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	08/13/2013 - 09/13/2013* FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond L. Solano, III, Partner & 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	Preparer 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:

The following observations pertain to the firm's preparation of sterile drug products.

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and 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) Lot #03292013M2 of Fentanyl (Preservative Free) 100mcg/mL stock solution failed sterility. There is no documentation of any out of specification (OOS) investigation performed by your firm or the 3rd party laboratory used to invalidate the result and justify re-sampling and re-testing the product. A second sample was sent to the lab for testing. The second sample passed sterility and the product was used to make 10 finished product lots (03262013M27, 03292013M18, 04012013M6, 04012013M15, 04022013M7, 04022013M8, 04092013M10, 04092013M11, 04092013M12 & 04092013M19) that were distributed to customers.

b) On 6/8/13 a 3rd party performed qualification of the Laminar Flow Hoods (LFH) in the cleanroom where sterile products are prepared. A leak was detected in the lower center portion of the HEPA filter in Hood #1. The previous qualification for this hood was performed on 11/1/12, at which time no leak was detected. No investigation was performed by your firm to determine what impact if any this leak would have on product quality. Your firm did not document the hood used for lots that were produced from 11/1/12-6/8/13. A review of the log for the [redacted] (b) (4) #4 from 3/27/13-6/7/13, which is used for some products made in Hood #1, there were at least [redacted] (b) (4) lots made in Hood #1 during that time period.

c) There were three (3) lots of Calcium Gluconate 10% (100mg/mL) Injectable (lot #s 03192013M15, 03222013M17 & 04032013M16) that had complaints of precipitation (complaint #s 804 & 812). Your firm recalled lot #s 03012013M28 & 04032013M16 due to precipitation. There is also documentation to show that lot #s 03192013M15 (stock solution and finished product), 04032013M16 (finished product) and 04162013M9 (finished product) failed endotoxin testing. All of these lots were distributed to customers. The Product - OOS Checklist indicates that there was inconsistency in results obtained but does not document what results your firm is referring to. Your firm has no documentation of any investigation identifying the cause of the precipitation or to demonstrate that the insolubility issue contributed to the endotoxin failures and

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was the cause of the product precipitating.

OBSERVATION 2

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

Specifically,

a) Your firm has not validated the sterilization process for any of the sterile drug products that you prepare. Your firm prepares various sterile drug products from bulk non-sterile APIs and excipients that are then either [redacted (b) (4)]. The drug products that are [redacted (b) (4)] sterilized include Papaverine 30mg/mL Injection (Preservative Free), Calcium Gluconate 2gm (Preservative Free) in 100mL Sodium Chloride 0.9%, Calcium Gluconate 1gm (Preservative Free) in 50mL Sodium Chloride 0.9% and Fentanyl Citrate 2mcg/mL with Bupivacaine HCl 0.125% (Preservative Free) in Sodium Chloride 0.9%. The drug products that are [redacted (b) (4)] sterilized include Testosterone Pellets 75mg tablet and 100mg tablet. Your firm does not have documentation to show how the specific [redacted (b) (4)] were chosen or whether [redacted (b) (4)] the product can have an effect on the final product. Your firm has no documentation of the qualification of the [redacted (b) (4)] used to [redacted (b) (4)] sterilize product or how the sterilization [redacted (b) (4)] were developed.

b) Your firm has not validated the process you use to sterilize stoppers and vials.

c) 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, [redacted (b) (4)] 10 mL vials are prepared aseptically in the ISO 5 laminar air-flow hood, and each vial is aseptically filled by injecting [redacted (b) (4)] using a sterile needle. [redacted (b) (4)] additional positive control vials are prepared by injecting [redacted (b) (4)], sterile needle into similar 10mL vials.

In routine production, your firm fills various size vials as well as syringes, and batch sizes can be in excess of [redacted (b) (4)] units.

Your firm performed a media fill on 4/5/13 for one Technician who works in the ISO 5 LFH using [redacted (b) (4)] 2mL vials and 3 control vials. There is documentation of another media fill for the same Technician using 10mL vials [redacted (b) (4)] filled and 10 control vials) that was performed on 4/5/13 as well. All other Technicians performed media fills in April and May 2013 using nine (9) 10mL vials. No media fills simulating actual production conditions or covering worst case or most challenging conditions have been performed for the other [redacted (b) (4)] employees that can work making sterile preparations. There is no documentation to show how your firm determined that the media fills performed using [redacted (b) (4)] 2mL vials and [redacted (b) (4)] 10mL vials closely simulated actual production conditions or covered worst case or most challenging conditions.

