

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

6000 Metro Drive, Suite 101  
Baltimore, MD 21215  
(410) 779-5455 Fax: (410) 779-5707

DATE(S) OF INSPECTION

5/10/2017 - 5/16/2017

FEI NUMBER

3011402879

Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: John W. Platt, Owner

FIRM NAME

J.W. Platt, RPh LLC, dba The Wellness Pharmacy

STREET ADDRESS

2228 Papermill Rd., Suite E

CITY, STATE AND ZIP CODE

Winchester, VA 22601-3681

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

Utensils used for drug preparation are potentially absorptive or additive such that they may alter the purity, identity, or strength of a drug product.

Specifically,

A. On May 10, 2017 we observed the preparation of hormonal BI-EST cream (b) (4)

pursuant to Rx (b) (6), (b) (7)(C)

During preparation we observed a rubber spatula was used for mixing. The spatulas are cleaned after use with tap water and soap and placed in a drawer for reuse. We observed discolored spatulas in the drawer for use for mixing drug products. The spatulas are not dedicated for the production of hormonal or other products.

OBSERVATION 2

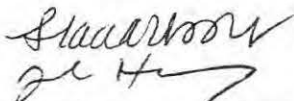
Equipment and utensils are not cleaned appropriately to prevent contamination of drug products.

Specifically, On May 10, 2017 we observed a technician clean the (b) (4) of an (b) (4) after producing BI-EST Cream (9:1) of (b) (4) pursuant to (b) (6), (b) (7)(C). The (b) (4) are direct

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EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Stacie A. Woods, Investigator  
Djamila Harouaka, Investigator

DATE ISSUED

05/16/2017

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product contact surfaces. The (b) (4) were cleaned using a discolored rag that had been sitting near the sink. The rag was (b) (4) and used to (b) (4) was in operation. A final rinse was performed with (b) (4) and the same discolored rag.

On May 16, 2017 we observed four rags resting on the sink and counter top next to the sink. There were two dirty glass beakers with glass stir bars in the sink. During the preparation of Hydroquine-Trentin-HC (b) (4) cream pursuant to Rx (b) (6), (b) (7)(C), I observed the technician clean the (b) (4) of the (b) (4) with one of the rags from the sink. The rag was (b) (4). The final rinse was performed with (b) (4)

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*Stacie Woods*  
*Djamila Harouaka*

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