OBSERVATION 1

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

a) Your firm uses water from a (b) (4) system for use in certain drug products whose formulation requires water. Your firm is also using the water from the (b) (4) system to make (b) (4) Water (b) (4) for use in certain drug products. Your firm has no documentation of testing performed (microbiological or analytical) to show the water at least at minimum meets the specifications for Purified Water, USP. Examples of lots made using the (b) (4) water include lot #11-27-2017@32 of Clonidine (Dye Free/Flavor Free) 0.05mg/1mL Suspension and lot #11-13-2017@3 of Omeprazole (Grape/Marshmallow) Standard + 2mg/mL Suspension. Examples of products made using the (b) (4) Water made from the (b) (4) water include lot #11-12-2017@12 of Dexamethasone/Mupirocin/Amphotericin B (b) (4) 0.1%/100mg/10mg/60mL Nasal Spray and lot #06-15-2017@21 of Tranexamic Acid 5% Solution.

b) Your firm uses Acetone CP grade for making drug products. The Acetone is labeled for “technical use only”. In the past 6 months your firm has made (b) (4) lots of drug products using Acetone CP including (b) (4)

(b) (4) of Squaric Acid Dibutyl Ester/Acetone 0.5% Solution and (b) (4)
(b) (4) of Diphenylcyclopropenone 5% Solution.

OBSERVATION 2

Hazardous or 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, I observed on 11/30/17 that the rubber spatulas used in the production of non-sterile drug products were discolored, cracked and damaged (unsmooth surface). There were several lots of different products made on the date including lot #11-30-2017@5 of Estradiol (E2)/Prog (P4) 0.5mg/100mg/GM Cream.