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	08/26/2014 - 09/15/2014* FEI NUMBER 3010810839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kelly A. Everett, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Ambient Healthcare of Central Florida Inc	202 SW 17th St Suite C
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34471-8138	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 are not followed.

Specifically, the pharmacy technician was observed not sanitizing items (e.g., vials) immediately prior to placing them into the ISO 5 hood while preparing sterile drug products.

OBSERVATION 2

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

Specifically, the pharmacy technician was observed placing his bare hands on the outside of his sterile gown (e.g., forearm section of the gown) while gowning to enter the ISO 7 area.

In addition while he de-gowned upon leaving the ISO 7 area, he slid his bare hands from top to bottom of his sterile gown once he hung it on a hook in the ante room. Personnel stated that the gown would be used throughout the day.

OBSERVATION 3

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

Specifically for your firm, which started preparing sterile drug products on 07/23/14 (currently preparing (b)(4) sterile drug products per day), your environmental monitoring program is inadequate based on the following:

A. Viable air sampling within your ISO 5 hoods and ISO 7 area is not conducted during daily

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	Michael H. Tollon, Investigator	09/15/2014

operations.

B. Surface sampling within your ISO 5 hoods is not conducted during daily operations.

C. Personnel monitoring (e.g., fingertip sampling) is not conducted during daily operations.

OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, there was no dynamic airflow pattern studies (smoke studies) available for the (b) (4) ISO 5 hoods inside your ISO 7 room, where sterile drug products are prepared.

OBSERVATION 5

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

Specifically, the suitability and efficacy of disinfecting agents and procedures have not been assessed to ensure potential contaminants are adequately removed from the surfaces in the classified areas (ISO 5 & 7).

OBSERVATION 6

Test procedures relative to appropriate laboratory testing for sterility are not followed.

Specifically, no sterility testing has been conducted for any of the distributed Gentamicin and Cefepime finished, sterile drug products prepared at your firm.

OBSERVATION 7

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

Specifically, I observed two patient specific prescriptions for the dispensing of Gentamicin (elastomeric

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pump containing 80 mg in 100 ml of normal saline) and Cefepime (35 ml syringe containing 1 g in 20 ml of sterile water) with a 9 day BUD. You could not provide an exact reference that supports this 9 day BUD for these specific container systems and concentrations dispensed.

*** DATES OF INSPECTION:**
08/26/2014(Tue), 08/27/2014(Wed), 09/02/2014(Tue), 09/15/2014(Mon)

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