DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772 Industry Information: www.fda.gov/oc/industry	11/06/2013 - 11/20/2013* FEI NUMBER 3005124205

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jeffrey A. Potter, Owner

FIRM NAME	STREET ADDRESS
Clinical Apothecaries	4087 Medina Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medina, OH 44256-5946	Compounding Pharmacy

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

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

Specifically, cleanroom technicians who engage in aseptic operations do not use sterile lab coats, sterile masks, sterile hair nets, or sterile shoe covers.

OBSERVATION 2

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, components used in the production of sterile drug products, are not tested for conformance with appropriate specifications of purity, strength, and quality, including the total bioburden of non-sterile raw materials.

OBSERVATION 3

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

Specifically,

a) Qualification studies have not been performed on the firm's [redacted] (b) (4) (Asset# 4.030.1), which is used to sterilize drug products and utensils. For example, studies utilizing current maximum load patterns for the [redacted] (b) (4) have not been conducted to demonstrate the equipment's ability to adequately sterilize glassware.

Addtionally, the process of sterilizing drug products has not been validated, including an evaluation of each cycle's

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impact to drug product identity, potency, quality, purity and stability.

b) Qualification studies have not been performed on the firm's [redacted] (b) (4) (Asset# 4.040.1), which is used to sterilize glassware, including beakers used for mixing. For example, studies utilizing current maximum load patterns for the [redacted] (b) (4) have not been conducted to demonstrate the equipment's ability to adequately sterilize glassware.

c) The media fill test procedure does not closely simulate the most challenging or stressful conditions encountered in high-risk sterile processing. For example, the current media fill test only involves [redacted] (b) (4) .

OBSERVATION 4

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

Specifically, all lots of finished sterile drug product do not undergo sterility and/or endotoxin testing. In addition, lots of sterile drug products produced in quantities greater then [redacted] (b) (4) units are only tested for sterility and endotoxins on a periodic basis; meaning, no frequency and/or timeframes have been established.

OBSERVATION 5

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, not all lots of sterile drug product are tested for potency prior to approval and release for distribution. Although certain lots of product are periodically analyzed for potency, there is no predetermined schedule stating the required frequency of testing.

OBSERVATION 6

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

Specifically, there is no written stability testing program in place to set appropriate expiration dates, continuously monitor the stability of batches on the market, and assess the on-going state of control of aseptic processing operations.

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OBSERVATION 7

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

Specifically, the firm does not monitor the environment within the ISO Class 5 laminar air flow hood during aseptic processing operations, including air and surface sampling, during every instance of sterile drug product manipulation.

OBSERVATION 8

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

Specifically, the firm uses [redacted] (b) (4) to clean the Prep Room, ISO 7 Ante Room, and ISO 5 Clean Room. The firm provided no evidence that the [redacted] (b) (4) had "sporacidal" activity. Furthermore, there has been no evaluation of the effectiveness of [redacted] (b) (4), a cleaning agent, or [redacted] (b) (4) a sanitizing agent, which are used to clean the floors, counters, and/or walls in the cleanroom, prep room, and anteroom.

*** DATES OF INSPECTION:**
11/06/2013(Wed), 11/07/2013(Thu), 11/19/2013(Tue), 11/20/2013(Wed)

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