Observation 1:

Non-microbial contamination was observed in your production area. Specifically, on 12/12/2017, rust-like stains were observed on the clean room (non-hazardous buffer room - ISO 7) floor adjacent to the Laminar Air Flow Hood (ISO 5 area). Additionally, rust-like stains were observed on the seat of a metal stool located in the clean room (non-hazardous buffer room). This stool was used during aseptic processing on 12/12/17.

Observation 2:

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. Specifically, your firm’s large batch media fill consists of 25 test vials however your firm routinely produces a sterile ophthalmic product (Cataractive 3) with a batch volume of 10 liters which is packaged in 2,000 individual units.

Observation 3:

The ISO 5 classified aseptic processing areas contained dust-collecting overhangs without adequate and frequent cleaning.
Specifically, on 12/12/2017, I observed the cleaning of the Laminar Air Flow Hood (ISO 5 area) by your Lab Coordinator prior to aseptic processing. During the cleaning of the hood canopy the plastic cover became dislodged exposing the inner housing of canopy/light fixture. The inner housing of canopy/light fixture and overhang is not included in your firm's cleaning procedures.