During an inspection of your firm I observed:

OBSERVATION 1

Your facility was designed and/or operated in a way that permits poor flow of materials.

Specifically,

Materials are brought into the ISO 7 Buffer room directly from an unclassified area through (b) (4) (Ll) For example, your firm utilizes this material (b) (4) to transfer in sterile processing supplies such as (b) (6) syringes, sterile spray bottles, sterile wipes and zip-lock bags.

I observed sterile production of Papaverine, Phentolamine, Alprostadil (15: 0.5: 25) in ML injectable, lot 07302018@18 for (b) (6) and Papaverine, Phentolamine, Alprostadil (25: 0.8: 20) in ML injectable, lot 07302018@17 for (b) (6) in your ISO 5 hood on 07/30/18.

OBSERVATION 2

Non-sterile bulk solutions are held for an extended period with no documentation to support the hold time.

Specifically,

Your firm prepares bulk stock solutions inside an uncertified hood and stores it inside a (b) (4) as an intermediary stock solution at (b) (4) for up to (b) (4) days after processing without (b) (4). For example, your firm produced (b) (4) of Alprostadil stock solution, lot 07122018@9 (Beyond use date 08/26/18) on 07/12/18. According to your firm management on 08/09/18, you do not require your intermediary stock solution

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to be (b) (4) prior to being (b) (4) for later use. Your firm utilized this lot of stock solution to produce the sterile products through (b) (4) in the ISO 5 hood on 07/12/18, 07/13/18, 07/16/18, 07/18/18, and 07/19/18.

Sterile product lots filled with Alprostadil stock solution lot 07122018@9

<table>
<thead>
<tr>
<th>RX</th>
<th>LOT</th>
<th>DRUG</th>
<th>FILLED</th>
<th>BUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>07122018@12</td>
<td>Phentolamine, Alprostadil Injectable 0.83MG/16.66MG</td>
<td>07/12/18</td>
<td>08/09/18</td>
</tr>
<tr>
<td></td>
<td>07132018@11</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/13/18</td>
<td>08/10/18</td>
</tr>
<tr>
<td></td>
<td>07132018@9</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/13/18</td>
<td>08/10/18</td>
</tr>
<tr>
<td></td>
<td>07132018@6</td>
<td>Alprostadil 20MCG/ML Aqueous SOLN</td>
<td>07/13/18</td>
<td>08/26/18</td>
</tr>
<tr>
<td></td>
<td>07162018@9</td>
<td>Phentolamine, Alprostadil Injectable 0.83MG/16.66MG</td>
<td>07/16/18</td>
<td>08/13/18</td>
</tr>
<tr>
<td></td>
<td>07162018@8</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/16/18</td>
<td>08/13/18</td>
</tr>
<tr>
<td></td>
<td>07162018@7</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/16/18</td>
<td>08/13/18</td>
</tr>
<tr>
<td></td>
<td>07182018@9</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/18/18</td>
<td>08/15/18</td>
</tr>
<tr>
<td></td>
<td>07182018@15</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/18/18</td>
<td>08/15/18</td>
</tr>
<tr>
<td></td>
<td>07192018@7</td>
<td>Papaverine, Phentolamine, Alprostadil Injectable</td>
<td>07/19/18</td>
<td>08/16/18</td>
</tr>
</tbody>
</table>

OBSERVATION 3
Your firm prepares multi-dose sterile drug products with an extended beyond use date without preservatives. Specifically,

AMENDMENT 1

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EMPLOYEE(S) SIGNATURE: Bei Y He, Investigator

DATE ISSUED: 8/10/2018
Acetylcysteine Ophthalmic solutions are produced by your firm without preservatives. This ophthalmic solution is dispensed to your patients as a multi-dose sterile product with a beyond use date of 45 days in frozen/refrigerated conditions.

Tacrolimus in Corn Oil NF Ophthalmic solutions are produced by your firm without preservatives. This ophthalmic solution is dispensed to your patients as a multi-dose sterile product with a beyond use date of 28 days in room temperature.

**OBSERVATION 4**

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

During sterile processing on 07/30/18, your Pharmacy Technician utilized non-sterile, low-shedding (b) (4) wipes sprayed with sterile (b) (4) (6) spray bottles into the ISO 5 hood. I observed sterile production of Papaverine, Phenolamine, Alprostadil (15: 0.5: 25) in ML injectable, lot 07302018@17 for (b) (6) and Papaverine, Phenolamine, Alprostadil (25: 0.8: 20) in ML injectable, lot 07302018@17 for (b) (6) in your ISO 5 hood on 07/30/18.

**OBSERVATION 5**

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DATE ISSUED: 8/10/2018
Equipment was not disinfected prior to entering the aseptic processing areas.

Specifically,

Prior to sterile processing, your firm attached a pre-moistened sterile mop head to sanitize the ISO 5 hood. I observed the foam mop head to be discolored with black colored residues on 07/30/18. I observed sterile production of Papaverine, Phenolamine, Alprostadil (15: 0.5: 25) in ML injectable, lot 07302018@18 for (b) (6) and Papaverine, Phenolamine, Alprostadil (25: 0.8: 20) in ML injectable, lot 07302018@17 for (b) (6) in your ISO 5 hood on 07/30/18.

*DATES OF INSPECTION
7/30/2018(Mon), 7/31/2018(Tue), 8/01/2018(Wed), 8/02/2018(Thu), 8/03/2018(Fri), 8/07/2018(Tue), 8/09/2018(Thu), 8/10/2018(Fri)