DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/22/2013
	FEI NUMBER 3004668624

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Shirley M. Spelich, Pharmacy Department Manager

FIRM NAME	STREET ADDRESS
THE COMPOUNDING SHOP, INC.	4000 Park St N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
St Petersburg, FL 33709-4034	Producer of sterile drugs

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, written, and followed.

Specifically,

a) During the aseptic preparation of Dexamethasone PF, lot # 03152013@20, performed on 3/20/13 by a pharmacy technician in ISO 5 hood in cleanroom #1, we observed the following deficiencies in aseptic technique:
   1) After touching an unsanitized pen to document information in the Logged Formula Worksheet located in the pass-thru tunnel between the pharmacy (uncontrolled area) and the ISO 7 cleanroom, the technician quickly proceeded to grab and transfer wrapped supplies and instruments stored in a cart in the ISO 7 cleanroom into the ISO 5 hood without proper sanitization of hands and supplies.
   2) The technician worked directly over (b) (4) closely lined-up open 10cc vials when manually filling them with a product-filled syringe fitted with a (b) (4).
   3) Once open vials were filled, the technician opened the wrapper containing (b) (4) rubber stoppers, and grabbed and pressed a stopper on each vial directly with her gloved hands. Gloved hands were sanitized only once at the beginning of the filling operation and no sanitized or (b) (4) tools were used to handle sterile containers and closures. No further sterilization is conducted for this preservative-free drug product and no sterility and endotoxin testing is performed.

b) During the repackaging operations of Bevacizumab 1.25mg/0.05ml injectable, lot # 03152013@19, prepared on 3/18/13 by a pharmacy technician in the ISO 5 safety hood in Chemo Room #1, we observed the following deficiencies in aseptic technique:
   1) A non-sterile mat stored in an open plastic bin in the ISO 7 cleanroom was placed directly onto the working surface of the ISO 5 hood without any sanitization. These single-use mats are previously stored uncovered and unwrapped on an open shelf in the pharmacy (uncontrolled area with a sink) until supply is depleted in the ISO 7 cleanroom, at which time they are transferred to the open bin in the ISO 7 cleanroom.
   2) The technician placed the decrimping tool, alcohol pads, and the sealed vial of bevacizumab (Avastin) directly onto the mat without proper sanitization of the supplies and gloved hands.

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3) After sanitization of hands, she decrimped the Avastin vial, removed the rubber stopper with gloved hands, and placed the open vial on a plastic holder placed onto the non-sterile mat. She then proceeded to work directly over the open vial to withdraw 0.05cc of bevacizumab to fill a total of (b) (4) syringes. Each syringe was recapped with its original cap. This operation lasted about 30-45 minutes and sanitization of hands was conducted once at the beginning of the operation.

The same deficiencies were observed in the repackaging of Bevacizumab 1.25mg/0.05ml injectable, lot # 03152013@20 (b) (4)) conducted immediately after the completion of the above named lot. Both lots were distributed the next day, 3/19/13 without completion of the (b) (4) sterility test performed by a contract laboratory. A 90-day expiration date of 6/13/13 was assigned to these preservative-free batches.

c) During the syringe filling operation of Morphine/Clonidine 25mg/500mcg/ml, lot 03192013@45 and Morphine Sulfate PF 100mg/ml injectable, lot 03192013@42, we observed the technician forcefully 'banging' the plunger end of the capped syringe against the surface of the ISO 5 hood in order to remove an air bubble from the large syringe. This practice observed for both fills can potentially increase particulates in the ISO 5 environment.

d) Media fills conducted by the firm within the ISO 7 (*ISO 5*) environments were found to be deficient in that:
1. They do not accurately simulate production processes and conditions that would best represent worst case conditions and optimize detection of any microbiological contamination. For example, the firm's media fill procedure uses ([redacted] vials and does not represent the worst possible case for 50 and 100 ml vials filled at the firm. Similarly, media fills do not demonstrate lengthy processes of 30-45 minutes as observed during repackaging operations of bevacizumab syringes on 3/18/13.
2. No growth promotion test is performed on the media prepared in-house to demonstrate that it promotes growth of gram-negative and gram positive bacteria, yeast and mold.
3. The media fill records do not include sufficient detail such as which ISO 5 environment or room was used to conduct each media fill.

