DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, Los Angeles District Office Address: 19701 Fairchild Irvine, CA 92612 Telephone: (949)-608-2900 Attention: Steven Porter, District Director Industry Information: www.fda.gov/oc/industry	03/21-24/2017, 03/27,28,30/2017
	FEI NUMBER 3005144312

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tenille D. Davis, Pharmacist In Charge

FIRM NAME	STREET ADDRESS
Civic Center Pharmacy, Inc.	7331 E. Osborn Drive Suite 208
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Scottsdale, AZ 85251	Producer of Sterile and Non-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) (WE) OBSERVED:

OBSERVATION 1
Personnel were observed using a non-sterile tool or manually contact the inner surface of the container or closure.

Specifically, on 03/21/2017, a Pharmacy Technician ((b) (6)) used their gloved hand and made contact with the inner surface of the vial stopper that contacts the BIMIX drug product, lot number 03/21/2017:0216.

This is a repeat Observation from the FDA Inspection dated November 2014.

OBSERVATION 2
There is inadequate HEPA filter coverage or airflow over the area to which sterile product is exposed.

Specifically, your firm's procedure for lyophilizing finished drug products includes (b) (4)
(b) (4)
The lyophilizer is located inside of the ISO 7 Clean Room, but it is outside of the ISO 5 environment.

OBSERVATION 3
The final containers/closures used for drug product intended to be sterile have not been sterilized or de-pyrogenated.

Specifically, your firm has no hold time studies for sterilized tools (such as (b) (4)) and for sterilized vials and stoppers that are stored in plastic bins and placed on carts located in the ISO 8 Prep Room and/or the ISO 7 Ante Room. These carts are transported to the ISO 7 Clean Room as needed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Stephanie A.	Stephanie A. Slater, Investigator	03/30/2017

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OBSERVATION 4

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

Specifically, the design of the ISO 8 Prep room is deficient.

There are two (2) return air vents located on the ceiling; one is on the ceiling in the corner of the room across from the entrance; one is on the ceiling directly in between (b) (4)

OBSERVATION 5

The batch records do not record the distinctive identification number, code and name of equipment to identify major equipment to show the specific equipment used in the manufacture of a batch of a drug product.

Specifically, I observed that your firm does not always document equipment in your batch records for non-sterile drug products, such as Melatonin capsules and (b) (4) . Moreover, the pH meters, (b) (4), (b) (4) , scales, (b) (4) hoods, and laminar flow hoods are not physically identified with equipment numbers.

SAS 03/30/2017

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Stephanie A. Slater	Stephanie A. Slater, Investigator	03/30/2017