During an inspection of your firm we observed:

Observation 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- The firm provided a report from the contract vendor on the smoke study qualification of the sterile production suites; however no video was taken of the smoke study and no description of the conditions during the smoke study was provided, so no confirmation of the smoke study could be reviewed. Additionally, no dynamic conditions to mimic sterile compounding were performed during the initial sterile compounding suite qualification.

- Environmental monitoring is only performed \((b) (4)\) \(\). SOP No. 9 “Environmental Monitoring/Testing” Revised/Reviewed: June 8th, 2016 states the following: Section 2 “Air sampling shall be done \((b) (4)\)”, Section 3 “Surface Testing shall be done every \((b) (4)\)”, and Section 6 “Verify the compounding areas meet USP <797> ISO 8, ISO 7, and ISO 5 air quality requirements”. “Testing is to be completed every \((b) (4)\)”.

Additionally, no particulate (non-viable) or microbial (viable) monitoring is performed during sterile production.

- Personnel monitoring is only performed \((b) (4)\) \(\). No personnel microbial monitoring is performed during or after sterile production. SOP No. 12 “Glove fingertip sampling procedure and documentation” Revised/Reviewed: June 27th, 2016 states “\((b) (4)\)” is deficient in that it does not require operators to roll their
fingertips from side to side.

SOP No. 13 "Garbing, Gowning and Gloving Process, Aseptic Technique Processes and Cleaning Processes Validation and Documentation" Revised/Reviewed: June 7th, 2016 is deficient in that it does not require any sampling of the gown such as forehead, face, shoulder, or chest areas.

**OBSERVATION 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

- SOP No. 10 "Garbing Procedure Technique" Revised/Reviewed: June 2nd, 2016 is deficient in that it does not state that face and neck areas should be completely covered. Furthermore, it does not address the exposure of street clothing in the ISO 7 room with an ISO 5 hood. On 09/26/16, we observed an employee working in the ISO 7 room with an ISO 5 hood exposed face, neck area, and street clothing while filling sterile Leuprolide Microdose 40 MCG/0.2 ML Injectable, Lot# LM-0926S16, batch.

- There is no written procedure and no qualification of the sterilization for the model use to sterilize drug products. No qualification has been performed. The following batches were produced and sterilized by:

<table>
<thead>
<tr>
<th>Product</th>
<th>Date Made</th>
<th>Lot</th>
<th>Sterilization Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol Valerate in Cottonseed</td>
<td>7/21/2016</td>
<td>E-0721S16</td>
<td>(b) (4)</td>
</tr>
</tbody>
</table>
Media fills do not simulate normal sterile production. The media fill for high risk production includes a media fill of which does not represent all vial sizes such as 10 ml in a vial and 2 ml in a vial.

### OBSERVATION 3
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,
- SOP No. 5 “Cleaning and Disinfection” Revised/Reviewed: June 7th, 2016 is deficient in that it does not state within the procedure the type of cloth to be used when applying the surface disinfectant. On 9/27/2016 we observed cleaning the ISO 5 hood with non-sterile,
lint free wipes which were sprayed with, in house sterilized with (b) (4) for the cleaning of the ISO 5 hood. Sterile wipes were available within the ISO 7 suite.

- On 9/27/2016 we observed (b)(6),(b)(7)(C) use "(b) (4)" brand duster mop heads to clean the floor of the ISO7 and ISO8 compounding areas with the sterilized (b) (4). The ISO5 hoods are located in the (b) (4) . However no evaluation has been made on the particulate load the duster mop heads may introduce into the ISO 7 and ISO 5 environments.

- According to SOP No. 5 the firm uses (b) (4) for the (b)(4) cleaning of the sterile compounding suites and ISO 5 hoods. The firm (b) (4), on a (b) (4) basis, (b) (4) for the (b) (4) cleaning. (b) (4) is labeled as a (b)(4) agent. SOP No. 5 does not specific application of the cleaner and surface contact time and no evaluation has been performed to demonstrate the efficacy of the cleaning agents used.

**OBSERVATION 4**

Master production and control records lack complete manufacturing and control instructions.

Specifically, the firm does not have a light box for the examination of compounded vials for the presence of particulate matter. As described by (b)(6),(b)(7)(C), the examiner (b) (4) and (b) (4) looking for particulate matter. The majority of the firm's sterile production is within amber vials which may be difficult to observe for particulate matter. The firm only uses a (b)(4) for the presence of particulate matter; there is no dark background to inspect for particulate matter that would not be visible with a white or light background. (Additionally, there is no eye examination or personnel qualification requirement for the examination of vials for particulate matter.

**DATES OF INSPECTION**

9/26/2016(Mon), 9/27/2016(Tue), 9/28/2016(Wed), 9/30/2016(Fri), 10/03/2016(Mon), 10/04/2016(Tue)