DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/22/2013
	FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond L. Solano, III, Partner and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Specialty Compounding, LLC	211 South Bell (Hwy 183 N)
CITY, STATE, ZIP CODE, COUNTRY Cedar Park, TX 78613	TYPE ESTABLISHMENT INSPECTED 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

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

Specifically,

a) On 3/18/13 I observed employee (b) wipe her bare forehead with her gloved hand while facing the ISO 7 clean room area, spray her glove with [redacted] and then resume filling operations under the ISO 5 Laminar Flow Hood (LFH). She was filling lot #03162013M1 of Magnesium Sulfate 2gm/100mL Sodium Chloride 0.9% 2gm/100mL Injectable. I also observed employee (b) wipe her bare forehead with her gloved hand while facing the ISO 7 clean room area, spray the glove with (b) (4) and then resume filling under the ISO 5 LFH. She was filling lot #03152013M14 of Acetylcysteine 20% Inhalation Solution. Neither operator changed their gloves after touching their bare skin.

b) On 3/18/13, a pharmacist from your firm (b)) was observed kneeling with hands and knees on the ISO 7 clean room floor retrieving vials that had fallen under a cart and to retrieve a plastic container that had fallen behind the laminar air-flow hood. The employee did not re-gown or change gloves after each instance and continued working in the clean room. The pharmacist was responsible for handling components (i.e. opening the overwraps for the IV bags, plastic trays with solutions and vials, and syringes) and transferring items to (b) Pharmacy Technicians under (b) ISO 5 laminar air-flow hoods. The pharmacist was also in charge of overseeing the aseptic processing for all (b) technicians working simultaneously while the following products were produced.

- Bupivicane Hydrochloride PF 0.75% Injectable, lot # 03182013M12
- DMPS (Dimercaptopropanesulfonic Acid) PF 5% Injectable, lot # 03182013S18
- Magnesium Sulfate 2GM/100mL Sodium Chloride 0.9% for Injection, lot # 03162013M1
- Cefazolin 2gm in 100mL Sodium Chloride 0.9% injectable, lot # 03152013M17
- Acetylcysteine 20% (using powder) 200MG/ML Inhalation Solution, lot # 03152013M14

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M. Annes, CSO Lucas B. Leake, CSO	03/22/2013

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/22/2013
	FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond L. Solano, III, Partner and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Specialty Compounding, LLC	211 South Bell (Hwy 183 N)
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cedar Park, TX 78613	Producer of Sterile Drug Products

OBSERVATION 2

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

Specifically,

a) The general gowning attire for entry into the ISO 5/ISO 7 classified areas consists of the following: a gown ("bunny suit") that has foot covers attached, a single hair net, safety glasses and a single ear-loop face mask. The operators also use a single pair of sterile gloves. On 3/18/13 we observed employee (b) don the gloves inside the ISO 5 laminar flow hood. The general gowning requirements leave exposed skin around the eyes, forehead and neck of the person preparing the sterile drug product.

b) Your firm is sterilizing via (b) (4) the gowns ("bunny suits") worn in the ISO 5 laminar flow hoods and the ISO 7 clean room. Your firm does not have any written procedures for the sterilization of the gowns and does not have documentation to show that the sterilization process has been validated.

OBSERVATION 3

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

Specifically,

a) Your firm is not doing environmental monitoring of the ISO 5 LFH (surface, viable and non-viable particulates) every day that your firm is preparing injectable drug products. Your current procedure is to obtain surface samples once per week from various sites in the ISO 5, ISO 7 and ISO 8 classified areas. Your firm is not obtaining surface samples every week from all sites listed in your Clean Room Facility Sampling Log. A review of the log from 1/4/13-3/15/13 indicates that no samples were obtained from the following sample sites on the following dates:

