DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax: (949) 608-4417 Industry Information: www.fda.gov/oc/industry	02/23/2016 - 03/14/2016* FEI NUMBER 3003436217

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nadia Mohamed Ibrahim Elsayed Ibrahim, Director of Operations/Pharmacist In Charge

FIRM NAME	STREET ADDRESS
South Coast Specialty Compounding, Inc.	9257 Research Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Irvine, CA 92618-4286	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 do not include adequate validation of the sterilization process.

Specifically,

A. Policy and Procedure Number 6.2.0 titled "Aseptic Technique Personnel Validation" is deficient in that it does not require the firm to perform media fill simulation with worst case scenario and does not address conducting media runs for the lyophilization process. For example,

a. Ascorbic Acid P-F Non-Corn 500mg/ml injectable lot # 11242015@48B was made with batch size of (b) (4) yielding (b) (4) vials (non-sterile to sterile production). The following table lists the media simulation (b) (4) not meeting worst case scenario performed by personnel involved in sterile production.

Title	Process mimic	Media Lot	Media volume	# of vials	Vial Size	Date
(b) (7) (C), (b) (6) Technician	Non-sterile to sterile	(b) (4)	(b) (4) ml	(b) (4) vials	(b) (4)	
Technician			ml	vials		
Technician			ml	vials		
NI, Pharmacist			ml	vials		
(b) (7) (C), (b) (6) Technician		(b) (4)	ml	vials		
Technician			ml	vials		
Technician			ml	vials		
NI, Pharmacist			ml	vials		

b. Artesunate Lyophilized Powder for Injection 60mg per vial lot # 02042016@2B was made with (b) (4) vial batch size yielding (b) (4) vials (b) (6), (b) (7)(C) echnician who has been making lyophilized products since (b) (6), (b) (7)(C) until now has not performed media fill testing simulating the lyophilization process. The first lyophilized product made by the (b) (7)(C), (b) (6) echnician was Chorionic Gonadotropin – Hydroxocobalamin Lyophilized Powder (5,000/2,500)

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U/mcg per vial lot # 10312015@1B exp 04/28/16. Only one pharmacist (b) (7)(C), (b) (6) conducted media fill simulation to mimic the lyophilization process as listed in the table below. (b) (7)(C), (b) (6) was not involved in the making of lyophilized products since about October 2015 when (b) (7)(C), (b) (6) started making lyophilized products.

Title	Process mimic	Media Lot	Media volume	# of vials	Vial Size	Date
(b) (7)(C), (b) (6) Pharmacist	Lyophilization	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

B. Policy and Procedure Number 3.9.0 titled "Lyophilizer Standard Operating Procedures" is deficient in that it does not address the (b) (4) of the Lyophilizer (b) (4) Systems, Serial # (b) (4) Model (b) (4)). Per NI, Pharmacist In-Charge (PIC), the Lyophilizer is (b) (4)
(b) (4)
(b) (4)
The firm has not qualified the number of vials that can be processed in one run. The following table shows examples of all four lyophilized products made at the firm.

Product	lot	BUD	Quantity	Yield	Vial size
Trimix #3 (Phent 1mg/papaverine 15 mg/pge1 20 mcg lyo sdv) (1/15)mg(20)mcg injectable	01082016@54B	6/11/2016	(b) (4)	(b) (4)	(b) (4)
Methyltetrahydrofolate lyophilized 20mg injectable	01082016@55B	7/6/2016	(b) (4)	(b) (4)	(b) (4)
Artisinate Lyophilized Powder 60 mg Injectable	02042016@2B	8/2/2016	(b) (4)	(b) (4)	(b) (4)
Chorionic Gonadotropin Hydroxocobalamin Lyophilized Powder (5,000/2,500)U/mcg injectable	01202016@2B	7/18/2016	(b) (4)	(b) (4)	(b) (4)

* Batch record does not specify vial size. Size verified by Director of Business Development.

C. The firm has not validated the use of (b) (4) as the firm (b) (4) In addition, the firm also does not record the types and (b) (4) used in the formula worksheet to indicate (b) (4) For example,

a. Ascorbic Acid P-F Non-Corn 500mg/ml injectable lot # 11242015@48B was made with batch size of (b) (4) yielding (b) (4) vials. Per NI, PIC (b) (4) (b) (4) but they were not recorded in the batch records.

b. Heparin/Lidocaine 3,300 IU/ML /Lidocaine 13.25 mg/ml solution lot # 02232016@2B was made with batch size of (b) (4) syring size yielding (b) (4) syringes. Per NI, PIC (b) (4) rather than (b) (4) but they were not recorded in the batch records.

