DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	04/15/2015 - 05/14/2015* FEI NUMBER 3006572203

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jennifer A. Siefert, President and Co-Owner

FIRM NAME	STREET ADDRESS
Central Illinois Compounding, Inc. dba Preckshot Professiona	4450 N Prospect Rd # 7
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Peoria Heights, IL 61616-6578	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 I 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. On 4/21/2015 I observed pharmacist (b) (6) pass (b) (6) gloved hands over open drug product containers, closures, and components while (b) (6) produced the sterile drug product Vancomycin 16mg/ml Ophthalmic Solution lot 04212015@6.

b. Media fills are deficient as follows:

i. The firm does not conduct media fills using the containers and closures into which ophthalmic sterile drug products are filled. Media fills are only conducted using (b) (4)

ii. Positive controls during media fills are made with unknown microorganisms. Specifically, instead of using identified cultures the firm (b) (4)

iii. Fewer units are filled during media fills than during some routine production batches. For example, Histamine Phosphate 2.75mg/ml Injectable lot number 02052015@41 consisted of approximately (b) (4) vials, whereas media fills consist of (b) (4) vials each.

c. Smoke studies are not performed under dynamic conditions.

OBSERVATION 2

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

Specifically,

a. The environmental and personnel monitoring covering the firm's production of sterile human and animal drug products is

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deficient as follows:

i. The firm does not monitor the air in the ISO 5 or ISO 7 areas for viable particulates.

ii. The firm does not monitor the air in the ISO 5 or ISO 7 areas for non-viable particulates during active conditions.

iii. The firm only monitors the air in the ISO 5 or ISO 7 areas for non-viable particulates during passive conditions approximately [redacted] (b) (4)

iv. The firm does not perform surface monitoring and personnel monitoring every time sterile drugs are produced. Surface monitoring and personnel monitoring occur approximately [redacted] (b) (4)

b. The pressure differentials between the ISO 7 buffer room, which contains the ISO 5 laminar flow hood where sterile drug products are produced, and the ISO 7 ante room and unclassified non-sterile lab are not continuously monitored during sterile drug production.

OBSERVATION 3

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

Specifically,

The garb worn by personnel while conducting aseptic filling of sterile human and animal drug products does not adequately protect the products as follows:

a. The gown, hair net, and mask that personnel wear while producing sterile drug products are not sterile.

b. The hair net and mask, which covers the nose, mouth, and chin, leave skin on the face and neck exposed.

c. The gown, mask, and hairnet are re-used throughout each day. They are stored in the ISO 7 ante room on a hook when not being worn.

OBSERVATION 4

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

Specifically,

The firm does not use sporicidal disinfectants in areas where sterile human and animal drug products are being produced.

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OBSERVATION 5

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically,

Certificates of Analysis for components used to produce sterile human and animal injectable drug products do not always indicate that they have been tested for pyrogens or bacterial endotoxins. For example:

a. Papaverine [redacted] (b) (4) lot [redacted] (b) (4) and Phentolamine [redacted] (b) (4) lot [redacted] (b) (4) which were used as components in Papaverine, Phentolamine, Alprostadil (24 : 0.8 : 20) 24mg/ 0.8mg/ 20mcg per ml Injectable lot 04142015@8, do not list pyrogen or bacterial endotoxin test results on their Certificates of Analysis.

b. Methylcobalamin lot [redacted] (b) (4), which was used as a component in Methylcobalamin 1000 mcg / ml Injectable lot 04132015@3, does not list pyrogen or bacterial endotoxin test results on its Certificate of Analysis.

OBSERVATION 6

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

Specifically,

Sterile human and animal drug products are not always tested for sterility or pyrogens. For example:

a. Prednisolone Sodium Phosphate 2% Ophthalmic Solution lot number 03302015@8, produced 3/30/2015, was not tested for sterility or pyrogens.

b. Ceftazidime PF 22.5 mg/ml Ophthalmic lot number 04142015@13, produced 4/14/2015, was not tested for sterility or pyrogens.

c. Edetate Disodium 3% Ophthalmic Solution lot number 04142015@9, produced 4/14/2015, was not tested for sterility or pyrogens.

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OBSERVATION 7

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,

Sterile human and animal drug products are not always tested for potency. For example:

a. Tacrolimus 0.02% Oil Ophthalmic Solution lot number 04152015@1, produced 4/15/2015, was not tested for potency.

b. Papaverine, Phentolamine, Alprostadil (24 : 0.8 : 20) 24mg/ 0.8mg/ 20mcg per ml Injectable lot number 04142015@8, produced 4/14/2015, was not tested for potency.

c. Methylcobalamin 1000 mcg / ml Injectable lot number 04132015@3, produced 4/13/2015, was not tested for potency.

OBSERVATION 8

The accuracy and sensitivity of test methods have not been established.

Specifically,

a. The firm has not validated the sterility testing it conducts on-site against any of its human and animal sterile drug products. Furthermore, the firm's sterility test method differs from USP <71> in that it [redacted] (b) (4) whereas USP <71> states that they are to be incubated at 20-25 C.

b. The sterility and endotoxin test methods that the firm's contract testing lab uses to test its human and animal sterile drug products have not been validated. For example:

i. Alprostadil 500 mcg/ml Injection lot number 02032015@2 was tested for sterility and endotoxins but neither of these test methods have been validated.

ii. Gentamicin (Bladder) Irrigation 480 mg/L lot number 02192015@12 was tested for sterility but the test method has not been validated.

iii. Histamine Phosphate Injection 2.75 mg/ml lot number 02192015@24 was tested for sterility but the test method has not been validated.

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OBSERVATION 9

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

Specifically,

The firm does not always have data to support the expiration periods it assigns to its sterile human and animal drug products. For example, many of the sterile drugs that the firm produces are dispensed frozen and have expiration periods of 45 days, yet the firm has no data to support these expiration periods. For example, this is the case for Papaverine, Phentolamine, Alprostadil (24 : 0.8 : 20) 24mg/ 0.8mg/ 20mcg per ml Injectable and Edetate Disodium 3% Ophthalmic Solution.

OBSERVATION 10

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

Specifically,

a. The thermometer in the incubator that the firm uses for human and animal drug product sterility testing and media fill incubation has not been calibrated.

b. The balance the firm uses for weighing non-sterile components for use in sterile human and animal drug products is not calibrated within its range of use. The lowest standard weight used in its most recent calibration was [redacted] (b) (4) yet:

i. On 4/15/2015 it was used to weigh [redacted] (b) (4) of Tacrolimus [redacted] (b) (4) for Tacrolimus 0.02% Oil Ophthalmic Solution lot 04152015@1.

ii. On 4/14/2015 it was used to weigh [redacted] (b) (4) of Phentolamine [redacted] (b) (4) for Papaverine, Phentolamine, Alprostadil (24 : 0.8 : 20) 24mg/ 0.8mg/ 20mcg per ml Injectable lot 04142015@8.

iii. On 4/13/2015 it was used to weigh [redacted] (b) (4) of Methylcobalamin for Methylcobalamin 1000 mcg / ml Injectable lot 04132015@3.

*** DATES OF INSPECTION:**
04/15/2015(Wed), 04/16/2015(Thu), 04/17/2015(Fri), 04/20/2015(Mon), 04/21/2015(Tue), 05/05/2015(Tue), 05/14/2015(Thu)

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