Observation # 1
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,
A. Progesterone SR 50mg Lot # 082416 was tested on 09/19/2016 by a third-party contract laboratory and the potency was found to be 84.6%. The product was released for dispensing on 08/24/2016.

B. The drug product, DILT/LIDO 2/5% ONT Lot # Di2Li5101819, was assigned a BUD of 11/18/2019. Your firm dispensed the product on 11/22/2019 (RX # ((6) )3) , 11/22/2019 (RX # ((6) )3) , and 12/03/2019 (RX # ((6) )3) which are beyond the BUD assigned to the product.

Observation # 2
Hazardous drugs were produced without providing adequate cleaning of utensils to prevent cross-contamination. Specifically,

Your firm is using a spatula with wooden handle to produce hazardous drug products within the hazardous negative pressure room. The wooden handle has a hard to clean surface which can potentially harbor microbial growth.

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