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	03/12/2013 - 03/15/2013
	FEI NUMBER 3003254930

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark C. Montgomery, President and CEO

FIRM NAME	STREET ADDRESS
Axium Healthcare Pharmacy dba Balanced Solutions Compounding	550 Technology Park, Suite 1008
CITY, STATE, ZIP CODE, COUNTRY Lake Mary, FL 32746-7131	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

Drug products failing to meet established standards, specifications, and quality control criteria are not rejected.

Specifically,

1. On 03/12/13, (b) (4) vials of already released and distributed (b)(4) -sterilized triamcinolone acetonide injectable solution (60mg/ml; 10 ml. on each vial) lot #01152013@12 were examined and 7 vials were observed containing black particles of un-known origin in the product. One of the vials appeared to contain more than one of these particles.
2. On 03/12/13, (b) (4) vials of already released and distributed sterile (b) (4) chromium chloride injectable solution (4 mcg/ml; 10 ml. on each vial) from lot #01182013@9 were examined and 1 vial was observed to contain a cloth-like filament of un-known origin.

OBSERVATION 2

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

Specifically,

On March 12, 2013, during an inspectional walkthrough of the processing area, I observed the following inside of the "ISO 5" area where all injectable drug products are prepared including BiMix Lot Number 03112013@7, prepared on this day:

1. Spills and splatters of amber and clear droplets and residue were observed stuck to the top of the (b) (b) (4) heating plate / stirrer on the table on the wall oppostite the entrance to the suite.
2. Splatters of a white residue approximately one foot in diameter on the hard transparent air guard behind the table where BiMix Lot Number 03112013@7 was prepared.
3. Segments of the "ISO 5" interior corner ceiling surface where observed to be cracked and/or peeling. These segments were observed lengthwise across both sides of the ceiling ranging in sizes up to 2-4 inches.

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4. The "ISO 5" room is (b) (4) sq ft room. Only 8 of the (b) segments of ceiling were covered with HEPA filters. Four of the (b) segments of the ceiling were filled with fluorescent light fixtures while the six remaining segments were ceiling tiles. The area above the processing table (Table 1) were BiMix Lot Number 03112013@7 was made has 1 light segment and 1 tile with no HEPA filters constituting a (b) space above where products are manually filled without HEPA filters. For reference this environmental sampling designation is ISO5T1 for this processing table.

On March 12, 2013 during an inspectional walkthrough of the processing area I observed the following inside of the firm's "ISO 7" ante room / gowning room to enter the sterile core where all sterile injectables are produced:

1. A wash sink with a "U" tube drain trap was observed in the Ante "ISO 7" room adjacent to the "ISO 5" room. Brown rust like coloring was observed in the base of the sink drain located in this area.

OBSERVATION 3

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

Specifically,

1. Aseptic process validations / media fill procedures do no simulate all production processes. All media fills are performed by SOP Number 310 "Sterile Compounding Process Validation (Media Fills)" which does not simulate the processes and practices for preparing of injectable drugs for commercial distribution.
2. There is no antimicrobial effectiveness testing data for injectable drug products containing preservatives, such as BetaMethasone 12 mg/mL Injectable Solution including lot 01172012@18.
3. On 03/13/13 during the preparing of Betamethasone 9 mg/ml injectable Suspension, lot 03122013@16 the following deficiencies were noted:

a) The preparing of Betamethasone injectable suspensions consists of (b) (4) . (b) (4) . (b) (4) . The product is not subjected to additional sterilization beyond this point. (b) (4) . (b) (4)

b) The technician was observed performing various tasks without sanitizing gloves, then manipulating sterile transfer tubing prior to (b) (4) . Betamethasone is not subjected to additional sterilizations methods beyond this point.

c) The technician was observed with gloved hand reaching into (b) beaker stirring contents during transfer of Betamethasone suspension into (b) (4) . Additionally, the (b) beaker was tilted out of line of air flow and toward the techicians body. Betamethasone is not subjected to additional sterilizations methods beyond this point.

