Observations 1-5 are applicable to ophthalmic drug products for animals produced by your pharmacy. These products are required to be sterile.

They include the following:
Cyclosporine Suspension 1% Ophthalmic Drops
Tacrolimus Suspension 0.02% Ophthalmic Drops
Tacrolimus Suspension 0.03% Ophthalmic Drops

**OBSERVATION 1**
Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,
All manipulations performed in the production of animal drug products required to be sterile are conducted in a non-classified, uncontrolled environment on the main pharmacy counter top.

**OBSERVATION 2**
Protective apparel is not worn as necessary to protect drug products from contamination.
Specifically, employees performing manipulations in the production of animal drug products required to be sterile do not wear sterile garb (gowns, hairnets, or sterile gloves) during production.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products required to be sterile are not established.

Specifically, you have not established any written procedures regarding the production of animal drug products required to be sterile.

OBSERVATION 4
The final containers/closures used for drug product required to be sterile were not sterile or pyrogen free.

Specifically, the final container/closure for animal drugs required to be sterile are not purchased sterile or pyrogen free and are not sterilized or depyrogenated prior to use.

OBSERVATION 5
There is no written testing program designed to assess the stability characteristics of drug products.
Specifically,
The 180 day beyond use dates (BUD) that you apply to drug products required to be sterile is not supported by a written stability study or sterility data.

OBSERVATION 6
You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,
You firm does not use a pharmaceutical grade water to compound human drug products; including but not limited to oral suspensions and solutions such as:
Nystatin 100,000 U/mL Suspension
Lansoprazole Suspension 7.5 mg/mL
Omeprazole Suspension 15 mg/mL
Zinc Sulfate Solution 10 mg/mL