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, expired bulk active pharmaceutical ingredients (APIs) were used in the production of drug products. Examples include but are not limited to the following:

- Estriol Vaginal Cream 0.5mg/ml (Rx (b) (6) ) made/dispensed on 03/21/18; Bulk API lot # (b) (4) - EXP 03/05/2018
- Estriol Vaginal Cream 0.5mg/ml (Rx (b) (6) ) made/dispensed on 09/06/18; Bulk API lot # (b) (4) - EXP 03/05/2018
- Domperidone 10mg Capsules (Rx (b) (6) ) made/dispensed on 09/23/18; Bulk API lot # (b) (4) - EXP 11/30/2016
- Omeprazole 2mg/ml suspension (Rx (b) (6) ) made/dispensed on 08/06/18; Bulk API lot # (b) (4) - EXP 02/2018
- Omeprazole 2mg/ml suspension (Rx (b) (6) ) made/dispensed on 09/07/18; Bulk API lot # (b) (4) - EXP 02/2018
Observation 2:

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, hormone and non-hormone containing drug products are compounded under a (b) (4) hood without any gowning or controls in place to prevent cross-contamination by personnel between batches.