e) There is no antimicrobial effectiveness data for injectable and opthalmic drug products containing preservatives such as (b) (4) or (b) (4) . Some of these drug products include Progesterone in Sesame Oil 100mg/ml injectable, hydroxyprogesterone caproate, and nandrolone decanoate (olive oil) 200mg/ml injectable. In addition, they have not evaluated whether the sesame oil or olive oil inhibit or promote growth of microorganisms.

OBSERVATION 2

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

Specifically, your firm has not established adequate written procedures for environmental monitoring (EM) that describe

timing of samples (during or at the conclusion of operations), specific sampling equipment and techniques, alert and action levels, and appropriate response to deviations from alert or action levels. Pharmacy technicians only follow the "Touch plate testing" form which lists (b) (4) general locations for air sampling (settle plate) and (b) locations for surface sampling (touch plates) without any instructions. Upon review of 2012-2013 EM records and interview of the pharmacy technician responsible for sampling, the following practices were found:

a) Surface samples are only taken after cleaning and sanitization of the ISO 5 hood and ISO 7 cleanroom and not during or immediately after production.
b) Sampling locations are not accurately specified when taken. For example, the touch sample location reported on the plate as "stainless steel table" was identified by the technician who took the sample as the ISO 5 hood surface and not the stainless steel table in the ISO 7 room; whereas the pharmacist who read the plate identified this location to us as the stainless steel table in the ISO 7 cleanroom. The location "stainless steel table" is actually the ISO 5 hood.
c) Results of plate readings performed by the pharmacists are not consistently recorded and do not show date of reading. It was reported that prior to the inspection plates were read after 14 days, and not after about 3-5 days of incubation. It was also reported that plates were often dry upon reading at 14 days.
d) There are no established alert limits. The pharmacist reported only an "action" level of (b) for both the ISO 5 and ISO 7 areas, without any justification for these limits.
e) No environmental monitoring was conducted between 12/3-19/12 and 1/7- 2/6/13 due to reported unavailability of plates. During the period of 1/7-2/6/13, the firm produced a total of (b) injectable and opthalmic drug products.
f) Environmental excursions are not investigated, organisms are not identified, and corrective action is not taken when action levels are exceeded. For example, these are some of the excursions that were recorded:

Date	Reading	Documented action
7/25/12	13 cfu in cart w/ supplies in Chem room (ISO 7)	"*will start wiping every day and re-test*"; no investigation was conducted and no ID was performed.
7/26/12	3 cfu in stainless steel table in chem room	No action. This location is referred by the technician as the ISO 5 hood.
7/26/12	3 cfu in stainless steel table in sterile room	No action. This location is referred by the technician as the ISO 5 hood.
7/30/12	5 cfu on stool in chem room	No action
8/10/12	12 cfu "finger touch"	No action. No investigation was conducted and no ID was performed.
8/21/12	"*Growth multiple colonies*" on stool in aseptic room.	No action. No investigation was conducted and no ID was performed.
9/10/12 & 10/12/12	4 cfu in stainless steel table in chem room	No action. This location is referred by the technician as the ISO 5 hood.

g) On 3/20/13, upon inspection of EM sample plates held next to the incubator awaiting reading by a pharmacist we observed a plate that showed a glossy white, large microbial colony that covered about 75% of the media. The plate was labeled as "3-15 stainless steel table sterile room"; this is the ISO 5 hood where all injectables are prepared. On 3/21/13, we verified that the plate was read; it was documented as +2 cfu and no action was taken. Upon interview of the pharmacist who read the plate, we found out that she did not know that the "stainless steel table" was the sample for the ISO 5 hood.

h) Fingertip sampling of pharmacy technicians performing aseptic operations in the ISO 5 hood is not conducted at least daily after production of sterile injectable, intrathecal and opthalmic drug products.

i) Viable monitoring of air (settle plate) is not conducted in the ISO 5 hood at least daily during production of injectable, intrathecal and opthalmic drug products.