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This is a repeat observation from the 3/18-22/13 inspection.

d) Your firm is not performing smoke studies in the ISO 5 Laminar Flow Hoods under dynamic conditions. These Laminar Flow Hoods are where your firm performs aseptic processing of sterile drug products.

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 Laminar Flow Hood (LFH) (surface, viable and non-viable particulates) every day that your firm is preparing injectable drug products. Your current procedure, SOP 3.030 Environmental Monitoring of the Clean Room Facility, version 4.0 effective 4/5/13, is to obtain surface samples [redacted] (b) (4) from various sites in the ISO 5, ISO 7 and ISO 8 classified areas.

Your procedure also requires monitoring of viable and non-viable particulates in the ISO 5, ISO 7 and ISO 8 classified areas once every [redacted] (b) (4) by a 3rd party vendor. The report from this 3rd party vendor indicates that the monitoring is not performed under dynamic conditions.

This is a repeat observation from the 3/18-22/13 inspection.

b) 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 4.0 effective 4/5/13, states for personnel monitoring that "after sterile compounding is completed for the day, and prior to cleaning, touch each gloved finger of each hand to the agar surface, making certain not to re-touch areas". The employees who work in these areas are not always sampling their gloves every day that they work in the ISO 5 LFH and/or ISO 7 clean room. A review of the Log of Use, Maintenance and Cleaning of Hood (LUMAC) for each of the [redacted] (b) (4) ISO 5 Laminar Flow Hoods from June 14, 2013-August 9, 2013 revealed that the following employees who worked the following dates did not sample their gloves.

[redacted] (b) (6) 7/12/13 ([redacted] (b) (4) lots) and 7/23/13 ([redacted] (b) (4) lots)

[redacted] (b) (6): 7/2/13 ([redacted] (b) (4) lots); 7/6/13 ([redacted] (b) (4) lot); 7/9/13 [redacted] (b) (4) lots); 7/11/13 [redacted] (b) (4) lots); 7/12/13 [redacted] (b) (4) lots); 7/19/13 [redacted] (b) (4) lots)

[redacted] (b) (6) 6/28/13 ([redacted] (b) (4) lots); 6/29/13 ([redacted] (b) (4) lots); 7/9/13 [redacted] (b) (4) lots); 7/11/13 [redacted] (b) (4) lots); 7/12/13 [redacted] (b) (4) lots); 7/19/13 [redacted] (b) (4) lots); 8/2/13 [redacted] (b) (4) lots); 8/9/13 [redacted] (b) (4) lots)

[redacted] (b) (6): 6/28/13 [redacted] (b) (4) lots); 7/1/13 [redacted] (b) (4) lots); 7/3/13 [redacted] (b) (4) lots); 7/15/13 [redacted] (b) (4) lots); 7/18/13 [redacted] (b) (4) lots); 7/23/13 [redacted] (b) (4) lots); 7/24/13 ([redacted] (b) (4) lots); 7/25/13 [redacted] (b) (4) lots); 7/26/13 [redacted] (b) (4) lots); 7/29/13 [redacted] (b) (4) lot); 7/30/13 [redacted] (b) (4) lots); 7/31/13 [redacted] (b) (4) lot); 8/1/13 [redacted] (b) (4) lots); 8/6/13 [redacted] (b) (4) lots)

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(b) (6) 6/18/13 (b) lots); 6/19/13 (lots); 6/20/13 (b) lots); 6/25/13 (lots); 6/26/13 (b) lots); 6/27/13 (lots); 6/28/13 (b lot); 7/2/13 (b)lots); 7/5/13 (b) lots); 7/8/13 (b) lot); 7/9/13 (b)lots); 7/10/12 (b) lot - 07092013M16 of Calcium Gluconate 2gm/100mL in NaCl 0.9%); 7/11/12 (b) lots); 7/15/13 (lots); 7/16/13 (b) lots); 7/18/13 (b lot); 7/22/13 (b) lots); 8/3/13 (b) lots)

(b): 6/13/13 (b) lots); 6/15/13 (b) lot); 7/1/13 (lots); 7/19/13 (lots)

