Observation 1:

Highly potent drugs such as buprenorphine HCl and hazardous drugs such as human chorionic gonadotropin (HCG) were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

A. Sources of potential cross contamination include the design and location of the equipment washing area where vials, beakers, and utensils are cleaned which is a single basin hand wash sink located in the ISO7 ante-room adjacent to the ISO 7 buffer room door. The buffer room door opens facing the recirculating air flow.
B. The use of non-sterile hair nets and face covers to prepare sterile drug products in the
(b) (4)

C. Sporicidal agents are not used in your facility’s cleanrooms and/or ISO 5 area within the
(b) (4)

D. The facility is also designed and/or operated in a way that permits poor flow of personnel or materials in that
the (b) (4), and non-sterile processing components are all stored in the ISO 7 ante-room. The presence of this equipment and operations of use may increase the presence of dust particles, increase the room humidity as well as elevate the room temperature. Higher particle counts surrounded by moist warm air may increase the rooms bacterial and fungal bio-burden.

These sterile and non-sterile human and animal drug preparations include the following:

- buprenorphine HCL 0.3mg/ml for injection 30 ml multi-dose vial (veterinary drug) lot BU030526
- tadalafil/arginine 20/300 mg capsules lot TAC201530
- metronidazole 5% ointment lot ABMO
- Z4 dental gel (lidocaine HCl 10%, prilocaine HCl 10%, tetracaine HCL 4%, phenylephrine 2%) lot Z4D003524
- Sermorelin+GHRP2+GHRP6 100/100/200 mcg troches lot SEM620684
- Nifedipine 0.3% lidocaine 1.5% ointment lot ABNFO
- No pain gel lidocaine HCl 0.1g, tetracaine HCL 0.04g, phenylephrine HCl 0.2g, prilocaine 0.1g lot Z4D003525
- HCG (human chorionic gonadotropin) troches 250 IU Lot HCGTR5058