OBSERVATION #1

On 10/17/17, an operator engaged in aseptic processing was observed with his upper torso inside the ISO 5 area with partially exposed skin while wearing a non-sterile mask, goggles, and hairnet.

OBSERVATION #2

On 10/17/17, an operator was observed sanitizing his gloved hands with non-sterile and then resuming aseptic processing in the ISO 5 area.

OBSERVATION #3

The wipes used for disinfecting the interior of the ISO 5 hood are not sterile.

OBSERVATION #4

The ISO 5 classified areas were not certified under dynamic conditions. Specifically, unidirectional air flow was not verified under operational conditions.

OBSERVATION #5

There is no evidence that testing is being performed for sterile products. For example, A. Tacrolimus Aqueous Ophthalmic 10ml 0.03% Suspension, lot #08312017@45 (Production date: 8/31/17 Beyond Use date: 12/29/17) was sterilized using a test. There was no evidence that the test was performed.

Stephen D. Brown, Investigator

10/27/2017
OBSERVATION #6

The use of the sporidical disinfectant, (b) (4) , in the ISO 5 areas is inadequate in that the contact time of (b) (4) minutes has not been substantiated.