Observation 1:

Hazardous drugs were produced without providing adequate cleaning of utensils and work surfaces to prevent cross-contamination.

Specifically, I observed the (b)(4) used to (b)(4), was stored in alcohol between use rather than cleaned (detergent and sanitized). You do not have documentation to support the cleaning practices and maintenance of the (b)(4).

Also, your operations include the preparation of non-sterile drug products that contain hormones, such as testosterone and progesterone, using reusable equipment that was cleaned with a (b)(4) with (b)(4) detergent or (b)(4) with (b)(4) soap. Working surfaces are wiped down using (b)(4). You do not have documentation to show that these methods are effective in removing and neutralizing these drug residues. Examples of these preparations include:

A. Testosterone (b)(4), lot (b)(4), drug substance was used to prepare "Test/DHEA/Prog/Anastrozole" troche butterscotch 110/10/5/0.5mg, lot 04/21/2017:0308.
B. Estriol, estradiol, progesterone, testosterone (lots (b) (4), and (b) (4) respectively) drug substances were used to prepare "Bi-est/prog/test" troche butterscotch 2.5/50/1.5mg, lot 05/15/2017:0251.

This is a repeat observation from Form FDA-483, dated 08/13/14.

Jennifer Lalama, Investigator

05/23/2017