DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

A. The firm’s SOP No. APS-SOP-0344 “503B Bulk Formulation—(b) (4) and Sealing Process” states to wipe down all work surfaces and equipment with a clean room wiped that has thoroughly wetted with (b) (4). However, on 08/20/2019 during the manufacturing of Norepinephrine 1mg/ml Lot# S1900185, an operator was observed not wiping down all work surfaces and equipment with a clean room wipe that has been thoroughly wetted with (b) (4).

B. The firm’s SOP No. APS-SOP-0308 “503B Syringe Compounding Aseptic Process” states to wipe the top seems around the raw syringe container with a (b) (4) cloth. Wipe top of the container (b) (4) Wipe bottom of the container (b) (4) making sure to get into crevices. Wipe all four sides of container (b) (4) Rotation of the container may be done for better angles to wipe. However, on 08/23/2019 during the manufacturing of Neostigmine Methylsulfate 5mg/5ml syringe. Lot# F1900899. an operator was observed wiping the bottom of the container (b) (4) with the (b) (4) cloth during drug production in the ISO 5 classified area.
## DATES OF INSPECTION
8/19/2019 (Mon), 8/20/2019 (Tue), 8/21/2019 (Wed), 8/22/2019 (Thu), 8/23/2019 (Fri), 8/26/2019 (Mon), 8/28/2019 (Wed)