DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically,

(b) (4) water produced by your (b) (4) system, (b) (4) has never been tested for microbial quality, nor are maintenance records maintained for (b) (4). This (b) (4) water is used in production of several drug products and bulk (b) (4), which is also used in the production of drug products. For example, the following prescriptions for drug products were produced with this (b) (4) water:

(b) (4) 10mg/mL suspension for Rx #(b) (6) on 01/15/2019
- Chlorpromazine 100mg/mL liquid for Rx #(b) (6) on 11/26/2018

OBSERVATION 2

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

Work surfaces and drug product production equipment, such as spatulas, mortars/pestles, beakers, an
mortar/pestle, balances, and capsule filling machines, are not rinsed with qualified water and/or with appropriate sanitizing agents after cleaning with a cleaner agent or soap/hot water, respectively. For example, only soap/hot water was observed to be used to clean and rinse production equipment/utensils after production of the following prescription drug products:

- Zonisamide 10mg/mL suspension for Rx #(6) on 02/13/2019
- Triamcinolone Acetonide 0.025% medicated Ceramic cream for Rx #(6) on 02/13/2019

Additionally, a cleaning agent spray was observed to be used in wiping the counter top and balance surfaces before and after production of each of these prescription (Rx) drug products.

*DATES OF INSPECTION
2/12/2019(Tue), 2/13/2019(Wed), 2/22/2019(Fri)