OBSERVATION 1

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

Specifically, on 05/30/2019, we observed boxes of drug products within expiry, stored on the floor of the pharmacy compounding room under filthy and uncontrolled temperature/humidity conditions. This facility is considered an "inactive compounding pharmacy", which is not maintained clean with the presence of dead insects and dirty floors within the drug storage room and at the moment of the inspection there were no temperature controls to assure that the drug products were maintained in adequate storage conditions. Some of the drug product found under these conditions include but not limited to:

- Oxaliplatin Injection 50mg/10mL, Lot#(b) (4) Exp: 07-2020
- (b) (4) (bortezomib) for Injection 3.5mg/vial, Lot#(b) (4) , Exp:05-2020
- Placitaxel Injection, USP 30mg/5mL, Lot#(b) (4) , Exp:07-2020
- (b) (4) for Injectable Suspension, 100mg/vial, Lot#(b) (4) , Exp:04-2021

Note: Due to your firm's lack of document control for the receipt, inventory, storage and use of these drug products there is no assurance on how long these drug products were exposed to the conditions aforementioned.

*Dates of Inspection: 05/30/2019(Thu), 05/31/2019(Fri), 06/05/2019(Wed) & 06/25/2019(Tue)