(b) 6/20/13 (b) lots); 6/21/13 (b lot); 6/25/13 (b lots); 7/5/13 (b) lots)

(b) (6) 6/27/13 (b) lots); 6/28/13 (b lot); 7/2/13 (b) lots); 7/3/13 (b) lots); 7/10/13 (b lot); 7/16/13 (b lot); 7/23/13 (1 lot); 7/24/13 (b lot); 7/25/13 (b) lots); 7/26/13 (b) lots); 7/30/13 (b)lot); 7/31/13 (b)lots); 8/1/13 (b) lots); 8/2/13 (b) lots)

This is a repeat observation from the 3/18-22/13 inspection.

OBSERVATION 4

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, SOP 9.060 Product Quarantine, Storage and Release, version 2.0 effective 7/13/11, states that "all compounded products shall be quarantined until documentation of release testing and inspections are complete and meet all release requirements". It also states that a Quarantine Form is to be completed "and when the release date has elapsed, attach the Quarantine Form to the completed formulation record for final approval by the Pharmacist-in-charge". It goes on to state that "early product release must be approved by the Pharmacist-in-charge, and a photocopy of the Quarantine Form must accompany the early release". Your firm is not always quarantining product until testing results have been received or documenting release of the finished labeled product. The Pharmacist-in-Charge is not always signing the Quarantine Form for release of product prior to receipt of all test results. For example,

a) Lot #02142013M29 of Ephedrine Sulfate (Preservative Free) 50mg/10mL (10mL syringe): The lot was made on 2/20/13. There is no documentation of when the lot was released. The lot was sent to a customer on 2/22/13. An email was sent from the 3rd party contract testing laboratory on 2/27/13 indicating that the product failed potency (assay was 87.24% - specification is (b) (4) The final lab report was dated 3/8/13. The lot was recalled by your firm on 3/6/13 due to the product being sub-potent.

b) Lot #02262013M17 of Ropivacaine 0.2% - ONQ Pump (Preservative Free): The lot was made on 2/27/13. The Formula Worksheet indicates that the lot was released on 2/28/13. There is no documentation to show the actual date that the product was sent to the customer. The final lab report for potency is dated 3/26/13 and indicates that the product was out of specification (assay 114.7% and specification is (b) (4)). The lot was recalled by your firm on 3/16/13 due to the product being super-potent.

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c) Lot #04172013M17 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The lot was made on 4/22/13. The lot was released on 4/22/13 and shipped to customers on that date. The lab report for sterility, endotoxin and potency assay is dated 5/7/13. There is no documentation that the Pharmacist-in-Charge released the product early prior to receiving all lab results as required by your SOP.

d) Lot #06142013M13 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The lot was made on 6/19/13. The lot was released on 6/21/13 (Quarantine Form signed) but part of the lot was shipped to a customer 6/20/13. The lab report for sterility and potency assay is dated 7/5/13. There is no documentation that the Pharmacist-in-Charge released the product early prior to receiving all lab results as required by your SOP.

e) Lot #07092013M13 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The lot was made on 7/12/13. The lot was released on 7/15/13 and shipped to customers on that date. The lab report for sterility and potency assay is dated 7/30/13. No endotoxin testing was performed on this lot. The lab report also indicates that the sample was received by the lab on 7/20/13. There is no documentation that the Pharmacist-in-Charge released the product or that a Quarantine Form was completed as required by your SOP.

f) Lot #07232013M16 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The lot was made on 7/25/13. There is no documentation to show when the lot was released. The lot was shipped to customers on 7/30/13 & 8/2/13. The lab report for sterility and potency assay is dated 8/5/13. The lab report also indicates that the sample was received by the lab on 7/29/13. There is no documentation of endotoxin testing for this lot. There is no documentation that the Pharmacist-in-Charge released the product or that a Quarantine Form was completed as required by your SOP.

g) Lot #06172013M17 of Calcium Gluconate 2gm/100mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The product was made on 6/18/13. The lot was released on 6/21/13 however, the lot was shipped to a customer on 6/20/13. The lab report for sterility and endotoxin testing is dated 6/24/13. There is no documentation of testing for potency for this lot. There is no documentation that the Pharmacist-in-Charge released the product early prior to receiving all lab results as required by your SOP.