- Site E (pass thru from prep room (ISO 8) to clean room (ISO 7): 1/4/13, 1/18/13, 1/25/13, 2/1/13 & 3/8/13.
- Site J (cart in ISO 7 clean room): 1/4/13, 1/11/13, 1/18/13, 2/1/13, 2/22/13 & 3/8/13.
- Site K (cart in ISO 7 clean room between hoods where pumps are located): 1/4/13, 1/18/13, 1/25/13, 2/1/13, 2/15/13, 2/22/13, 3/8/13 & 3/15/13.
- Site L (located in ISO 7 clean room near window): 1/4/13, 1/11/13, 1/18/13, 1/25/13, 2/1/13, 2/15/13, 2/22/13, 3/8/13 & 3/15/13.
- Site M (pass thru from prep room to room where chemo drugs are prepared): 1/4/13, 1/11/13, 1/18/13, 2/1/13, 2/22/13, 3/8/13 & 3/15/13.

There was no documentation of any surface sampling performed the week of 2/11-15/13 or the week of 2/25-3/1/13.

b) There is no documentation to justify the alert and action levels that have been defined for the ISO 5 LFH, ISO 7 clean

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M. Annes, CSO Margaret M. Annes Lucas B. Leake, CSO LBL	03/22/2013

room, ISO 8 ante room (gowning area) and the prep room where mixing operations occur.

c) Your firm is not monitoring the gloves of each operator working in the ISO 5 LFH and ISO 7 clean room each day that sterile drug products are prepared. SOP 3.030 Environemntal Monitoring of the Clean Room Facility, version 3.0 effective 6/1/11, states that "personnel touch plates shall be sampled(b) [redacted]" and that sampling is of "[redacted](b) (4)[redacted]". The employees who work in these areas are sometimes sampling their gloves one time per week. For example, a review of the Cleanroom Facility Personnel Touch Plate Log from 9/1/12-present, shows there were no samples taken from any employee on the following dates: 9/4-5, 10-12, 17-20, 24-25 & 27/12, 10/3, 9-11, 16-18, 22-23 & 25/12, 11/7, 13-14, 19-21, 26-27 & 29/12, 12/3-7, 10-13, 17-19, 24-28 & 31/12, 1/2-3, 7-8, 10-11, 14-17, 21-25 & 28-31/13, 2/1, 4-6, 8, 11-14, 18-20, 22 & 25-28/13 and 3/4-7 & 11-15/13. Injectable drug products were prepared on each of these days. On the dates listed for January 2013 approximately(b) lots of injectable drug products for office stock or hospital use were prepared on those dates. On the dates listed for February 2013, approximately (b) lots of injectable drug products for office stock or hospital use were prepared on those dates. On the dates listed for March 2013, approximatley(b) lots of injectable drug products for office stock or hospital use were prepared on those dates.

In addition, entries in the log are not documented as they occur so it is not possible to verify the exact date that samples were taken.

d) Per SOP 3.030 Environmental Monitoring of the Clean Room Facility, version 3.0 effective 6/1/11, states that "if an excursion occurs above an action level, the Pharmacist-in-charge or Quality Control Officer must be notified and investigation and corrective action should occur. This may include, but is not limited to, the following actions: *** Identification of microbial isolates to determine origin *** review of pressure differential information *** Review of HEPA and clean room certification *** Review of Logs of Use, Maintenance and Cleaning (LUMACS) ***".

A review of the Clean Room Facility Surface Sampling Log from7/19/12 -3/15/13, shows that there were numerous environmental monitoring (surface sampling) excursions (above alert and/or action levels) during this time with no documentation of investigations or corrective actions taken. For example,

