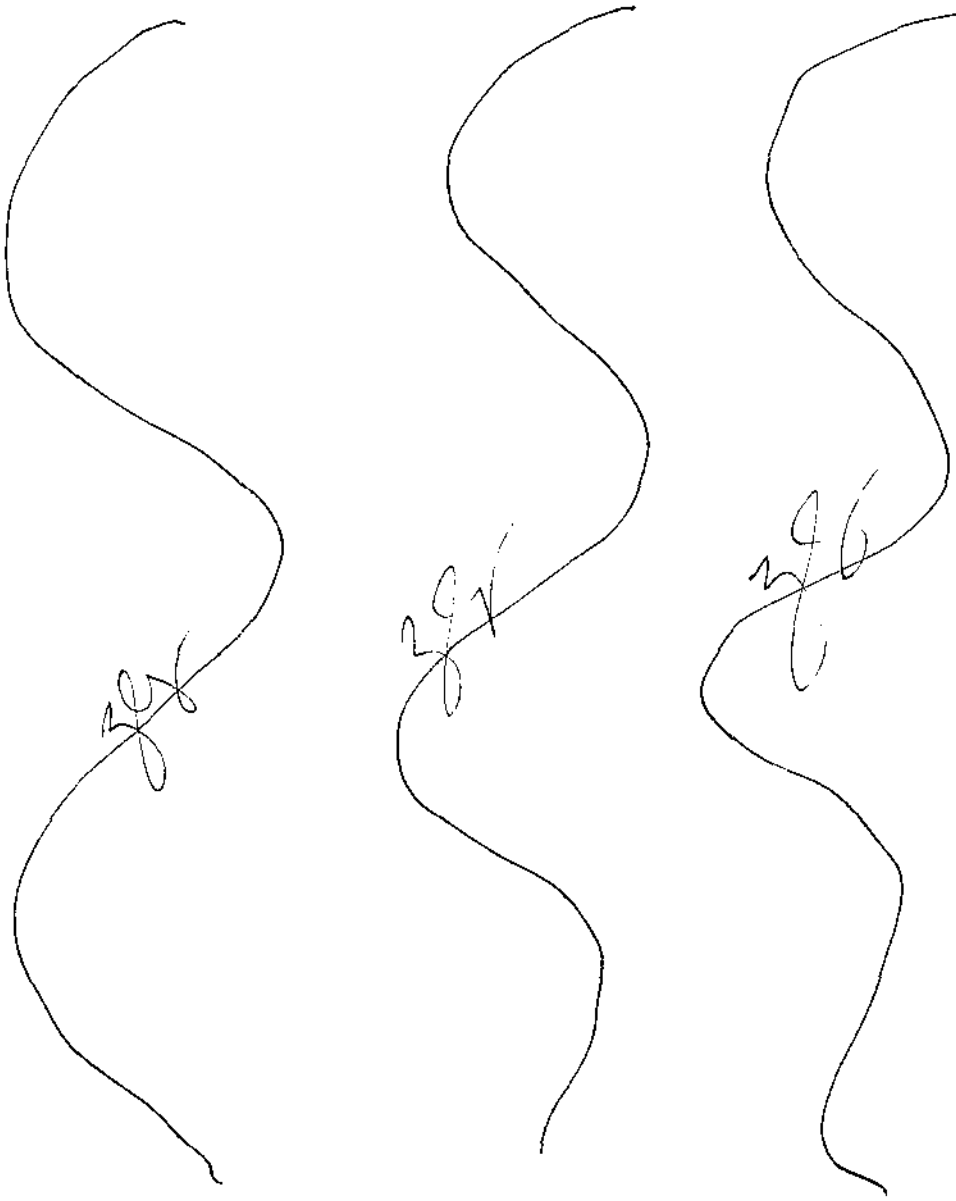

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