Observation 1:

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

Specifically, these drug products are prepared and handled without providing adequate cleaning and sanitization of work surfaces and reusable equipment such as spatulas, stainless steel spoons, ungulator jars, mixing mill equipment, and the ungulator to prevent cross-contamination. Your operations include the preparation of non-sterile drug products that contain anti-neoplastic agents such as fluorouracil and hormones such as testosterone using reusable equipment that is cleaned using either municipal water, dish detergent, reverse osmosis water rinse, and of the mixing mill equipment used to prepare topical drug products. You do not show that these methods are effective in removing these drug residues. Examples of these preparations are as follows:

A. Fluorouracil 5 % cream lot used to prepare 5-fluorouracil 2.5%/calcipotriene 0.0025% cream lot

B. Testosterone USP lot used to prepare testosterone 50 mg/chrysin 25 mg/progesterone 10 mg KE cream lot