OBSERVATION 3

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a) On 3/18/13 upon inspection of the ISO 5 horizontal laminar flow hood used to prepare sterile injectable and opthalmic products in vials, the following deficiencies were observed:

1. At least ten (10) exposed rust areas around the top light panel.
2. A white patch about 2"x2" on the the HEPA filter about 12" inches from the bottom surface and the right side panel. This patch was reported by a pharmacy technician as a "repair patch" that has been there for a long time.
3. Numerous splattered brownish stains across the lower half of the HEPA filter and cover grill.
4. Dark areas of different sizes on several places on the HEPA filter.

b) On 3/20/12 **3**, upon inspection of the vertical laminar flow biosafety ISO 5 hood where repackaging operations of bevacizumab are conducted, brownish areas appearing to be rust were observed below the bottom air vent across the front side of the hood.

c) On 3/18/13, while observing re-packaging operations of Bevacizumab, lot # 03152013@19 and 03152013@20, we observed brownish stains resembling rust on the surface and legs of the stainless steel table in the ISO 7 cleanroom. We observed the technician place a tray of eighty (80) empty syringes on top of this table and then placing the tray directly on the ISO 5 surface of the hood without sanitizing the bottom of the tray.

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OBSERVATION 4

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

a) None of the finished sterile drug products produced at the firm have undergone microbiological method suitability testing. The method suitability testing is required to demonstrate the drug product test samples do not inhibit growth in sterility test media. For example;

1. The firm performs in-house sterility testing on all intrathecal sterile drug products that include such finished products as: morphine sulfate injection, morphine/baclofen injection, hydromorphone/bupivacaine injection, and, morphine/fentanyl/clonidine injection. Sterility testing is performed by (b) (4) of up to (b) (4) drug products with different formulations into one sterility growth vial containing (b) (4) The firm has not performed method suitability testing for the pooling of these drug products into one test. Also, there is no reconcilability of the sterility of each individual lot.

2. The firm uses a contract testing laboratory to conduct sterility testing on finished sterile drug products such as Avastin (Bevacizumab). The contract testing laboratory has not conducted method suitability testing on the Avastin (Bevacizumab) sterility test.

b) The firm prepares (b) (4) or (b) (4) for use in performing microbiological sterility testing on all intrathecal sterile drug products. A review of the firm's (b) preparation found:

1. The firm routinely sterilizes the prepared medium by (b) (4). The manufacturer's preparation instructions state to (b) (4) the prepared medium at (b) (4). The firm has not performed any studies to show the (b) (4) is equivalent to the manufacturer's validated (b) (4). Additionally, the firm's (b) (4) have not undergone (b) (4) and the (b) (4) gauges have not been calibrated.

2. The manufacturer's preparation instructions state to verify the final pH of the sterilized media is (b) units. The firm does not check the pH of the sterilized media.

3. The firm does not use suitable strains of indicator microorganisms when performing growth promotion testing on the (b) sterility test media. Instead, a technician 'spits' saliva into a specimen cup, dilutes with water and uses a (b) aliquot for the growth promotion.

4. The firm does not document the in-house sterility testing on raw data worksheets. There is no documentation of

test sample preparations, materials and instruments used, and consistent documentation of final test result readings of the sample and controls.

