

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

158-15 Liberty Avenue
Jamaica, NY 11433
(718) 340-7000 Ext:5301 Fax:(718) 662-5661

DATE(S) OF INSPECTION

3/30/2016-4/18/2016*

FBI NUMBER

3010285019

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Alfonse Muto, Sr. , Owner

FIRM NAME

Pine Pharmacy and Home Care Products
Center, Inc.

STREET ADDRESS

5110 Main St

CITY, STATE, ZIP CODE, COUNTRY

Williamsville, NY 14221-5256

TYPE ESTABLISHMENT INSPECTED

Sterile Drug Producer

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

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

Specifically, the operator's neck area is not fully covered allowing exposed neck skin over the critical ISO 5 laminar flow area where sterile drug products are processed.

On 4/1/16, excessive conversation was observed between (b) (4) operators while each was preparing Avastin Inj sterile drug product in an ISO 5 zone.

OBSERVATION 2

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

Specifically,

a. The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily during periods of production and at the end of operations. This monitoring is only performed (b) (4).

b. Environmental monitoring for non-viable particulates is only performed during the (b) (4) (b) (4) by an outside vendor.

c. The ISO 7 clean rooms, the ISO 7 anteroom, and the unclassified surrounding areas are only monitored for air pressure differentials (b) (4)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Karen L Kosar, Investigator

DATE ISSUED

4/15/2016

4/18/2016

X Karen L Kosar
Karen L Kosar
Investigator
Signed by: Karen L Kosar-S

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OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the storage of in-process materials.

Specifically, there are no separate facilities, for processing operations, to prevent contamination from beta-Lactam injectable drugs, such as Ceftriaxone. This beta-Lactam (b) (4) which is contained in glass vials, is processed in the same ISO 5 hood as are sterile injectable non beta-Lactam drugs. There is no assurance that a potential breakage of the glass vial and consequent (b) (4) spill would not contaminate other sterile drug products.

OBSERVATION 4

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

Specifically, you have not validated the (b) (4) sterilization process used for your sterile drug products, such as Progesterone in Sesame Oil Inj. within your (b) (4). In addition, your (b) (4) used to (b) (4) sterilize drug products has not been qualified for use.

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Karen L Kosar, Investigator	<input checked="" type="checkbox"/> Karen L Kosar Investigator Signed by: Karen L Kosar - 8	DATE ISSUED 3/18/2016 4/18/2016

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Specifically, your firm does not test every sterile drug lot produced for sterility or endotoxins. In addition, you do not perform antimicrobial effectiveness testing for sterile drug products containing preservatives such as Protamine Zinc Insulin Inj.

OBSERVATION 6

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

Specifically,

a. Sterile (b) (4) are prepared for various products from non-sterile ingredients. These (b) (4) can be held for up to (b) (4) as for (b) (4) injection and (b) (4) injection. Your firm has not conducted any studies to support the stability/sterility over the time periods that (b) (4) are prepared (b) (4).

b. Your firm has not tested for sterility over the assigned Beyond Use Date (BUD) for any sterile injectable or sterile ophthalmic except for Avastin Inj. For example, your firm has not conducted any testing to support the BUDs such as 90 days refrigerated for Phenylephrine-Tropicamide injection or 90 days refrigerated for Ascorbic Acid injection. You have no data to assure that the sterility and potency will be maintained over the time period of the BUD.

c. Your firm only performs potency testing related to (b) (4)

OBSERVATION 7

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Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, visual checks of sterile injectable drugs for clarity/discoloration or particulates/contaminants are not performed against contrasting backgrounds.

OBSERVATION 8

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically, surface samples obtained from the critical ISO 5 surfaces and glove finger tips along with other clean room surfaces are placed on (b) (4) plates. They are (b) (4) who have not been trained in determining that.

***DATES OF INSPECTION**

3/30/2016(Wed),3/31/2016(Thu),4/01/2016(Fri),4/05/2016(Tue),4/07/2016(Thu),4/18/2016(Mon)

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	<input checked="" type="checkbox"/> Karen L Kosar Investigator Signed by: Karen L Kosar-5	