h) Lot #06272013M13 of Calcium Gluconate 1gm/50mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The lot was made on 7/1/13. There is no documentation to show that the lot was approved and released. There is no documentation of any endotoxin or potency testing for this lot. The lab report for sterility testing is dated 7/16/13. The lot was shipped to a customer on 7/1/13. There is no documentation that the Pharmacist-in-Charge released the product early prior to receiving all lab results as required by your SOP.

i) Lot #07092013M16 of Calcium Gluconate 2gm/100mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The lot was made on 7/10/13. The Formula Worksheet indicates that the lot was released on 7/11/13 but the Quarantine Form was not signed. The lab report for sterility and endotoxin is dated 7/29/13. The product was not tested for potency. The product was shipped to customers on 7/11/13. There is no documentation to show that the Pharmacist-in-Charge released the product early or signed the Quarantine Form as required by your SOP.

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j) Lot #07112013M9 of Calcium Gluconate 1gm/50mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The lot was made on 7/15/13. There is no documentation to show that the lot was approved and released. There is no documentation of any endotoxin or potency testing for this lot. The lab report for sterility testing is dated 7/30/13. The product was shipped to customers on 7/15/13 & 7/17/13. There is no documentation to show that the Pharmacist-in-Charge released the product early or signed the Quarantine Form as required by your SOP.

k) Lot #07252013M1 of Calcium Gluconate 2gm/100mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The lot was made on 7/29/13. The Formula Worksheet indicates that the lot was released on 7/30/13 but there is no Quarantine Form. The lab report for sterility and endotoxin is dated 8/7/13. The product was not tested for potency. The product was shipped to a customer on 7/30/13. There is no documentation to show that the Pharmacist-in-Charge released the product early or signed the Quarantine Form as required by your SOP.

l) Lot #07252013M4 of Calcium Gluconate 1gm/50mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The lot was made on 7/29/13. The Formula Worksheet indicates that the lot was released on 7/30/13. There is no documentation of potency testing for this lot. The lab report for sterility and endotoxin testing is dated 8/7/13. The lot was shipped to a customer on 7/30/13. There is no documentation to show that the Pharmacist-in-Charge released the product early or signed the Quarantine Form as required by your SOP.

OBSERVATION 5

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

a) Complaint records are incomplete or missing. For the year 2013, the following complaint records are missing: 718, 719, 725, 726, 740, 741, 743, 744, 749, 751-754, 762-764, 789-791, 795-797, 810-811, 814-820, 829, 833, 836, 838, 843, 845, 852, 854, 855, 859, 879, 881, 902 & 905. There is no documentation of any investigation having been conducted for any of these complaints.

b) Investigations into other complaints are incomplete. For example,

i) Complaint #735 states that "the 2 bottles dispensed were discolored upon p/u". This is related to lot #01312013S25 of C-Wilson Modified Solution. The "outcome of investigation" was reported as "remaking into syringes and sending to L.L.". There is no documentation of any investigation conducted or the cause of the discoloration.

ii) Complaint #747 does not include any documentation of any investigation performed. The complaint states the the "Pt reports that new Bi-est did not "feel" as before. - feels like she felt before taking medication".

iii) Complaint #778 states that the complaint is that "Pt complained about the lot of the medication". There is no specific

description of the complaint or the product involved. There is only a lot number recorded. The record states that the "pH was 7.5 (too low to stay in soln)" and the "out come of investigation" is that the "pH should be (b)(4) to prevent falling out - remade new lot w/correct pH". There is no documentation of any investigation having been conducted for this complaint.

iv) Complaint #827 states that the there is a burning feeling with the methotrexate being used by the complainant. The firm did not document the correct lot number given to the complainant so they couldn't verify the pH of the product. There is a note that they will replace the product and retrieve the lot number when the complainant comes to pick it up. There is no further documentation to show if the product was returned or if an investigation was then conducted. The complaint noted that the burning feeling was similar to what had occurred when the complainant had a vial of another lot of Methotrexate that was recalled.

v) Complaint #s 804 & 812 are both related to lot #s 03192013M15 & 03222013M17 (#804) and 03222013M16 & 04032013M17 (#812) Calcium Gluconate 10% (100mg/mL) precipitating out of solution. There is a note in complaint #812 that they have "investigated the issue to determine a different vendor's prod. is better solubilized". There is no documentation of the investigation.

vi) Complaint #865 states that the "pt claimed discolorations pain/burning on injection site". The product is listed as lot #04012013S39 of Progesterone 250 mg/mL Injection. There is no documentation of an investigation and the document only notes that the patient was told to return the vials and they would " be replaced w/ fresh lot".

vii) Complaint #870 states that the vials received by the complainant were "unusable and had crystallized". The "outcome of investigation" only states that product was "resent at no charge". There is no documentation of any investigation. The product listed in the complaint is C-Progesterone 100mg/mL Oil but no lot number is listed.