OBSERVATION 5

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

Specifically,

a) Your firm failed to validate the (b) (4) used to sterilize all intrathecal, injectable and opthalmic drug products produced by your firm from non-sterile components. In addition, your firm has not established (b) (4) bioburden limits in order to determine if it exceeds the maximum (b) (4) capability of the (b)

b) (b) (4) sterilization process parameters for (b) (4) sterilization of injectable drug products prepared from non-sterile components have not been validated. Drug products such as Glycerin injectable are prepared from non-sterile liquid glycerin and not (b) (4) prior to (b) (4) sterilization. These products are not tested for sterility prior to release.

c) The results of the bubble point test performed after conducting sterilization by (b) (4) of all injectable, intrathecal and opthalmic drug products were not documented by the firm prior to 3/14/2013.

OBSERVATION 6

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

Specifically,

a) The inital qualification of the ISO 7 cleanrooms and the ISO 5 hoods completed on 4/14/12 by a contractor after the construction of the new cleanroom was performed under static "as built" conditions only. The (b) (4) re-qualification performed on 10/3/12 reported that "up to two pharmacy personnel" were present in the cleanroom during qualification; however, these individuals were not identified and no one at the firm remembers being inside the cleanroom during its latest qualification. Smoke studies of laminar air flow were reported as acceptable, but were not recorded and the report did not clearly specify if taken under dynamic conditions.

b) Monitoring of (b) (4) magnehelic gauges ((b) as identified on the gauge) for air pressure between the pharmacy, anteroom, and two (2) cleanrooms is deficient in that:

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1. From 4/17/12 thru 3/20/13, the differential pressure readings for magnehelic gauges (b) (4) were reported as "0.003"; gauge (b) was reported as reading "0"; and gauge (b) reading was not recorded. The log states the following: "*0.02 or below- See Pharmacist.*" When we read the gauges on 3/20/13, we found the following: gauge (b) read "0" (anteroom); gauge (b) read "0.04" (cleanroom #1); gauge (b) read "0.03" (chemo room # 2); and gauge (b) (chemo room #1) read "-0.03". The pharmacy technician was not reading the gauges correctly and therefore the documentation did not reflect actual readings. Furthermore, the excursion of "0" reading in gauge (b) showing no differential air pressure between the anteroom and the pharmacy washing area had been recorded by the same pharmacy technician since 4/17/12 but no notification was made to a pharmacist, and no investigation or corrective action had been taken as of 3/20/13. These records are not reviewed by a pharmacist.

2. No written procedures describing monitoring of differential air pressure in the cleanrooms have been implemented.

3. These magnehelic gauges were reported as newly installed in April 2012 but no calibration certificates were provided. There are no written procedures for calibration of magnehelic gauges.

OBSERVATION 7

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

Specifically,

a) The suitability, efficacy, and limitations of disinfecting agents and procedures have not been assessed to ensure potential contaminants are adequately removed from surfaces in the ISO 5 & 7 classified areas. For example,
   1. On a (b) basis, (b) (4) are used in this sequence to mop floors in the ISO 7 room. The firm lacked data to demonstrate the effectiveness of these disinfectants. In addition, there was no asssurance that the (b) (4) mop pads are non-shedding.
   2. On a (b) (4) basis, a third-party contractor cleans the ISO 5 & 7 classified areas with (b) (4) (b) (4) on a rotating basis. A (b) disinfectant cleaner, (b) (4), has recently been added to the rotation schedule; however, the firm lacked data to demonstrate the effectiveness of these disinfectants against spores.

b) The firm sterilizes (b) (4) by (b) (4) into amber glass bottles with a spray nozzle. These bottles were observed in unlabeled conditions throughout the pharmacy and ISO 5 & 7 areas and were used to sanitize hands, equipment and supplies. An expiration date was not assigned to the sterilized (b) and the firm lacked documentation to demonstrate the effectiveness of the sterilization process of non-sterile (b) and sterilization of spray nozzles soaked in (b) (4) for an undetermined amount of time. In addition, the firm lacked data to

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demonstrate that the sterile (b) in spray bottles remains sterile until consumed.

c) Non-sterile wipes are used to wipe the interior surfaces of the (b) (4) ISO 5 hoods.

d) Documentation of (b) (4) cleaning for the months of January and February 2013 is incomplete in that cleaning of the sterile room and anteroom was not documented for the month of January 2013; similarly, cleaning of the chemo rooms 1 & 2 and certain areas of the sterile room were not documented for the month of February 2013. Therefore, it is not known if the third-party contractor conducted the required cleaning activities during these months.

e) A small broom was observed in the ISO 7 anteroom immediately below the air hand dryer. This broom cannot be properly cleaned and sanitized and would potentially generate excessive particulates.

