

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 3/9/2020-3/16/2020*
	FEI NUMBER 3016458098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Wayne L. Wallace, Owner & Pharmacist

FIRM NAME The Medicine Shoppe Pharmacy	STREET ADDRESS 3524 B Tamiami Trl
---	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Port Charlotte, FL 33952-8100	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-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 WE OBSERVED:**

**OBSERVATION 1**

The (b) (4) intended to render final product sterile was not adequate to accomplish sterilization and was (b) (4)

Specifically, on 3/10/20, your firm produced ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) lot (b) (4) (Rx (b) (6) without utilizing a sterile (b) (4) (b) (4) According to your firm's Pharmacist he failed to use a sterile (b) (4) for any drug products intended to be sterile that was dispensed by his firm.

**OBSERVATION 2**

Vermin was observed in your production area.

Specifically, from 3/9-3/10/20 dead ants were observed on the floor of the unclassified general production area and dead cockroaches were observed within the drawer adjacent to the (b) (4) hood where sterile and non-sterile drug products are produced.

**OBSERVATION 3**

Personnel performed aseptic processing outside of an ISO 5 classified aseptic processing area.

Specifically, on 3/10/20, your firm produced ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) lot (b) (4) (Rx (b) (6) ) in an unclassified (b) (4) hood. In addition, the final containers/closures used for the drug product intended to be sterile were not sterilized.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Kayla V Sprague, Investigator - Dedicated Drug Cadre	Jessica L. Pressley Investigator Signed By Jessica L. Pressley -S Date Signed 03-16-2020 10:56:25 X	DATE ISSUED 3/16/2020

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 3/9/2020-3/16/2020*
	FEI NUMBER 3016458098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Wayne L. Wallace, Owner & Pharmacist

FIRM NAME The Medicine Shoppe Pharmacy	STREET ADDRESS 3524 B Tamiami Trl
---	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Port Charlotte, FL 33952-8100	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drugs
---	---

**OBSERVATION 4**

You did not have a HEPA filter over the area to which sterile product was exposed.

Specifically, your firm's unclassified (b) (4) hoods fail to contain HEPA filters. Instead, your firm is currently utilizing household air filters that can potentially shed particulates. On 3/10/20, your firm produced ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) ), lot (b) (4) (Rx (b) (6) within the (b) (4) hood.

**OBSERVATION 5**

The ISO 5 classified aseptic processing areas had difficult to clean, particle-generating and visibly dirty equipment or surface.

Specifically, from 3/9-3/11/20, your firm's (b) (4) hoods (b) (4) adjacent to the sink (b) (4) (b) (4) nearest to the exit door) were observed cluttered with un-clean or stained balances, storage bins with miscellaneous utensils and (b) (4) hoods (nearest to the exit door) contains brown stains within close proximity to the (b) (4) household filters (potential to shed particulate's). On 3/10/20, your firm's Pharmacist produced ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) lot (b) (4) (Rx (b) (6) ) within the hood (b) (4)

**OBSERVATION 6**

Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.

Specifically, your firm's facility design is inadequate for sterile production as it contains two exit doors leading to the parking lot, a sink adjacent to a (b) (4) hood, a kitchen dishwasher, storage of bulk drug substances and miscellaneous items stored within cardboard boxes. In addition, your firm failed to monitor pressure differentials within the unclassified production area.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Kayla V Sprague, Investigator - Dedicated Drug Cadre	Jessica L Pressley Investigator Signed By Jessica L Pressley -S Date Signed 03-16-2020 10:56:25 X	DATE ISSUED 3/16/2020

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 3/9/2020-3/16/2020*
	FEI NUMBER 3016458098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Wayne L. Wallace, Owner & Pharmacist

FIRM NAME The Medicine Shoppe Pharmacy	STREET ADDRESS 3524 B Tamiami Trl
---	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Port Charlotte, FL 33952-8100	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drugs
---	---

**OBSERVATION 7**

Sinks or drains were present in the cleanroom where the ISO 5 classified aseptic processing area was located.

