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, your firm used components that were not pharmaceutical grade to produce drug products that included, but were not limited to, the items listed below.

A.) Non-pharmaceutical grade water was purchased by your firm and it was used to produce multiple nasal spray drug products. Examples include, but are not limited to, the drug products listed below.

1. Approximately lots of C-Ketamine Nasal Spray were produced between February 2019 and May 2019.
2. Approximately lots of C-Oxytocin 24 units/mL Nasal Spray were produced between February 2019 and May 2019.
3. Approximately lot of C-Lidocaine HCl 4% Glycerin Nasal Spray was produced in April 2019.

Your firm has not submitted any samples of this water to your contract laboratory to test for microbial limits and/or other analytical properties to show it is equivalent to pharmaceutical grade water.

B.) Non-pharmaceutical grade ingredient, Oxytocin, was purchased and used by your firm to produce non-sterile sublingual tablet and non-sterile nasal spray drug products. Examples include, but are not limited to, the drug products listed below.

1. Approximately lots of C-Oxytocin Sublingual Tablets were produced between February 2019 and
May 2019.
2. Approximately(b) (4) lots of C-Oxytocin 24 units/mL Nasal Spray were produced between February 2019 and May 2019.

The Certificate of Analysis and container label for the Oxytocin states that this ingredient is “Not for Human or Vet use without sterile processing.”

**OBSERVATION 2**
You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, your firm does not have cleaning procedures in place to ensure the prevention of cross-contamination of hazardous drugs. Examples include, but are not limited to, the cleaning of work surfaces, compounding equipment, and utensils, which are located and/or used to produce hazardous drug products in the non-sterile compounding room. Examples of hazardous drug products made at your firm include, but are not limited to, C-Oxytocin Sublingual Tablets and C-Oxytocin Nasal Spray.

**DATES OF INSPECTION**
5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed), 5/17/2019(Fri)