DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
You failed to prevent contamination while working in the aseptic production area (ISO 5 hood).

Specifically,

A) On 08/02/2017, I observed an aseptic operator produce sterile Magnesium Chloride Hexahydrate (PF), 5ml vial 200 mg/ml injectable. During production, I notice the operator spray his gloves with sterile (b) (4) over open vials. The open vials contained finished sterile drug product.

B) Your media fills are not representative of your aseptic production operations. The media fills conducted aseptically (b) (4) Specifically, your firm produces sterile drug products using bulk drug substances with volume sizes of up to (b) (4) ml. For example:
   - On 06/29/2017, you produced (b) (4) ml of Ascorbic Acid (PF, Corn Free) 500 mg/ml injectable. The product was filled in 50ml vials with lot number 06292017@6. You produced a total of (b) (4)

OBSERVATION 2
you failed to adequately clean or disinfect the ISO 5 hood and equipment used in production.

Specifically,
A) Smoke studies utilizing (b) (4) base smoke were conducted in the ISO 5 hood on 12/20/2016 and 06/26/2017. Upon completion of smoke studies, there is no documentation indicating the production area was cleaned to remove smoke residue. The following sterile drug products were produced after the completion of the smoke study re-certification in the ISO 5 hood:
- On 12/20/2016 – Acetylcysteine ophthalmic 10% solution lot 12202016@41 and Acetylcysteine ophthalmic 20% solution lot 12/20/2016@42.
- On 06/26/2017 – Trimix 30/1/0.02 mg/ml injectable lot 06262017@25.

B) On 7/30/2017, during the sterile facility tour, I noticed a bottle of (b) (4) [redacted], a commercialized liquid detergent used for dishwashing. The liquid dishwashing soap was witnessed on the sink in the Ante Room (ISO 8 room). Your firm’s management informed me the soap was used to wash glassware to be used in the sterile hood.