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 pursuant to Rx 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 of an after producing BI-EST Cream of pursuant to . The are direct
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-HIC (b) (4) cream pursuant to Rx (b) (4), 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).