OBSERVATION 1
You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, during environmental sampling of classified cleanroom suites on 05/30/2019, the following were recovered from ISO 5 laminar flow hoods:

-1 cfu/m³ during fungal air testing, identified as Geotrichum sp. at "(b) (4)”, referring to the hood on the (b) (4)
-1 cfu on a fungal contact plate, identified as a non-sporulating fungus at “(b) (4)”, referring to the hood on the (b) (4)

Several of your employees verbally confirmed that a retrospective investigation into potentially affected lots made in these hoods was not performed.

OBSERVATION 2
(b) (4) testing to the (b) (4) was not performed.

Specifically, the gauge used to measure pressure on the (b) (4) tester was last calibrated on 10/26/2017. We observed this gauge being used during a (b) (4) test of a (b) (4) used during production of lot number 07082019%383@3, product ESC01: epinephrine HCl (PF/SF)/lidocaine HCl (PF) in BSS 0.025%/0.75%.
OBSERVATION 3
Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

a. Sterile lint-free wipes are stored outside the ISO 5 laminar flow hood, on top of the hood. These wipes are exposed to the ISO 7 environment. During production on 07/08/2019, these wipes were placed inside the ISO 5 laminar flow hood without being sprayed with sterile syringes and sterile syringes were placed on top of these wipes.

b. During production of several batches on 07/09/2019, the Pharmacy Technician transferring materials to the cart in the material entry room sprayed various materials with sterile syringes but did not cover all surfaces with sterile wipes. Materials include vials of sterile individually-wrapped needles, and individually-wrapped sterile wipes. The cart containing these materials were carted into Suite ISO 7 and the materials were transferred into the ISO 5 laminar flow hood and used in production.

OBSERVATION 4
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, uni-directional airflow was not verified under operational conditions. Your firm’s Pharmacist-in-Charge reported that when recertification of the cleanrooms was performed on or around dynamic conditions were simulated by the recertification company employees by moving their hands inside the hood and walking around the room.