OBSERVATION I

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Specifically, your firm's acceptable range for potency is (b) (4) However, drug products that were sub-potent or super-potent were prepared and dispensed. For example:

1. Rx (b) (6) , Progesterone 100mg suppositories, dated 03/30/2017 was sub-potent. This drug product is for human use. Testing performed on 04/18/2017 resulted in 76.4% potency. The product was re-tested on 05/02/2017 and with a potency result of 84.6%. An additional re-test on 06/12/2017 resulted in 79.9% potency.

2. Rx (b) (6) , Budesonide 1mg capsules, dated 03/15/2017 was sub-potent. This drug product is for veterinary use. Testing performed on 03/27/2017 resulted in a potency of 84.2%.

3. Rx (b) (6) , Fluoxetine 30mg capsules, dated 08/31/2017 was super-potent. This drug product is for veterinary use. Testing performed on 09/16/2017 resulted in a potency of 113%.

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OBSERVATION 2

You produced highly potent or hazardous drugs without providing adequate cleaning of work surfaces and utensils to prevent cross-contamination. Specifically,

On 12/12/2017, a pharmacy technician produced cortisone 5mg capsules pursuant to Rx (b) (6). After production of this prescription, the technician cleaned the work surface and apparatus with (b) (4). I (SD) observed the bottom of the technician's lab coat sleeve come into contact with white powder that was on the work surface. After cleaning, the technician proceeded to produce theophylline 130mg capsules pursuant to Rx (b) (6), while wearing the same lab coat.

Your firm produces capsules containing:

(1) hormones such as progesterone, estradiol, thyroid hormones (T3 and T4) and testosterone
(2) steroids such as cortisone and prednisolone
(3) hazardous drugs such as chlorambucil, azathioprine, cyclophosphamide, and hydroxyurea

The apparatus used to prepare capsules for hazardous drugs and highly potent drugs is non-dedicated. The apparatus is cleaned with soap and water following the preparation of hazardous drugs or capsules with colors. The apparatus is routinely cleaned with (b) (4) and periodically cleaned with dish soap and water.
OBSERVATION 3

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Specifically,

(A) Simple syrup lot (b) (4), prepared on 11/20/2017, was made using (b) (4) Amlodipine Besylate liquid stock lot (b) (4), prepared on 12/05/2017, was made using simple syrup lot (b) (4).

(B) (b) (4) solution lot (b) (4), prepared on 10/10/2017, was made using simple syrup. The lot number of the simple syrup used was not recorded. Lot (b) (4) of (b) (4), incorrectly recorded as (b) (4), was used to make Gabapentin lot (b) (4) on 12/05/2017. Gabapentin liquid stock lot (b) (4) was used to make Gabapentin 100mg/ml suspension #30 pursuant to Rx (b) (6) on 12/11/2017.

(C) Master Suspension lot (b) (4), prepared on 11/16/2017, was made using (b) (4) water. Master Suspension lot (b) (4) was used to make Tylosin Tarterate stock solution lot (b) (4) on 11/24/2017. This stock solution was used to prepare Tylosin 100mg/ml solution #100 pursuant to Rx (b) (6) on 12/11/2017.