DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/10/2014 - 10/09/2014* FEI NUMBER 3005144312

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Tenille D. Davis, Pharm D., RPh, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Civic Center Pharmacy	7331 E Osborn Dr Ste 208
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Scottsdale, AZ 85251-6420	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 I OBSERVED:

OBSERVATION 1

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

Specifically,
Environmental Monitoring of the firm's ISO 5 environments and ISO 7 Cleanroom environments used to produce sterile drug products is not conducted during active processing and does not represent actual conditions, for example:

a) Your firm does not routinely conduct viable particulate air monitoring during actual aseptic processing of drug products in the ISO 5 hoods. Viable particulate air monitoring is only conducted every 6 months by an outside contractor.

b) Your firm does not routinely conduct viable particulate air monitoring of the ISO 7 cleanroom during active processing of drug products. The ISO 5 Laminar air flow hoods are located within the ISO 7 cleanroom. Viable particulate air monitoring is only conducted every 6 months by an outside contractor.

c) Your firm does not routinely conduct non-viable particulate air monitoring during actual aseptic processing of drug products in the ISO 5 hoods. Non-viable particulate air monitoring is only conducted every 6 months by an outside contractor.

d) Your firm does not routinely conduct non-viable particuate air monitoring of the ISO 7 environments during active processing of drug products. The ISO 5 Laminar air flow hoods are located within the ISO 7 cleanroom. Non-viable particulate air monitoring is only conducted every 6 months by an outside contractor.

e) Your firm does not actively monitor cleanroom pressure differentials during aseptic processing of drug products. Differential pressures of the ISO 7 Anteroom, ISO 7 Cleanroom and other areas are manually read and recorded once per day in the (b) (4) to the start of productsion under static condition. There is no further monitoring of the cleanroom pressure differentials either manually or by electronic devices during production.

f) Your firm does not conduct adequate surface environmental monitoring (work surfaces, floors, walls, ceilings) that represent actual conditions. It was explained that surface environmental monitoring is conducted on a weekly basis and samples are collected (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joey V. Quitania, Investigator JQuitania 10/09/14	10/09/2014

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g) Your firm does not routinely conduct personnel monitoring (fingertips, hands, arm, chest) during or post drug production for pharmacists and technicians that process drug products intended to be sterile in aseptic processing areas. Personnel fingertips are only monitored every (b) months.

OBSERVATION 2

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

Specifically,

a) There are established written procedures. However, SOP 8.030, Vers 1.0, "Sterilization and Depyrogenation of Serum Vials and Stoppers", eff 12/18/13 and your firm's process for handling sterilized vials has not been well established or well designed to prevent microbiological contamination.

For example, on 09/11/14, I observed your procedure for removing sterilized vials from the (b) (4) autoclave. The autoclave is located in the ISO 8 (Class 100,000) Compounding room. (b) (4) . Section 9 of SOP 8.030 does not provide adequate instructions on the handling of sterilized vials.

b) Your firm's process for aseptically filling and stoppering vials has not been well designed to prevent microbiological contamination.

For example, on 09/11/14, I observed your procedure for stoppering aseptically filled vials. (b) (4) The stoppering process is manual and this process repeated until all of the approximately (b) (4) vials were stoppered. (b) (4) . Furthermore, the open vials were subjected to an extended exposure time to the environment.

On 09/11/14, I also observed the filling process of vials. The process is (b) (4) I observed the technician's arm, at times, hover over unstoppered vials as the vials were being filled. The technique employed may interrupt the HEPA filtered first air protection to the unstoppered vials.

c) Articles entering the ISO 5 environment are not always disinfected before introduction.

For example, on 09/11/14, the (b) (4) containing stoppers was not wiped down as it was passed from the (b) (4)

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(b) (4) without being disinfected as it passed into higher air quality environments on 09/11/14.

d) Cleanroom certification of the firm's ISO 5 Hoods used to aseptically process drug products does not include performing smoke studies to demonstrate the air flow is smooth, laminar, and without turbulence under dynamic conditions.

*** DATES OF INSPECTION:**
09/10/2014(Wed), 09/11/2014(Thu), 10/09/2014(Thu)