DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

(b) (4) intended to render final product sterile was not adequate to accomplish sterilization.

Specifically,

a. Your firm failed to conduct [](b)(4) testing on [](b)(4) used to sterilize Atropine Sulfate 0.01% Sterile Ophthalmic Solution, lot 021219OS1010, manufactured on 02/12/19, with a beyond-use date (BUD) of 180 days.

b. Your firm released products purported to be sterile despite the failure of the [](b)(4) intended to render final product sterile was not adequate to accomplish sterilization. For example:

- Prednisolone/Ketorolac 1%/0.5% Ophthalmic Solution, lot 021319OS1001, manufactured on 02/13/19, with a BUD of 180 days, was released with a (b) (4) testing result of (b) (4), which is below the manufacturer’s specification of (b) (4).
- Timolol/Brimonidine/Dozolamide 0.5%/0.2%/2% Ophthalmic Solution, lot 02072019OS1006, manufactured on 02/07/19, with a BUD of 180 days, was released with a (b) (4) testing result of (b) (4), which is below the manufacturer’s specification of (b) (4).

*DATES OF INSPECTION*

8/28/2018(Tue), 8/29/2018(Wed), 8/30/2018(Thu), 8/31/2018(Fri), 9/04/2018(Tue), 9/05/2018(Wed), 9/06/2018(Thu), 9/07/2018(Fri), 4/17/2019(Wed), 4/18/2019(Thu), 4/25/2019(Thu)
### DEPARTMENT OF HEALTH AND HUMAN SERVICES
### FOOD AND DRUG ADMINISTRATION

**DISTRICT ADDRESS AND PHONE NUMBER**
22215 26th Ave SE Suite 210  
Bothell, WA 98021  
(425)302-0340 Fax:(425)302-0404

**DATE(S) OF INSPECTION**
8/28/2018-4/25/2019*

**FEIN NUMBER**
3014549846

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED**
Amy A. Frost, Pharmacist-in-Charge

**FIRM NAME**
Pinnacle Compounding

**STREET ADDRESS**
1120 Kensington Ave Unit E

**CITY, STATE, ZIP CODE, COUNTRY**
Missoula, MT 59801-5619

**TYPE ESTABLISHMENT INSPECTED**
Compounding Pharmacy

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**SEE REVERSE OF THIS PAGE**

**EMPLOYEE(S) SIGNATURE**
Christopher R Czajka, Investigator  
Andrew K Haack, Generic Drug User Fee Amendments (GDUFA)

**DATE ISSUED**
4/25/2019