i) On 8/31/12 the samples from the ISO 7 clean room floor (Site G) were reported as TMTC (too many to count) and 10cfu.
ii) On 9/7/12 the samples from the ISO 7 clean room floor (Site G) were reported as 17cfu and 20+cfu. The samples from the ISO 8 prep floor (Site B) were reported as 24 and TMTC.
iii) On 9/14/12 the sample from the Ante room where gowning occurs (Site F) was reported as 24+.
iv) On 9/21/12 the samples from the ISO 7 clean room floor (Site G) and the ante room (Site F) were both reported as 10+cfu. The sample from the chemo room (room where chemo drugs are prepared) was 12cfu.
v) On 11/2/12 the sample results for the prep room floor (Site B) was 12+cfu and TMTC.
vi) On 12/7/12 the samples from the prep floor (Site B) were reported as "lot".
vii) On 1/11/13 the samples from the ante room (Site F) were reported as 10cfu and 10+cfu.
viii) On 2/22/13 the samples from the ante room floor (Site F) were reported as "lot" and TMTC.

Alert levels for these areas are(b) for surfaces and(b) for floor. Action levels for these areas are (b) for surfaces and (b) for floors. There is no documentation of any investigation or corrective actions taken in response to these sample

results.

OBSERVATION 4

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

Specifically,

Media fills performed by your firm with each of the operators that work in the ISO 5 LFH do not closely simulate actual production conditions or cover worst case or most challenging conditions.

SOP 9.110 Sterile Compounding Process Validation (Media Fills), version 4.0 effective 3/21/12, states that for media fills for non-sterile to sterile preparations, (b) (4) vials are prepared aseptically in the ISO 5 laminar air-flow hood, and each vial is aseptically filled by injecting (b) (4) through a (b) (4) using a sterile needle. (b) additional positive control vials are prepared by injecting (b) (4) through an (b) (4), sterile needle into similar (b) vials.

In routine production, your firm fills various size vials as well as syringes, and batch sizes can be in excess of (b) units. For example,

- (b) 10mL vials of lot #03152013M22 of Furosemide 10mg/mL Injectable were filled on 3/21/13
- (b) 2mL vials of Morphine Sulfate (Preservative Free) 0.5mg/mL Injectable were filled on 3/19/13
- (b) 100mL vials of Calcium Gluconate 10% (100mg/mL) Injectable were filled on 3/20/13

OBSERVATION 5

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

Specifically, your firm does not have adequate data to justify the Beyond Use Date (BUD) placed on injectable drug products. (b) (4) injectable drug products prepared by your firm have been tested by a contract testing lab in a "time point study". There is no written protocol to show how the time point study was to be conducted i.e. time points tested, what tests are to be performed at each time point and storage of samples. Sterility testing was not routinely performed at the end of shelf life (BUD). You also stated that other BUDs were determined by literature review.

For example,

a) Hydromorphone (Preservative Free) Stock Injection 50mg/mL has a BUD of 180 days. Your firm states that this BUD is based on samples sent to your contract testing lab. Sterility was only tested at 11 days.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/22/2013
	FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond L. Solano, III, Partner and Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Specialty Compounding, LLC	211 South Bell (Hwy 183 N)
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cedar Park, TX 78613	Producer of Sterile Drug Products

b) Ephedrine Sulfate (Preservative Free) 50mg/mL Injectable has a BUD of 90 days. You state that this is based on information from a book by Lawrence Trissel. The book only discusses potency under specific packaging and storage conditions and does not address sterility of the product.

c) Fentanyl (Preservative Free) 50mcg/mL has a BUD of 150 days at room temperature. Your firm states that this BUD is based on a sample sent to your contract testing lab. Sterility testing was only performed at 106 days.

OBSERVATION 6

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

Specifically, your firm does not conduct routine sterility or endotoxin testing for all injectable drug products currently produced. You stated that the stock solutions are routinely tested for sterility and endotoxins but that finished product is not routinely tested unless (b) units or more are filled or (b) [redacted]. Stock solutions are used to fill finished product.

