DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	04/13/2015 - 04/17/2015
	FEI NUMBER 3011396023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Masoud Rashidi, PharmD, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Innovative Compounding Pharmacy	820 Wales Dr Ste 3
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Folsom, CA 95630-5546	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

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

Specifically,

On 13Apr15 during a walk-through inspection, and 15Apr15 prior to aseptic processing, spatters of material were observed on the ceiling of the ISO-5 [redacted] (b) (4) LAF hood where aseptic filling occurs; according to the cleaning log, the hood was in a clean status and cleaned on Friday 10Apr15.

OBSERVATION 2

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

Specifically,

A. Non-sterile wipes are used to clean the ISO-5 LAF hood where aseptic filling occurs.

B. Non-sterile and non-lint free mop-heads are used to clean the ISO-7 anteroom and buffer room areas that area adjacent to the ISO-5 LAF hood where aseptic filling occurs.

C. The cleaning procedure provides minimal detail regarding the technique for cleaning the ISO-5 LAF hood where aseptic filling occurs.

D. No records were available demonstrating the disinfectant solution of [redacted] (b) (4) solution used to clean the ISO-5 LAF hood is effective against spores throughout the solution's [redacted] (b) (4) use period. The [redacted] (b) (4) and sterile [redacted] (b) (4) are the only two disinfectants used to clean the ISO-5 LAF hood.

E. Although the formula worksheet for [redacted] (b) (4) solution states [redacted] (b) (4)

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[redacted] (b) (4) there is no prior cleaning step performed to remove soil and debris prior to disinfection.

F. Although cleaning procedure 3.070, "Maintenance of the Aseptic Compounding Area" states the walls in the ISO-7 anteroom and buffer areas are cleaned [redacted] (b) (4), the Pharmacy Manager stated [redacted] (b) (4) disinfectant is used to clean floors and walls in these areas. No records were available demonstrating this cleaning agent is effective against spores.

OBSERVATION 3

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

Specifically,

A. Environmental monitoring for viable and non-viable particulates is never performed during routine aseptic filling operations. The firm's only routine environmental monitoring consists of sterile glove touch plate monitoring. However, this touch plate monitoring is performed inconsistently and not after each aseptic processing filling operation.

B. The pressure differential monitoring gauge between the ISO-7 area and the unclassified area is not continuously monitored or alarmed. In addition,

i. The monitoring gauge is not calibrated.

ii. The firm is only monitoring the differential pressure flow from one (1) of [redacted] (b) (4) passage ways from the ISO-7 cleanroom area into adjacent unclassified areas.

iii. Pressure monitoring records dated between 13Jan15 and 13Apr15 revealed 65 of [redacted] (b) (4) records where the room differential was less than the 0.05 inches of water required by SOP 3.040, "Environmental Monitoring of Aseptic Compounding Area: Air Exchange Pressure Differential". Furthermore, 62 of [redacted] (b) (4) of those readings were ≤0.04 inches of water.

OBSERVATION 4

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

Specifically,

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A. Six (6) of six (6) reviewed formula worksheets ("compounding logs") for [redacted] (b) (4) injectable products do not include records of [redacted] (b) (4). However, procedure 8.030, [redacted] (b) (4) states [redacted] (b) (4) shall be performed on all [redacted] (b) (4) and documented on the "compounding log sheet".

In addition, the [redacted] (b) (4) has not been validated for its intended purpose.

B. The pressure gauge used to demonstrate sterilization [redacted] (b) (4) is not calibrated.

C. Smoke studies evaluating unidirectional HEPA airflow in the ISO-5 aseptic filling area have never been performed.

D. Media fill records do not include a record of the incubated media fill vials; In addition, there is no record of incubator temperature during the media fill incubation period.

OBSERVATION 5

Results of stability testing are not used in determining appropriate storage conditions and expiration dates.

Specifically,

On 15Apr2015, we observed a 5ml vial of Testosterone Cypionate 200mg/ml lot#03102015@5 for injection stored at room temperature that was produced on 10Mar2015 and assigned a 3-month beyond use date (BUD) of 8Jun2015. Sterility, endotoxin, strength and purity testing over the BUD has never been performed for this formulation of sterile injectable product.

OBSERVATION 6

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. A process is not established to prevent product mix-ups between expired and in-date anticipatory compounded products; several examples of expired products were observed co-mingled with in-date product anticipatory compounded products were noted.

B. A clear solution with no identifiable contents or expiration date was observed on 13Apr15 and 15Apr15 in an unlabeled spray bottle located in the ISO-7 anteroom; the pharmacy manager said it was non-sterile [redacted] (b) (4)

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C. A discolored cloth towel was the only hand-drying towel located at the hand washing sink used for preparation of non-sterile products.

OBSERVATION 7

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

The ISO 5 and ISO 7 Cleanroom are not qualified under dynamic conditions. For example, dynamic viable and non-viable particle monitoring studies have never been performed during qualification. In addition, the firm has never evaluated particle counts during use of a [redacted] (b) (4) [redacted] in the ISO-7 ante room.

OBSERVATION 8

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

Protective apparel is not worn as necessary to protect drug products from contamination. Specifically, personnel do not wear sterile gowns, hoods, or sterile sleeve covers during aseptic processing. In addition, preparation of sterile product is performed by personnel with exposed skin on their face and neck.

OBSERVATION 9

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

Specifically,

A. Sterility and endotoxin testing is not consistently performed on compounded sterile products. For example,

i. Zero (0) of [redacted] (b) (4) lots (0%) of Testosterone Cypionate 200 mg/mL Inj. Soln. produced between 18Dec14 and 15Apr15 were tested for sterility or endotoxin; the product was assigned a beyond use date (BUD) of 90 days from its manufactured date and stored at

room temperature.

ii. Eight (8) [redacted] of Bi-Mix Papavarine/Phentolamine 30mg/2mg/mL Inj. Soln. produced between 01Jan15 and 15Apr15 were tested for sterility or endotoxin; the product was assigned a BUD of 30 days from its manufacturing date and stored at 2 - 8°C.

B. Storage periods of finished product not tested for sterility consistently exceed the timeframes required by the Standard Operating Procedure (SOP) 1.040, "Pharmaceutical Compounding - Sterile Preparations as per USP<797>". According to the SOP, in the absence of passing a sterility test, the storage period for any product prepared from [redacted], shall not exceed [redacted] days at cold temperature.

For example, Tri-Mix 30 mcg/30mg/2mg/mL Inj. Soln., Lot 01272015@25, which was prepared from [redacted] on 27Jan2015, was assigned a 30-day BUD and stored at cold temperature. It was not tested for sterility.

OBSERVATION 10

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

Specifically,

Six (6) of six (6) reviewed formula worksheets for sterile injectable products did not include a record of visual inspection of the finished product.

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."