

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875		DATE(S) OF INSPECTION 12/9/2015-1/7/2016*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thomas E. Silvonek , Owner		FEI NUMBER 3005231215
FIRM NAME Dorneyville Pharmacy	STREET ADDRESS 3330 Hamilton Blvd	
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4537	TYPE ESTABLISHMENT INSPECTED 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

Each lot of drug product containers and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

On 12/15/15, it was observed that one of the (b) (4) used during the 12/9/15 (b) (4) of (b) (4) Vials in the (b) (4), had failed.

The current process of using (b) (4) during the sterilization of containers and closures allows them to be (b) (4)

Currently, results are read and interpreted (b) (4). In this particular event, the results of the failure were not immediately reported to the sterile area supervisor and the affected vials were available for use in the production of finished drug products.

OBSERVATION 2

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

Specifically,

The (b) (4) (b) (4) used as a component in the production of various sterile drug products is being dispensed from an (b) (4) (b) (4) by (b) (4) (b) (4). The (b) (4) (b) (4) in the ISO 7 Ante Room and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE James M Mason, Investigator	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	DATE ISSUED 1/7/2016

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875		DATE(S) OF INSPECTION 12/9/2015-1/7/2016*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thomas E. Silvonek , Owner		FEI NUMBER 3005231215
FIRM NAME Dorneyville Pharmacy	STREET ADDRESS 3330 Hamilton Blvd	
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4537	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	

(b) (4) for use in the production of sterile drug products in the ISO 5 laminar flow hood.

OBSERVATION 3

Clothing of personnel engaged in the manufacturing of drug products is not appropriate for the duties they perform.

Specifically,

a.) On 12/21/15, I observed an employee enter the ISO 7 Ante Room, put on shoe covers and a face mask and then proceed to walk the length of the room up to the door for the ISO 7 (b) (4) without having performed hand washing, putting on a hair net or donning a gown and sterile gloves. The employee then walked back to the entrance of the Ante Room, removed the face mask and placed it back into storage with the clean face masks. They removed their shoe covers and placed them on the floor. The employee left the room without disposing of the face mask or shoe covers.

b.) The gowning and components worn by operators in the ISO 5 area are not sterile. Gowns and gowning components, such as hair nets, beard nets and face masks, are stored (b) (4) such that they are exposed to the uncontrolled environment outside the ISO 7 area.

c.) When fully gowned, operators have exposed skin on their neck, face and forehead while working in sterile areas.

d.) Gowns are (b) (4).

e.) The gowning process is not standardized among all personnel working in the sterile production area. Some operators are putting on their gowns prior to washing their hands while others are washing their hands and then putting on their gown.

f.) There is no evidence to support that the sanitizer used on gloved hands is sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE James M Mason, Investigator	DATE ISSUED 1/7/2016
	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875		DATE(S) OF INSPECTION 12/9/2015-1/7/2016*
		FEI NUMBER 3005231215
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thomas E. Silvonek , Owner		
FIRM NAME Dorneyville Pharmacy	STREET ADDRESS 3330 Hamilton Blvd	
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4537	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	

OBSERVATION 4

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

Specifically,

There is no written procedure or stability program established to test the sterility, potency, and endotoxin levels of sterile drug products.

You have not determined through testing, if your sterile drug products remain free of microorganisms and endotoxins and maintain potency for the duration of their shelf lives.

OBSERVATION 5

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

Specifically,

The process used to (b) (4) sterilize drug products made from non-sterile components has not been validated.

You have not conducted any testing to support the shelf life of (b) (4) (b) (4) used in the production of sterile drug products.

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

You do not conduct potency testing of drug products prior to release.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE James M Mason, Investigator	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	DATE ISSUED 1/7/2016

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875		DATE(S) OF INSPECTION 12/9/2015-1/7/2016*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thomas E. Silvonek , Owner		FEI NUMBER 3005231215
FIRM NAME Dorneyville Pharmacy	STREET ADDRESS 3330 Hamilton Blvd	
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4537	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	

OBSERVATION 7

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

Specifically,

Your environmental monitoring program is inadequate in that:

- a) Collection of air samples for viable and non-viable particles is only performed (b) (4).
- b) Personnel monitoring of operator gloves is only performed (b) (4) (b) (4)
- c) The collection frequency of surface samples is inadequate in that the time between surface sample collections has exceeded (b) (4).