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d) Technician who was wearing a non-sterile gown was observed extending his arm over a (b) vial tray containing (b) open exposed vials. The technician continued filling in this manner potentially contaminating the vials in the tray.

e) Technician was observed exiting the "ISO 5" area into the adjacent "ISO 7" Ante room on 3 or more occasions during which exposed product was mixing. Betamethasone is not subjected to additional sterilizations methods beyond this point.

f) Technician was observed throughout the time moving in a manner that did not appear measured, slow, or deliberate. The technician freely moves in the entire (b) sq foot "ISO 5" area without restriction.

OBSERVATION 4

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

Specifically,

1. On 3/12/13 I observed, Clean Room Surface Sampling Log showing zero CFU's for results of surface samples for ISO5T1, ISO5T2, and ISO5T3 taken on 3/8/13. The (b)(4) plates for these surface samples were in a bin on the table. These plates were not due for a final reading until 3/15/13. I inspected the (b)(4) plate for ISO5T1 and observed a colony on the plate which was stored at room temperature.

2. The area in which sterile injectable products are compounded is lacking in that the ISO 5 classification of this area has not been properly qualified in that there has been no airflow studies (smoke studies) performed and there has been no HEPA filter integrity testing.

3. The firm does not monitor viable particulates in the area where injectable drug products during normal operation.

4. There is no monitoring of non-viable and total particulates in the area where sterile injectable drug products are compounded during or immediately after producing each lot of sterile injectable drug products. The Pharmacist In Charge stated they conduct non-viable air monitoring and surface samples when they are not in operation in the ISO 5 hood producing sterile drug products (b) (4) .

5. Personnel monitoring is limited to the gloves only.

OBSERVATION 5

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

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1. The (b) sterilization process for producing batches of injectable product has not been validated. The firm has no documentation to qualify the (b)(4) used with regards to bacterial retention, extractables, and hardware compatibility. The firm has no documentation to challenge the bacterial retention of the (b)(4) with challenge organisms or bioburden quantity. Dry ingredients used may be non-sterile such as the Bethamethasone Phosphate USP used to manufacture Bethamethasone 12 mg/mL Injectable. The bioburden for these ingredients is not tested for by the firm.

2. The firm has not validated the (b)(4) sterilization processes such as those used to process Triamcinolone Acetonide 60 mg/mL Inj Susp lot 01152013@12.

3. The firm has not validated bulk sterilization processes by (b)(4) such as the bulk sterilization of Methylprednisolone Acetate 60 mg/mL Inj Susp (including lot 02092012@3) prior to filling. The product is filled from this bulk without further sterilizing methods being applied such as sterile (b) (4).

4. The firm has not validated the sterilization process for components such as the stoppers used for sterile injectable vials by (b)(4) used in products such as Methylprednisolone Acetate 60 mg/mL Inj Susp including lot 02092012@3.

5. The firm has not validated the sterilization / (b)(4) process for any vials processed at this site such as those used in the manufacturing of Methylprednisolone Acetate 60 mg/mL Inj Susp including lot 02092012@3.

OBSERVATION 6

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

Specifically, gowning worn by the Technician inside of the "ISO 5" area where all injectable drug products are prepared such as the aseptically prepared and filled product Betamethasone 9 mg/mL injectable suspension consists of non-sterililized garb including only bouffant cap, non-sterile Kendall Chemo-Safety (open-back tie) gown, face mask, shoe covers and sterile gloves. This face and neck is left uncovered and exposed.

OBSERVATION 7

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

Specifically,

1. For any lot of injectable drug product that is less than (containers no testing is needed.

2. The firm may additionally employ a "skip lot testing" procedure where lots of injectable and ophthalmic product are

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frequently released and distributed without testing. Examples include Cyclosporin 2% Ophthalmic, lots 02182013@12, 02142013@13 and 01042013@1.

OBSERVATION 8

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the receipt, identification, storage, and withholding from use of components and drug product containers pending sampling, testing, or examination by the quality control unit before release for manufacturing or packaging.

Specifically,

Stoppers used in the manufacture of aseptically filled injectable drug products are stored in a bin in the "ISO 5" area uncovered.

OBSERVATION 9

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically,

1. The firm's data that are supporting product expiration dates for sterile processed products is not based on site specific, processing conditions at this facility. An example is the BUD date of 180 days for such as Methylprednisolone Acetate 60 mg/mL Injectable Suspension and Betamethasone 9 mg/mL Injectable Suspension.
2. None of the formulations produced by your firm have been placed on long term stability to determine an appropriate BUD.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."