Specifically, from 3/9-3/11/20, a sink was observed adjacent from a (b) (4) hood within your firm's unclassified general production area utilized for sterile and non-sterile drug production.

**OBSERVATION 8**

Personnel engaged in aseptic processing were observed with exposed wrists, exposed hair and exposed mouth.

Specifically, on 3/10/20, during the production of the ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) ), lot (b) (4) (Rx (b) (6) ) your firm's Pharmacist was observed with exposed wrists, hair and mouth as he was not donned in garb.

**OBSERVATION 9**

Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

Specifically, on 3/10/20, during the production of ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) ), lot (b) (4) (Rx (b) (6) ) your firm's Pharmacist was observed wearing non-sterile gloves.

**OBSERVATION 10**

Personnel manually contacted the inner surface of the container or closure.

Specifically, on 3/10/20, during the production of the ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) ) lot (b) (4) (Rx (b) (6) ) your firm's Pharmacist was observed touching the inner surface of the eye dropper cap with his non-sterile gloved hands.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Kayla V Sprague, Investigator - Dedicated Drug Cadre	Jessica L Pressley Investigator Signed By Jessica L Pressley-S Date Signed 03-16-2020 10:56:25 X	DATE ISSUED 3/16/2020

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 3/9/2020-3/16/2020*
	FEI NUMBER 3016458098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Wayne L. Wallace, Owner & Pharmacist

FIRM NAME The Medicine Shoppe Pharmacy	STREET ADDRESS 3524 B Tamiami Trl
---	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Port Charlotte, FL 33952-8100	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drugs
---	---

**OBSERVATION 11**

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your firm's Pharmacist stated he is using non-sterile (b) (4) and household paper towels to clean the unclassified (b) (4) hoods. On 3/10/20, your firm's Pharmacist produced ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use (firm used (b) (4) lot (b) (4) (Rx (b) (6) within the (b) (4) hood.

**OBSERVATION 12**

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically, your firm fails to use a sporicidal agent within your firm's unclassified (b) (4) hoods. According to your firm's Pharmacist, he only uses non-sterile (b) (4) to clean the (b) (4) hoods when needed.

**OBSERVATION 13**

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically, from 3/9-3/11/20, your firm's production area where ophthalmic Cyclosporin/Coconut Oil 2% eye drops for veterinary use are produced was observed to have unsealed, one cracked, and one visibly brown stained ceiling tile.

**OBSERVATION 14**

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Kayla V Sprague, Investigator - Dedicated Drug Cadre	Jessica L Pressley Investigator Signed By Jessica L Pressley -S Date Signed 03-16-2020 10:56:25 X	DATE ISSUED 3/16/2020

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 3/9/2020-3/16/2020*
	FEI NUMBER 3016458098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Wayne L. Wallace, Owner & Pharmacist

FIRM NAME The Medicine Shoppe Pharmacy	STREET ADDRESS 3524 B Tamiami Trl
---	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Port Charlotte, FL 33952-8100	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drugs
---	---

You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically, on 3/4/20 your firm produced the following non-sterile drug products: Estradiol 0.01% Vaginal Cream, Rx (b) (6) (no lot #), expiration: 12 months (hazardous drug product) and Hydromorphone 1mg/mL Suspension, Rx (b) (6) (no lot #), expiration: 12 months (non-hazardous drug product) within an unidentified (b) (4) hood without providing adequate containment, segregation, and/or cleaning of the work surfaces. In addition, your firm does not have specific procedures on how to contain and clean hazardous/potent drugs utilizing a deactivation agent or on how to handle spillage.

**\*DATES OF INSPECTION**

3/09/2020(Mon), 3/10/2020(Tue), 3/11/2020(Wed), 3/16/2020(Mon)

X Kayla V Sprague  
Investigator - Dedicated Drug Cadre  
Signed By: Kayla V. Sprague -S  
Date Signed: 03-16-2020 10:56:50

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Investigator Kayla V Sprague, Investigator - Dedicated Drug Cadre	Jessica L Pressley Investigator Signed By: Jessica L. Pressley -S Date Signed: 03-16-2020 10:56:25 X	DATE ISSUED 3/16/2020