OBSERVATION 1

Hazardous drugs were compounded without providing adequate containment or cleaning of multi-use equipment to prevent cross-contamination.

Specifically,
During the compounding operations observed on 10/29/2019 of Estradiol + Testosterone 0.01% + 0.01% in 30 g, we notice that once the Estradiol was collected and weighed it was placed on the working surface next to other raw materials without proper containment. Your firm compounds the following hazardous drugs: Progesterone Micro USP Capsules, Biestrogen + Testosterone in Phyto Base, Estradiol + Estriol + Progesterone in HRT, and Estradiol + Progesterone Capsules. In addition, there is a lack of cleaning with an adequate deactivating agent to ensure that residue of hazardous drugs is absent from multi-use equipment such as (b) (4) (b) (4) (b) (4) (b) (4)

and plastic syringe.

OBSERVATION 2

Non-Pharmaceutical grade components are use in the formulation of non-sterile drug products.

Specifically,

a. Non-pharmaceutical grade component (b) (4) was observed on the shelf. This component was used in the formulation of the following non-sterile drug products:

  - Biestrogen + Testosterone in Phyto Base 1.2 + 1.2 mg/gm, lot 193007D, produced on July 30, 2019.
  - Biestrogen + Testosterone in Phyto Base 1.2 + 1.2 mg/gm, lot 190410A, produced on October 04, 2019.
b. There is no assurance that the (b) (4) used as a component in the formulation of non-sterile drug products, complies as pharmaceutical grade (b) (4). Examples of products produced with this (b) (4) as a component are:

- Pyridoxine Suspension 50mg/ml, lot 193007F, produced on July 30, 2019
- Minoxidil 5% Scalp Solution 30ml, lot 192708G, produced on August 27, 2019.
- Aminophyllin in HRT 10% 100mg/g, lot 192709A, produced on September 27, 2019.