OBSERVATION 6

Written complaint records do not include, where known, the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant.

Specifically, in reviewing the complaints from 2013, not all information was always documentated on the Customer Complaint Record including the nature of the complaint and the product and lot number. For example,

a) Complaint #747 does not include the lot number of the product or the name of the exact drug product in question.

b) Complaint #778 lists a lot number for the product but not the name of the product in question.

c) Complaint #857 states that the product is labeled wrong and lists a lot number but does not list a product. The document also states to refer to the "recall record" but does not state which recall it is referring to.

d) Complaint #858 does not list the product, lot number, nature of complaint or date that the complaint was received. The

document only states that "(b) (6) - called pt. to follow-up on reaction. Pt. is doing ok - no problems".

OBSERVATION 7

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

Specifically,

SOP 9.060 Product Quarantine, Storage and Release, version 2.0 effective 7/13/11, states that "the Pharmacist-in-charge shall prepare and review all compounding records to assure that errors have not occurred in the compounding process". It also states that "the compounding record shall include…total number of dosage units compounded…the name of the person who prepared the preparation…name of the compounder who approved the preparation…date preparation was compounded…". This information is not always being documented on the Formulation Worksheet. For example,

a) Lot #07092013M13 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): the Formulation Worksheet does not indicate the actual number of vials that were filled. The form indicates that (b) (4) labels were printed. Theoretical yield based upon the note made on the worksheet that the vials were 2.5mL and the amount of bulk solution made ((b) (4) mL), would be (b) (4) vials. The firm only has documentation to show that (b) (4) vials were sent to customers. The Formula Worksheet also does not indicate who filled the vials or the actual date that the bulk solution was prepared and the vials filled and labeled. The worksheet states that the lot was made on 7/9/13 however, according to the (b) (4) log, the lot was filled on 7/12/13.

b) Lot #04172013M17 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The Formula Worksheet states that the product was made on 4/17/13 but the documentation of the (b) (4) indicates that the lot was (b) (4) on 4/22/13.

c) Lot #06142013M13 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The Formula Worksheet states that the product was made on 6/14/13 but the documentation of the (b) (4) indicates that the lot was (b) (4) on 6/19/13.

d) Lot #07232013M16 of Papaverine (Preservative Free) 30mg/mL Injectable (2mL vial): The Formula Worksheet does not indicate who filled the vials or the actual date that the vials were filled and labeled. The Formula Worksheet states that the lot was made 7/23/13 but the (b) (4) log indicates that the lot was (b) (4) on 7/25/13.

e) Lot #07112013M9 of Calcium Gluconate 1gm/50mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The Formula Worksheet does not indicate who filled the bags or the actual date that the drug product was (b) (4) and labeled. The Formula Worksheet states that the product was made on 7/11/13 but the (b) (4) log indicates that it was filled on 7/15/13.

f) Lot #06272013M13 of Calcium Gluconate 1gm/50mL (Preservative Free) in Sodium Chloride 0.9% for Injection: The

Formula Worksheet does not indicate the actual date that the product was [redacted] (b) (4) into the bags. The Formula Worksheet states that the lot was made on 6/27/13 but the [redacted] (b) (4) log indicates that the lot was filled on 7/1/13. There is also no documentation of any [redacted] (b) (4) performed on the [redacted] (b) (4) used to sterilize this lot.

g) The Formula Worksheet for lot #04172013S48 of Human Chorionic Gonadotropin (HCG) does not have the dates the product was prepared. The record shows when the [redacted] (b) (4) was performed but does not have the dates that the product was filled, placed into the freezer or placed into the freeze dryer for lyophylization.

