

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

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

DATE(S) OF INSPECTION

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

Civic Center Pharmacy, Inc.

STREET ADDRESS

7331 E. Osborn Drive Suite 208

CITY, STATE AND ZIP CODE

Scottsdale, AZ 85251

TYPE OF ESTABLISHMENT INSPECTED

Producer of Sterile and Non-Sterile Drug Products

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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)

Stephanie A. Slater, Investigator

DATE ISSUED

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
	<i>Stephanie A. Slater</i>	Stephanie A. Slater, Investigator	03/30/2017