OBSERVATION 8

There are no written standards or specifications, methods of testing, methods of cleaning, and methods of sterilization to remove pyrogenic properties.

Specifically,

a) The (b) (4) cycle has not been validated. The firm uses (b) (4) for all glass vials and beakers used in the filling of all injectable ~~and intrathecal~~ drug products. The firm has not verified the effectiveness of the (b) (4) using (b) (4) The bacterial endotoxin test should be performed on the (b) (4) to verify the cycle is capable of achieving a 3-log reduction in endotoxins. Endotoxin testing is not routinely performed on all injectable and intrathecal drug products.

b) The (b) sterilization (b) (4) cycles have not been validated . The firm (b) (4) rubber stoppers to be used in the filling of injectable ~~and intrathecal~~ drug products in vials. The firm does not document (b) (4) or time for any of the stopper (b) (4) runs.

c) Wrapped glass vials, rubber stoppers and beakers sterilized and (b) (4) in-house are not identified with a sterilization date, cyle, expiration date or a unique number that would allow traceback to the (b) (4) or (b) (4) load/batch.

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OBSERVATION 9

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

Specifically,

a) Operators performing aseptic operations in ISO 5 hoods re-use sterile gowns throughout a production day. As sampling of sleeves is not performed, your firm has no assurance that the sterility of the sleeves is maintained. During the preparation of Dexamethasone PF, lot 03152013, on 3/20/13, we observed the technician sitting in front of the ISO 5 hood and the bottom of the sleeves frequently touching the ISO 5 working surface of the hood.

b) Facility-dedicated scrubs and shoes for all employees (including those working in the cleanrooms) are stored on an open shelf rack in the firm's bathroom where employees change their clothes before going into the controlled cleanrooms **to don sterile garments**. The firm's bathroom is not a suitable area for changing into facility-dedicated clothing.

OBSERVATION 10

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

Specifically,

a) Injectable drug products prepared from non-sterile components and (b) sterilized are not routinely tested for potency, sterility and endotoxin prior to release. Some of the injectable drug products include: methotrexate, testosterone, mitomycin, polidocanol, and dexamethasone.

b) Intrathecal drug products such as morphine sulfate, morphine/clonidine, and hydromorphone are not tested for potency and endotoxin prior to release.

OBSERVATION 11

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

Specifically,

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a) Your firm lacked valid analytical and sterility data to support the 90-day expiration date assigned to repackaged syringes of preservative-free Bevacizumab drawn from single-use vials. According to your firm's personnel, the expiration date was based on an article published in the U.S. Opthalmic Review 2007 which stated that the potency of Bevacizumab in syringes degraded 8.8% at three (3) months. However, this information is not specific to your firm's operations and does not address potential sterility issues.

b) Your firm lacked analytical and sterility data to support the expiration date of 90 days for preservative-free injectable drug products such as Dexamethasone P.F. 4mg/ml injectable prepared from non-sterile components.

OBSERVATION 12

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

Specifically, the firm does not have a written program for and does not calibrate the following equipment:

a) The refrigerator thermometers have not been calibrated. The firm's refrigerators are used to store such bulk products such as Avastin, Ascorbic Acid Injection, Amphotericin B, and retention samples of sterilized finished drug products.

b) The autoclave thermometers and pressure gauges have not been calibrated.

c) The depyrogenation oven thermometer has not been calibrated.

d) The thermometer in the firm's incubator has not been calibrated. The incubator is used to conduct in-house finished product sterility testing, media fills, and incubation of microbiology plates used in environmental monitoring.

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