For example,

- lot #02262013M8 of Fentanyl (NICU Syringe) 10mcg/mL Injectable was not tested for sterility
- lot #03182013S18 of DMPS (Dimercaptopropanesulfonic Acid) (Preservative Free) 5% Injectable was not tested for sterility or endotoxins
- lot #03112013S23 of Sodium Phenylbutyrate 200 mg/mL Injectable was not tested for sterility or endotoxins
- lot #03132013S32 of Glutathione/Adenosine Triphosphate 100mg/1mg/mL Injectable was not tested for sterility or endotoxins
- lot #03152013S8 of Hydrogen Peroxide (Preservative Free) 3.75% Injectable was not tested for sterility or endotoxins
- lot #03152013S24 of Methylcobalamin (Preservative Free) 12.5mg/mL Injectable was not tested for sterility or endotoxins
- lot #03182013S13 of Methylcobalamin/Folic Acid (Preservative Free) 1mg/10mg/mL Injectable was not tested for sterility or endotoxins

OBSERVATION 7

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, your firm does not conduct routine potency testing for all injectable drug products currently produced. You stated that the stock solutions are routinely tested for potency but that finished product is not routinely tested unless (b) units or more are filled or (b) [redacted]. Stock solutions are used to fill finished product.

For example,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M. Annes, CSO Margaret M. Annes Lucas B. Leake, CSO	03/22/2013

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/22/2013
	FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond L. Solano, III, Partner and Pharmacist-in-Charge

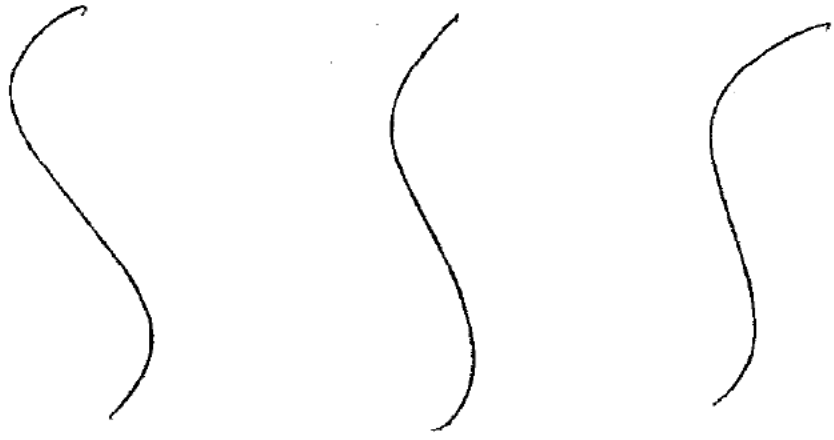
FIRM NAME	STREET ADDRESS
Specialty Compounding, LLC	211 South Bell (Hwy 183 N)
CITY, STATE, ZIP CODE, COUNTRY Cedar Park, TX 78613	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

- lot #03182013S18 of DMPS (Dimercaptopropanesulfonic Acid) (Preservative Free) 5% Injectable was not tested for potency
- lot #03112013S23 of Sodium Phenylbutyrate 200 mg/mL Injectable was not tested for potency
- lot #03132013S32 of Glutathione/Adenosine Triphosphate 100mg/1mg/mL Injectable was not tested for potency
- lot #03152013S8 of Hydrogen Peroxide (Preservative Free) 3.75% Injectable was not tested for potency
- lot #03152013S24 of Methylcobalamin (Preservative Free) 12.5mg/mL Injectable was not tested for potency
- lot #03182013S13 of Methylcobalamin/Folic Acid (Preservative Free) 1mg/10mg/mL Injectable was not tested for potency

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 did not document the use of a (b) (4) used (b) (4) as cleaning agents in the ISO 5, ISO 7 and ISO 8 classified areas. These products were observed in storage in the ISO 8 classified Ante room and the Sterile Prep room. SOP 3.020 Cleaning and Maintenance of the Clean Room Facility, Version 2.0 effective 6/1/11, states to "Document the disinfectant in use on the Cleaning and Maintenance of the Clean Room Facility form".



SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Margaret M. Annes, CSO Margaret M. Annes
Lucas B. Leake, CSO

DATE ISSUED
03/22/2013