OBSERVATION 8

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. 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 [redacted] (b) (4) the gowns ("bunny suits"), shoe covers, hair covers and face masks worn in the ISO 5 laminar flow hoods and the ISO 7 clean room. Your firm does not have documentation to show that the sterilization process has been validated. You stated that you developed the current sterilization process in conjunction with your consultant and ANSI/AAMI/ISO 17665:2006 Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. You have no documentation to show that the [redacted] (b) (4) being used has been qualified (Installation Qualification and Operational Qualification) or that a Performance Qualification has been performed as described in ANSI/AAMI/ISO 17665:2006.

This is a repeat observation from the 3/18-22/13 inspection.

OBSERVATION 9

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

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	08/13/2013 - 09/13/2013* FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond L. Solano, III, Partner & 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	Preparer of sterile drug products

Your firm has not validated the lyophylization process for the Human Chorionic Gonadotropin (HCG) injectable product and the Sermorelin Lyophylized 15mg Injectable (Preservative Free). This includes failure to qualify the freezer and freeze-dryer used to freeze and then dry the drug product, failure to have written procedures for the actual lyophylization process, and failure to establish and monitor operating parameters for the lyophylization process (i.e. length of time to freeze, length of time to dry, pressure, temperature, etc.). [redacted] There were approximately [redacted] of HCG and [redacted] of Sermorelin made from 6/18/13-8/8/13.

OBSERVATION 10

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm has no documentation to show that you have validated the cleaning processes used to clean the ISO 5 and ISO 7 classified areas. SOP 3.060 Sanitation of the Prep Room, Ante-Room, Chemo Room and Clean Room, version 1.0 effective 4/5/13, states that surfaces will be wiped [redacted] with either [redacted], a sanitizing agent that is rotated [redacted] will be used followed by the [redacted]. The sanitizing agents include [redacted] There is no documentation to show the concentration of the [redacted] to be used, just that [redacted]. Your firm has not conducted any disinfectant effectiveness studies for the cleaning agents your firm is using.

OBSERVATION 11

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

Specifically,

a) Your firm does not have adequate data to justify the Beyond Use Date (BUD) placed on injectable drug products. Thirteen additional injectable drug products have been tested in a "time point study" by your contract testing lab since the previous inspection on 3/18-22/13. There is no written protocol to show how the time point study is to be conducted i.e. time points tested, what tests are to be performed at each time point and storage of samples. You do not have any documentation of a plan to send other products for testing or how you track what products have or will be sent for testing. BUDs on products can range from 14 days to 180 days.

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For example,

- Papaverine (Preservative Free) 30mg/mL Injection has a BUD of 180 days at room temperature. There is no documentation of any testing performed to justify the BUD placed on this product.
- Calcium Gluconate in Sodium Chloride 0.9% (1gm and 2gm products) have a BUD of 60 days at room temperature. There is no documentation of any testing performed to justify the BUD placed on this product.

This is a repeat observation from the 3/18-22/13 inspection.

b) Your firm has not conducted any container closure integrity studies.

OBSERVATION 12

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

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 [redacted] (b) (4) are filled or if they are multi-use vials. Stock solutions are used to fill finished product.

For example,

- lot #06272013M13 of Calcium Gluconate 1gm (Preservative Free) in 50mL Sodium Chloride 0.9% was not tested for endotoxins and and [redacted] (b) (4) /50mL bags were made.
- lot #07112013M9 of Calcium Gluconate 1gm (Preservative Free) in 50mL Sodium Chloride 0.9% was not tested for endotoxins and [redacted] (b) (4) /50mL bags were made.
- lot #07092013M13 of Papaverine (Preservative Free) 30mg/mL (2mL vial) was not tested for endotoxins. It is not clear from the Formula Worksheet how many vials were filled but there is documentation to show that [redacted] (b) (4) vials were shipped to customers.
- lot #07232013M16 of Papaverine (Preservative Free) 30mg/mL (2mL vial) was not tested for endotoxins and [redacted] (b) (4) vials were made.

This is a repeat observation from the 3/18-22/13 inspection.

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

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Cedar Park, TX 78613	Preparer of sterile drug products

OBSERVATION 13

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 [redacted] (b) (4) are filled. Stock solutions are used to fill finished product.

