

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331- 4900 Fax: (973) 331- 4969  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/28 - 29/2019, 11/01/2019, 11/04/2019, 11/13/2019, 11/14/2019
	FEI NUMBER 3005824513

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Mr. Jeff Ryzoff, RPh. Pharmacist in Charge**

FIRM NAME Pharmaview Inc (DOB: Far Hills Pharmacy)	STREET ADDRESS 405 Main St
CITY, STATE AND ZIP CODE Bedminster, NJ 07921-2605	TYPE OF ESTABLISHMENT INSPECTED Producer of 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 (I) (WE) OBSERVED:

**OBSERVATION 1**

Hazardous drugs were compounded without providing adequate containment or cleaning of multi-use equipment to prevent cross-contamination.

Specifically,

During the compounding operations observed on 10/29/2019 of Estradiol + Testosterone 0.01% + 0.01% in 30 g, we notice that once the Estradiol was collected and weighed it was placed on the working surface next to other raw materials without proper containment. Your firm compounds the following hazardous drugs: Progesterone Micro USP Capsules, Biestrogen + Testosterone in Phyto Base, Estradiol + Estriol + Progesterone in HRT, and Estradiol + Progesterone Capsules. In addition, there is a lack of cleaning with an adequate deactivating agent to ensure that residue of hazardous drugs is absent from multi-use equipment such as (b) (4) (b) (4) (b) (4) and plastic syringe.



**OBSERVATION 2**

Non-Pharmaceutical grade components are use in the formulation of non-sterile drug products.

Specifically,

a. Non-pharmaceutical grade component (b) (4) was observed on the shelf. This component was used in the formulation of the following non-sterile drug products:

- Biestrogen + Testosterone in Phyto Base 1.2 + 1.2 mg/gm, lot 193007D, produced on July 30, 2019.
- Biestrogen + Testosterone in Phyto Base 1.2 + 1.2 mg/gm, lot 190410A, produced on October 04, 2019.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Emmanuel J. Ramos Maldonado, CSO Rose Jean-Mary, CSO	DATE ISSUED 11/14/2019
			

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- Testosterone in Phyto Base 4mg/ml, lot 190306D, produced on June 03, 2019.

b. There is no assurance that the (b) (4) used as a component in the formulation of non-sterile drug products, complies as pharmaceutical grade (b) (4). Examples of products produced with this (b) (4) as a component are:

- Pyridoxine Suspension 50mg/ml, lot 193007F, produced on July 30, 2019
- Minoxidil 5% Scalp Solution 30ml, lot 192708G, produced on August 27, 2019.
- Aminophyllin in HRT 10% 100mg/g, lot 192709A, produced on September 27, 2019.

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