This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, the firm has not performed any sterility testing of sterile processed ophthalmic drugs. For example:

- **Vancomycin 25 mg/mL, Rx 833772, processed on 5/5/2014**
- **Cyclosporin 1% Suspension, Rx 834991 processed on 6/19/2014**

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, environmental monitoring of the (b) (4) does not occur each time a sterile ophthalmic drug is formulated therein. For example:

- **Vancomycin 25 mg/mL, Rx 835433 processed on 7/10/2014**
- **EDTA 1%, Rx 834105 processed on 7/18/2014**
- **Amikacin 40, Rx 833412 processed on 5/28/2014**

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the prior to release.

Specifically, the firm fails to assure that each batch of processed sterile ophthalmic drug meets appropriate potency limits prior to distribution. For example:

- **Scopolamine 0.25% O.D., Rx 833107, processed on 7/1/2014**
- **Tobramycin 14mg/mL O.D., Rx 835876, processed on 7/23/2014**
- **Timolol 0.25% O.D., Rx 833295, processed on 7/31/2014**
OBSESSION 4

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

Specifically, the [b](4) area is in an unclassified area. Examples of drugs processed in the [b](4) area are:

- Tobramycin 14 mg/mL, Rx #835177, produced on 6/26/2014
- EDTA 1%, Rx #834105, produced on 7/18/2014
- Vancomycin 25 mg/mL, Rx #835872, produced on 7/30/2014

OBSESSION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the [b](4) area used for sterilization of drug products has not been qualified for each drug product as to absorption and adsorption characteristics.

- PHMB 0.02% O.D., Rx #833338, produced on 5/7/2014
- EDTA L.0% O.D., Rx #834105, produced on 5/16/2014
- Glutathione 100 mg/mL, Rx #834775, produced on 6/12/2014

OBSESSION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is no stability data for any sterile ophthalmic drugs processed by this firm including Amikacin 40 (9 day BUD), Scopolamine 0.25% O.D. (3 day BUD) and Cyclosporin 2% (9 day BUD).

* DATES OF INSPECTION: 08/06/2014 (Wed), 08/08/2014 (Fri), 08/21/2014 (Thu)