For example,

- lot #01172013M33 of Methotrexate Injectable 25mg/mL Preservative Free was not tested for potency
- lot #06172013M17 of Calcium Gluconate 2gm (Preservative Free) in 100mL Sodium Chloride 0.9% was not tested for potency and [redacted] (b) /100mL bags were made.
- lot #06272013M13 of Calcium Gluconate 1gm (Preservative Free) in 50mL Sodium Chloride 0.9% was not tested for potency and [redacted] (b) /50mL bags were made.
- lot #07092013M16 of Calcium Gluconate 2gm (Preservative Free) in 100mL Sodium Chloride 0.9% was not tested for potency and [redacted] (b) /100mL bags were made.
- lot #07112013M9 of Calcium Gluconate 1gm (Preservative Free) in 50mL Sodium Chloride 0.9% was not tested for potency and [redacted] (b) /50mL bags were made.
- lot #07252013M1 of Calcium Gluconate 2gm (Preservative Free) in 100mL Sodium Chloride 0.9% was not tested for potency and [redacted] (b) /100mL bags were made.
- lot #07252013M4 of Calcium Gluconate 1gm (Preservative Free) in 50mL Sodium Chloride 0.9% was not tested for potency and [redacted] (b) /50mL bags were made.

This is a repeat observation from the 3/18-22/13 inspection.

OBSERVATION 14

Records fail to include an individual inventory record of each component, reconciliation of the use of each component, and drug product container with sufficient information to allow determination of any associated batch or lot of drug product.

Specifically, individual inventory records are not accurate for excipients and non-controlled substances used as Active Pharmaceutical Ingredients (API) and do not document all shipments and quantities received for each lot. For example,

a)The Inventory and Use for Specific Chemical log shows that Lot # [redacted] (b) (4) of Calcium Gluconate USP Anhydrous Powder (Injectable) was used in [redacted] (b) finished product lots. The running inventory record shows there to be -3635.65gm in inventory. When the product was sampled on 8/16/13 there was approximately 2320gm in stock.

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b) The Inventory and Use for Specific Chemical log shows that lot [redacted] (b) (4) of Edetate Disodium USP Dihydrate has an inventory of 400.053 grams. When the product was sampled on 8/16/13 the firm had approximately 200gm in inventory.

OBSERVATION 15

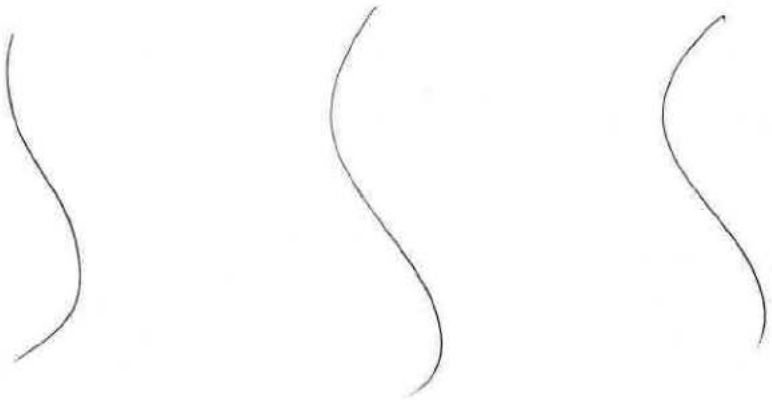
Batch production and control records do not include a description of drug product containers and closures used for each batch of drug product produced.

Specifically, the vials, stoppers and crimps used for each lot of drug product that is prepared are not always documented on the Formula Worksheet. For example,

a) The Formula Worksheet for lot #04172013S48 of Human Chorionic Gonadotropin (HCG) does not have a description or the lot numbers for the vials, stoppers and crimps used to prepare this lot. The Formula Worksheet does not have the dates the product was prepared.

b) The Formula Worksheet for lot #07162013S50 of Human Chorionic Gonadotropin (HCG) that was made from 7/17-23/13 does not have a description or the lot numbers for the vials, stoppers and crimps used to prepare this lot.

*** DATES OF INSPECTION:**
08/13/2013(Tue), 08/14/2013(Wed), 08/15/2013(Thu), 08/16/2013(Fri), 08/20/2013(Tue), 08/21/2013(Wed), 08/22/2013(Thu), 08/27/2013(Tue), 08/28/2013(Wed), 08/29/2013(Thu), 08/30/2013(Fri), 09/04/2013(Wed), 09/05/2013(Thu), 09/06/2013(Fri), 09/09/2013(Mon), 09/11/2013(Wed), 09/12/2013(Thu), 09/13/2013(Fri)



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