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OBSERVATION 2

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

Specifically, Policy and Procedure Number 2.5.3 titled "Donning Sterile Garments" is deficient in that it does not state that forehead and neck areas should be completely covered. On 02/23/16, we observed (b) (4) employees working in the ISO 7 room with (b) (4)(b) (7)(C). ISO 5 hoods having partially exposed foreheads (b) (7)(C). (b) (6) Technician and (b) (7)(C). (b) (6) Technician) and partially exposed neck area (b) (6) Technician only) while filling sterile Heparin/Lidocaine 3300 IU/ml /265 mg/ml syringes (lot #02232016@2B) and Methylcobalamin 25mg/ml (Lot#12032015@2B) respectively.

OBSERVATION 3

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

Specifically,

A. Policy and Procedure Number 6.5.0 titled "Environmental Monitoring" is deficient in that

   a. The firm does not perform environmental monitoring with active air sampling continuously during production of sterile drug products.

B. Policy and Procedure Number 6.5.1 titled "Gloved Fingertip Sampling" is deficient in that

   a. Section 1 states '(b) (4) ' and does not require operators to roll their fingertips from side to side. This practice was observed on 03/02/16 during environmental monitoring (b) (4) .

   b. "Daily Environmental Monitoring and Gloved Fingertip Sampling Program Log" states to (b) (4) (b) (4) (b) (4) On 03/02/16, we observed personnel sampling was performed on fingertips (b) (4) .

C. The firm follows Policy and Procedure Number 6.5.2 titled "Glove/Sterile Gown Initial Qualification" to perform initial qualification of operators working on sterile drug products with no growth result as shown in the table below. This procedure does not require the firm to roll their fingers from side to side.

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Initials, Title	Date Qualified	Date Qualified	Date Qualified	Comment
(b) (6), (b) (7) (C) Technician	(b) (4)			No incubation temperature recorded
Technician				
Technician				N/A
NR*, Pharmacist				No incubation temperature recorded and same recorded date and time qualified
(b) (7) (C), (b) (6) Pharmacist				

*NR is the same employee listed as NI, PIC

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. SOP number 6.14.0 Titled "Particulate Testing for Sterile Drug Preparations" section IV.6 states that the inspector is to "(b) (4) (b) (4)" However, during the walkthrough on 2/23/2016, we observed the inspector (Pharmacist) only visually inspecting Ascorbic Acid in amber vials (Lot# 02222016@1B) (b) (4).

B. There is no procedure to test for particulate matter for finished sterile drug products stored in amber vials after non-sterile to sterile, lyophilization, or (b) (4) sterilized process. Per, NI, PIC, the firm switched most of the clear vials to amber vials approximately a(b) (4) ago.

Preparation	Product	Lot #	BUD
Non-sterile to sterile	EDTA Calcium Disodium PF 300mg/ml Injectable	01272016@1B	7/25/2016
	MIC-B12-B6 Solution (25/50/50/5/30)mg/ml injectable	02092016@10B	4/9/2016
	MIC-B12-B6-LCarnitine (lipoden	01282016@7B	3/28/2016

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	plus) (25/50/50/5/50/50)mg/ml injectable		
	Taurine 50mg/ml injectable	01272016@3B	4/26/2016
Lyophilized	Chorionic Gonadotropin-Hydroxycobalamin Lyophilized Powder 5,000/2,500) U/MCG	01202016@2B	7/18/2016
	TRIMIX #3 (Phent 1 mg/Papaverine 15mg/pge1 20mcg lyo sdv) (1/15)mg(20)mcg injectable	01082016@54B	6/11/2016
	Methyltetrofolate lyophilized 20mg injectable	01082016@55B	7/6/2016
	Artesunate lyophilized powder 60 mg injectable	02042016@2B	8/2/2016
(b) (4) Sterilized	Triamcinolone-moxifloxacin suspension injection (15/1) mg/ml injectable	12152015@41B	6/122016

C. The firm does not have a written procedure on how to (b) (4) whether products made are individual units or a batch. Per DS, Director of Business Development, the firm normally (b) (4) when the firm makes a batch. There is no documentation on the formula worksheet to capture (b) (4) . The following products were (b) (4) was adequate to protect product integrity:

