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 WE OBSERVED:

OBSERVATION 1

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

a) You do not monitor the air quality for non-viable particles within the critical fill zone (ISO 5 environment) during Blow Fill Seal production operations for the sterile ophthalmic drug production of 1% Cyclopentolate HCl, 1% Tropicamide, and 2.5% Phenylephrine HCl.

b) You have not certified at the point of use the (b) (4) during Blow Fill Seal production operations for the sterile ophthalmic drug production of 1% Cyclopentolate HCl, 1% Tropicamide, and 2.5% Phenylephrine HCl.

c) The surfaces within the critical fill zone (ISO 5 environment) are not sampled as part of your environmental monitoring program.

d) You do not perform any monitoring of personnel engaged in Blow Fill Seal manufacturing operations of sterile ophthalmic drug products.

OBSERVATION 2

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

Specifically,
a) Validation of the product as conducted in the for the dated: 2/16/17, is inadequate because:

1) The firm did not evaluate which product is the worst-case representative product for the validation. No analysis or rationale as to why or how the firm determined to use as the worst-case representative product versus is provided in the report.

2) Evaluation of using did not include the firm's standard practice of . Rather, the without evaluating its effect when exposed to the compounded product.

b) Media fills did not represent the most challenging conditions, specifically, the duration of the manufacturing run.

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

a. Cleaning validation is inadequate and fails to demonstrate that the cleaning material can effectively be recovered from surfaces of the firm's equipment. Inconsistent recovery results, not meeting the acceptance criteria, were observed among different analysts conducting in the Final Summary Report of Results: Protocol for of.
OBSERVATION 4
Results of stability testing are not used in determining expiration dates.

Specifically, the raw data was not available for Research & Development completed to the (b)(4) of (b)(4) for the ophthalmic drug products: 1% Cyclopentolate HCl, 1% Tropicamide, and 2.5% Phenylephrine HCl.

OBSERVATION 5
The labels of your outsourcing facility’s drug products are deficient.

Specifically, the following information is not found on some of your drug product labels:

a) The statements “This is a compounded drug” and “Office use only”;

b) The address and phone number of your facility;

c) The date that the drug was compounded;

d) Storage and handling instructions;

e) The national drug code number, if available.
Examples of drug products that do not contain this information:
- Cyclopentolate HCl 1% 0.5 ml-Printed Label for Vial
- Phenylephrine HCL 2.5% 0.5 ml-Printed Label for Vial
- Tropicamide 1% 0.5 ml-Printed Label for Vial

*DATES OF INSPECTION*
2/27/2017(Mon), 2/28/2017(Tue), 3/01/2017(Wed), 3/02/2017(Thu), 3/03/2017(Fri), 3/06/2017(Mon), 3/07/2017(Tue), 3/08/2017(Wed), 3/17/2017(Fri)