DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You produced hazardous drugs without providing adequate containment, segregation and cleaning of work surfaces to prevent cross-contamination.

Specifically,

On 04/24/2018, I observed the production of prescription (estrogen and testosterone vaginal cream) and Methimazole 2.5mg/0.1mL, Lot 0424A, used in the filling of prescription . The scale was not cleaned in between the weighing of ingredients, including the active ingredients: methimazole, estrogen, and testosterone. In addition, the hood used to produce these drug products was not cleaned in its entirety in between the production of each drug product.

OBSERVATION 2

You produced beta-lactam drugs without providing adequate containment, segregation and cleaning of work surfaces to prevent cross-contamination.

Specifically,

Beta-lactam drug products are produced in the same hood as other drug products without appropriate segregation and cleaning of the hood and equipment. For example, on 04/17/18, your firm produced prescription for Amoxicillin 125mg/mL followed by prescription for Progesterone,
Estrogen, and Testosterone cream without cleaning the hood and equipment in between the production of each drug product.

**OBSERVATION 3**

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Your firm has not conducted any testing (microbial and analytical) of the water system. This water has been used as a component during the production of various drug products. For example, water was used in the formulation for Potassium Bromide 250mg/mL, prescription # and Glutaraldehyde 5% Aqueous Solution, prescription #.