Preparation	Product	Lot #	BUD
Non-sterile to sterile ((b) (4) (b) (4)	Phentolamine 4MG/Pappvarine 30Mg/Atropine 0.2 Mg per ml injectable	0222016@62	4/7/2016
	Acetylcarnitine 200 MG/ML INJ Solution Injectable	02222016@51	4/7/2016
	Hydrogen Peroxide PF 3% Injectable	02222016@41	4/7/2016
	Methylcobalimin 12.5 MG/Folinic Acid 25MG/ML P-F Injectable	02222016@34	4/7/2016

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	Phentolamine 1MG/Papaverine 30MG/PGE1 10mcg per ml Injectable	02222016@60	4/7/2016
	Phentolamine 1mg/papaverine 30mg/PGE1 20MCG per ml Injectable	02222016@55	4/7/2016
	Prostaglandine E1 100MCG Injection Solution Injectable	02222016@47	5/30/2016

OBSERVATION 5

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

Specifically,

A. Policy and Procedure Number 4.1.0 titled "Clean Room, Cleaning, and Maintenance of" is deficient in that

   a. Section B.3 under Cleaning Schedule states "Use (b) (4) wipes to clean counters, work surfaces, scales and equipment." Per PIC (b) (4) used is non-sterile.

   b. There is no scientific rationale for the use of sporicidal cleaning agent, (b) (4) for (b) (4) (b) (4)

B. Policy and Procedure Number 3.9.0 titled "Lyophilizer Standard Operating Procedure" is deficient in that it does not state

   a. whether (b) (4) and (b) (4) are sterile – in actual practice, the firm used non-sterile (b) (4) (b) (4) per the Director of Corporate Development

   b. the lyophilizer cleaning log only documents the use of the (b) (4) and not (b) (4)

   c. the location of cleaning (ISO 7 or non-classified area) where the lyophilizer is to be cleaned

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Per the NI, PIC, this section applies to cleaning of the inside and outside of the lyophilizer.

C. The firm has not conducted cleaning validation studies of the (b) (4) non-sterile drug products such as Ascorbic Acid and Heparin/Lidocaine. The firm also has no written cleaning procedure for the cleaning of the (b) (4). The cleaning of the (b) (4) is documented on a cleaning log titled "Sanitary (b) (4) Cleaning Log" with (b) (4).

OBSERVATION 6

There was a failure to handle and store drug product containers and closures at all times in a manner to prevent contamination.

Specifically,

Policies and Procedures 3.3.1 titled "Vials, (b) (4)" 3.3.2 titled "Glassware for Sterile Compounding – (b) (4)," and 3.3.3 titled "(b) (4) Stoppers – (b) (4)" are deficient in that

A. The sterilized vials and stoppers are stored in (b) (4) production area for future use as needed without any expiration or end of use date. On 02/23/16, we observed several (b) (4) vials and stopper bags labeled "sterilized" were stored on shelves situated in (b) (4) production area.

B. No hold-time studies have been conducted to assure sterility of the container / closure systems. For example, vials which were used to produce the following products had the following hold-times.

Product	Container/Closure	Lot No.
Triamcinolone / Moxifloxacin Inj TS Lot # 02092016@60B	Vial	(b) (4)
	Stopper	
Phentolamine / Prostaglandin Lyo Lot # 02112016@6B	Vial	(b) (4)
	Stopper	(b) (4)
Taurin Inj Lot # 11232015@46B	Vial	(b) (4)
	Stopper	

(b) (4)

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OBSERVATION 7

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

A. The firm has no written procedure to describe the number of items allowed to be placed in ISO 7 filling room. On 02/23/16, we observed this ISO 7 filling room to have a (b) (4) , four carts full of bags, containers on the floor, and equipment while (b) (4) technicians were working.

B. On 02/24/16, we observed the double-doors in the back of the facility have gaps at both the bottom (approximately 1/2 inch) and top (approximately 1/16 inch) of the door when they are closed. One of the doors was not tightly shut and the rolling door was also not shut. The double door is located between the non-classified production area and an exterior metal roll up door.

C. On 03/02/16, we observed a single door in the back of the facility had been kept open using a door stopper.

D. There are one restroom and one break room located in the main production area where personnel wearing scrubs and shoe covers throughout the day can enter restroom and break room and then go back into sterile production area where sterile gowning is not completely donned.

OBSERVATION 8

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

Specifically, the pH meter used to measure the product pH has been calibrated (b) (4) pH levels, i.e. (b) (4) The following products, however, were tested outside the calibrated range:

A. Heparin/Lidocaine, 1/11/16, lot no. 01112016@55B, pH (b) (4)
B. Poly-MVA solution, 1/8/16, lot no. 01082016@1B, pH (b) (4)
C. Folic Acid solution, 9/17/15, lot no. 09172015@27B, pH (b) (4)

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