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

OBSERVATION 1
Beta-lactam drugs were produced without providing adequate containment, cleaning of work surfaces, utensils/equipment and personnel to prevent cross-contamination.

Specifically, between 04/10/2017-04/09/2019, your pharmacy produced \((b)(4)\) beta-lactam drug products in your non-hazardous area on work surfaces also used for the production of non-beta lactam products.

a) Your pharmacy cleans work surfaces \((b)(4)\) in your non-hazardous area with \((b)(4)\).

b) Your pharmacy does not have dedicated equipment for beta-lactam and non-beta lactam products. Production equipment is shared between both beta-lactam and non-beta lactam products.

c) Equipment used to produce beta-lactam products is cleaned with \((b)(4)\) and rinsed with distilled water. Following cleaning, this equipment is used for any non-hazardous product, including a non-beta lactam product.

OBSERVATION 2
Hazardous drugs were produced without providing adequate cleaning of utensils/equipment to prevent cross-contamination.

Your pharmacy produces approximately \((b)(d)\) different drug products in your hazardous room and approximately \((b)(d)\) patient-specific prescriptions per day. Specifically, between 04/12/2018 to 04/12/2019, your pharmacy produced \((b)(d)\) testosterone prescriptions from the Active Pharmaceutical Ingredient (API) testosterone and \((b)(d)\) progesterone prescriptions from the API progesterone.
a) Your pharmacy does not have dedicated equipment for hazardous drugs. Production equipment is shared between the products produced in your hazardous room. Dirty equipment (used to produce hazardous drug products) is cleaned with (b) (4) and distilled water.