DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

**OBSERVATION 1**

Disinfecting agents and used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

Per SOP 02-04.02 "Cleaning and Disinfecting of the Sterile Compounding Area" cleaning agents used in the ISO classified work areas are described as an "(b) (4)" however, during review of the cleaning agent "(b) (4)" it was confirmed the agent is not sterile.

*DATES OF INSPECTION*

10/02/2019(Wed), 10/03/2019(Thu), 10/04/2019(Fri), 10/08/2019(Tue)