DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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 the certification by your third-party contractor on 10/30/2017, there were 73 CFUs found in the viable air sample inside your ISO 5 compounding hood and no identification of the CFUs were done and no evaluation of drug impact were conducted at the time.

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically,
a) On 8/7/2018, during the sterile production of an amphotericin B 0.15% ophthalmic solution, lot #R1419080718, we observed rust on the wheels of the cart located inside the clean room (ISO 7) adjacent to the ISO 5 hood.

b) On 8/10/2018, during the cleaning of the ISO 5 hood, we observed duct tape attached to a power cord on the front right side of the ISO 5 hood.

**OBSERVATION 3**
Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

On 8/10/18, during your cleaning of your ISO 5 hoods, we observed the operator use a non-sterile chemical disinfectant inside the ISO 5 classified hoods with sterile wipes.

**OBSERVATION 4**
Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

The sporicidal agent used in your ISO 5 area requires a contact time of 60 minutes in order to eliminate spores. Your current procedure, SOP 7.012 Sporicide Hood Cleaning - Cleaning, states that the sporicide is applied with a total wet contact time of 60 minutes.
OBSERVATION 5

No endotoxin testings are done for multi-dose products which are not produced with a preservative to ensure product sterility.

Specifically,

On 8/7/2018, we observed the production of amphotericin B 0.15% ophthalmic solution, lot #R1419080718, was produced without an addition of a preservative and labeled with a beyond use date of seven days refrigerated with no testing of endotoxin conducted.

*DATES OF INSPECTION
8/06/2018(Mon), 8/07/2018(Tue), 8/08/2018(Wed), 8/09/2018(Thu), 8/10/2018(Fri), 8/15/2018(Wed)