OBSERVATION 8

Approved drug product containers and closures are not retested or reexamined as appropriate for identity, strength, quality and purity after storage for long periods with subsequent approval or rejection by the quality control unit.

Specifically,

Finished product containers and closures for sterile drug products, such as vials and stoppers which are sterilized on-site, lack expiration dating to indicate how long the materials are fit for use.

Additionally, this is also the case for beyond use dates of product contact equipment, such as (b) (4) and (b) (4) used in the production process.

During the sterilization process, equipment, containers and closures are (b) (4) and sterilized in a (b) (4). Once the (b) (4) (b) (4), the equipment, containers, and closures are placed into (b) (4) (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE James M Mason, Investigator	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	DATE ISSUED 1/7/2016

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875		DATE(S) OF INSPECTION 12/9/2015-1/7/2016*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thomas E. Silvonek , Owner		FEI NUMBER 3005231215
FIRM NAME Dorneyville Pharmacy	STREET ADDRESS 3330 Hamilton Blvd	
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4537	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	

There is no documentation on the (b) (4) or the materials indicating when they were sterilized or how long they are able to be used.

OBSERVATION 9

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

As noted in a previous observation, on 12/15/15, it was observed that one of the (b) (4) (b) (4) used during the 12/9/15 (b) (4) of (b) (4) Vials in the (b) (4) (b) (4), had failed.

At the time the failure was identified during the inspection, the Sterile Compounding Area Supervisor had not been notified of the failure. At that time, the (b) (4) glass vials that failed this (b) (4) were available for use in the production area.

The subsequent investigation found that none of the vials that failed the (b) (4) had been used to produce sterile drug products. However, this was the extent of the investigation. There was no determination as to the root cause for the failure of the (b) (4).

OBSERVATION 10

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

Specifically,

You have not conducted sterility and endotoxin testing of the sterile drug products you produce.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE James M Mason, Investigator	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	DATE ISSUED 1/7/2016

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

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875	12/9/2015-1/7/2016*
	FEI NUMBER
	3005231215

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thomas E. Silvonek , Owner

FIRM NAME	STREET ADDRESS
Dorneyville Pharmacy	3330 Hamilton Blvd

CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18103-4537	Producer of Sterile Drugs

* Exception: Sterility testing was conducted for (b) (4) of each of the following:

Tacrolimus 0.02% Ophthalmic (lot #06222015)
Chorionic Gonadotropin (HCG) (lot #06232015@7)
Phenol 5% (lot 11052015@62)
Glutathione 200mg/ml injectable (lot #11092015@7)

OBSERVATION 11

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Specifically,

The stainless steel preparation table located in the ISO 7 "Ante Room" is not maintained in a good state of repair in that it has discolored spots across the surface of the table which cannot be removed by cleaning.

OBSERVATION 12

Employees are not given training in the particular operations they perform as part of their function , current good manufacturing practices and written procedures required by current good manufacturing practice regulations .

Specifically,

Employees working in the sterile area have not been trained on the procedures for working in the sterile area.

Additionally, they do not have access to any written procedures, in the event they needed to refer to them during the course of operations.

OBSERVATION 13

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James M Mason, Investigator	1/7/2016
	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	

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

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875	12/9/2015-1/7/2016*
	FEI NUMBER
	3005231215

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thomas E. Silvonek , Owner

FIRM NAME	STREET ADDRESS
Dorneyville Pharmacy	3330 Hamilton Blvd

CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18103-4537	Producer of Sterile Drugs

Written distribution procedures are not established .

Specifically,

You do not have a written procedure in place to facilitate the recall of drug product(s), if necessary.

OBSERVATION 14

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

Specifically,

Your procedure titled "CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY" (SOP Number 3.020, Version 1.0) does not specify the contact time for cleaning solutions to be applied to surfaces to ensure effective cleaning.

***DATES OF INSPECTION**

12/09/2015(Wed),12/10/2015(Thu),12/15/2015(Tue),12/16/2015(Wed),12/21/2015(Mon),12/30/2015(Wed),1/07/2016(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James M Mason, Investigator	1/7/2016
	<input checked="" type="checkbox"/> James M Mason James M Mason Investigator Signed by: James M. Mason -S	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."