OBSERVATION #1

Your firm produced highly potent drugs without providing adequate cleaning of work surfaces and utensils to prevent cross-contamination.

Specifically,

A. Drug products including Testosterone and Estriol are produced under a hood. Your procedures document that is used to clean the work surface in the hood between preparations. Your firm has no evidence to show that the use of will effectively remove residues which might be present on the hood surface after production.

B. Your firm uses household dish liquid detergent and potable water for the cleaning of utensils such as rubber spatulas used in the processing of highly potent drug substances such as Estriol or Progesterone. All utensils are then washed in a dishwasher before subsequent use. I noted that several rubber spatulas used to transfer product were heavily stained.

Your firm has no evidence to show that your cleaning procedures can adequately remove residual drug products or detergent.

OBSERVATION #2

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. For example, your firm uses water in specific formulations requiring water. The water is also used to produce Water which contains. Your firm has no testing data to demonstrate that the Water meets, minimally, the specifications for Purified Water USP. Some examples of drug
products which used (b)(4) Water include the following:

A. Lidocaine 10% Prilocaine 10% Tetracaine 10% Phenylephrine 2%, lot #22983 was used with Rx #(b)(6) dated 9/21/18.

B. Lidocaine 10% Prilocaine 10% Tetracaine 10% Phenylephrine 2%, lot #22867 was used with Rx #(b)(6) dated 8/27/18.