DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, your firm uses (b) (4) water in certain drug products whose formulation requires water. Your firm is also using the (b) (4) water to (b) (4) Water (b) (4) and (b) (4) Water (b) (4) for use in certain drug products. Your firm does not perform testing (analytical or microbiological) to show the water at least at minimum meets the specifications for Purified Water, USP.

Examples of products made using the (b) (4) water include:

- Lot #BDI-HIG:73 of Tetracaine HCl Nasal 2.5% Solution prepared on 11/12/18
- Lot #BDIJHH:11 of Chloral Hydrate 100 mg/mL Syrup prepared on 11/15/18
- Lot #BDJDEH:64 of (b) (4) Water prepared on 11/27/18

Examples of lots made using the (b) (4) Water made from the (b) (4) water include:

- Lot #BDFIEEE:17 of Ketamine Spray 20% Nasal prepared on 8/24/18 using (b) (4) Water (b) (4) Water
- Lot #BDEEDJ:67 of Diclofenac/Hyaluronic Acid 3%/1.74% Gel prepared on 7/19/18 using (b) (4) Water (b) (4)
OBSERVATION 2
There is no written testing program designed to assess the stability characteristics of drug products.
Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on all your drug products. For example,

a. Your firm has no documentation to justify the BUD placed on lot #BDJDEH:64 prepared on 11/27/18 and lot #BDIIDF:41 prepared on 11/12/18 of (b)(4) L-4. The BUD assigned was 180 days after preparation.

b. Lot #BDJHH:11 of Chloral Hydrate 100 mg/mL Syrup prepared on 11/15/18 contains (b)(4) water. The BUD assigned is 90 days after preparation at room temperature.

OBSERVATION 3
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.
Specifically, your firm does not conduct routine testing for potency for all drug products produced by your firm.

*DATES OF INSPECTION
12/11/2018(Tue), 12/12/2018(Wed), 12/13/2018(Thu), 12/19/2018(Wed)