DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Suite 4-930 Cincinnati, OH 45202 513-322-0700	02/14/2022 – 02/17/2022, 02/22/2022, 02/23/2022, 03/10/2022, 03/14/2022
	FEI NUMBER 3012315020
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Blake E. McLeod, Pharmacist-in-Charge	
FIRM NAME TMC Acquisition LLC dba Tailor Made Compounding	STREET ADDRESS 200 Moore Drive
CITY, STATE, ZIP CODE, COUNTRY Nicholasville, KY 40356-8512	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Personnel conducted aseptic manipulations in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

In the (b) (4) airflow ISO 5 hood your technicians were observed interrupting ISO 5 air in the following instances:

a. On 02/16/2022, in the (b) (4) ISO 5 cleanroom ((b) (4) room), while your technician was producing Methylcobalamin 1mg/mL in 10mL vials, batch 02162212(b)(4) your technician was observed reaching over the opened bag of (b) (4) vials to grab a (b) (4). This occurred two more times during production of the batch. Additionally, your technician had their head with exposed skin inside the "ISO 5 hood" environment the entire time compounding activities were being performed. This batch of (b) (4) vials was quarantined by your pharmacy on 02/17/2022.

b. On 02/22/2022, in the (b) (4) ISO 7 cleanroom ((b) (4) room), while your technician was producing Methylcobalamin 10mg/mL in 10mL vials, batch 02222207(b)(4), your technician was observed leaning their head and upper body into the ISO 5 hood while filling the vials with the sterile injectable drug product. This batch of (b) (4) vials ((b) (4) vials pulled for testing) was released on 03/02/2022 and (b) (4) vials were distributed to patients in (b) (4) states as of 03/09/2022.

c. On 02/23/2022, in the (b) (4) ISO 7 cleanroom ((b) (4) room), while your technician was producing Semaglutide/Cyanobalamin 5mg/0.2mg/mL in 2mL vials, batch 02232210(b)(4), your technician was observed leaning their head into the ISO 5 hood while filling the vials with the sterile injectable drug

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product. Additionally, your technician's gloved hand was over open vials and then immediately filled them with the sterile injectable drug product. This batch (b) (4) vials ((b) (4) pulled for testing) was released on 03/01/2022 and (b) (4) vials were distributed to 282 patients in (b) (4) states as of 03/10/2022.

d. On 02/23/2022, in the (b) (4) ISO 7 cleanroom ((b) (4) room), while your technician was producing Semaglutide/Cyanobalamin 5mg/0.2mg/mL in 2mL vials, batch 02232202(b)(4) your technician was observed (b) (4) the filled vials, while their clinched hand (containing stoppers) was over exposed sterile injectable product vials. This batch of (b) (4) vials ((b) (4) vials pulled for testing) was released on 02/28/2022 and (b) (4) vials were distributed to 341 patients in (b) (4) states as of 03/08/2022.

e. On 03/10/2022, in the (b) (4) ISO 7 Cleanroom (b) (4) room), while your technician was producing Calcium Chloride 100mg/mL in 30mL vials, batch 03102214(b)(4) your technician was observed reaching over the exposed (b) (4) placed on the ISO 5 hood benchtop and then proceeded to use the (b) (4) to aseptically fill vials with the sterile injectable drug product, Calcium Chloride. This occurred one more time during the production of the batch. This batch is currently pending release for distribution by your pharmacy.

Since 04/30/2021 your pharmacy has had five sterility failures on finished sterile injectable drug products. Your pharmacy routinely releases sterile injectable drug products prior to obtaining USP 71 sterility results. (b) (4) batches have failed USP 71 testing after initially passing the (b) (4) test and being placed into release status. One batch (Trimix Injectable Batch 07222130(b)(4) vials) was released on 07/30/2021and dispensed to 9 patients on 07/30/2021 – 08/09/2021 in (b) (4) states ((b) (4)) and recalled on 08/10/2021 after approximately 10 days in release status.

OBSERVATION 2

Personnel manually contacted the inner surface of the container or closure.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
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Specifically,

During production of the following sterile injectable drug products, your technicians were observed (b) (4) and touching the inner surface of the stoppers (a product contact surface) with their gloved hands throughout the entire (b) (4) process of vials containing sterile injectable drug product:

a. On 02/14/2022, in the (b) (4) ISO 7 cleanroom (b)(4) room) during sterile production of Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch 02142220(b)(4), the technician (b) (4) vials and (b) (4) vials and was observed (b) (4) to obtain more stoppers and repeating the same activity; each time having direct gloved hand contact with the inner product contact surface of the stoppers. This batch ((b) (4) vials pulled for testing) was released on 02/18/2022 and (b) (4) vials were distributed to two patients in (b) (4) and (b) (4) as of 02/28/2022.

b. On 02/16/2022, in the (b) (4) ISO 5 cleanroom ((b) (4) room) during sterile production of Methylcobalamin 1mg/mL in 10mL vials, batch 02162212(b)(4), the technician (b) (4) vials and was observed having direct gloved hand contact with the inner product contact surface of the stoppers while (b) (4) each vial. This batch was quarantined by your pharmacy on 02/17/2022.

c. On 02/22/2022, in the (b) (4) ISO 7 cleanroom ((b) (4) room) during sterile production of Methylcobalamin 10mg/mL in 10mL vials, batch 02222207(b)(4), the technician (b) (4) vials and was observed having direct gloved hand contact with the inner product contact surface of the stoppers while (b) (4) each vial. This batch ((b) (4) vials pulled for testing) was released, and (b) (4) vials were distributed to 34 patients in (b) (4) states as of 03/09/2022.

d. On 02/23/2022, in the (b) (4) ISO 7 cleanroom ((b) (4) room) during sterile production of Semaglutide/Cyanocobalamin 5mg/0.2mg/mL in 2mL vials, batch 02232210(b)(4), the technician (b) (4) vials and was observed having direct gloved hand contact with the inner product contact surface of the stoppers while (b) (4) each vial. This batch ((b) (4) vials pulled for testing) was released on 03/01/2022 and (b) (4) vials were distributed to 282 patients in (b) (4) states as of 03/10/2022.

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e. On 02/23/2022, in the (b) (4) ISO 7 cleanroom ((b) (4) room) during sterile production of Semaglutide/Cyanobalamin 5mg/0.2mg/mL in 2mL vials, batch 02232202(b)(4), the technician (b) (4) vials and was observed (b) (4) obtain more stoppers and repeating the same activity; each time having direct gloved hand contact with the inner product contact surface of the stoppers. This batch ((b) (4) vials pulled for testing) was released on 02/28/2022 and (b) (4) vials were distributed to 341 patients in (b) (4) states as of 03/08/2022.

f. On 03/10/2022, in the (b) (4) ISO 7 cleanroom (b) (4) room) during sterile production of Calcium Chloride 100mg/mL in 30mL vials, batch 03102214(b)(4) the technician (b) (4) (b) (4) vials and was observed (b) (4) to obtain more stoppers and repeating the same activity; each time having direct gloved hand contact with the inner product contact surface of the stoppers. This batch is currently pending release for distribution by your pharmacy.

(b) (4) is a routine practice at your pharmacy during production of sterile injectable drug products.

OBSERVATION 3

Non-microbial contamination was observed in your production area.

Specifically,

a. On 02/14/2022, the technician stated the (b) (4) ISO 7 cleanroom ((b) (4) room) was clean and ready for compounding use. While the technician was producing Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch 02142220(b)(4), the following were observed in the ISO 7 cleanroom:
   - Apparent yellow staining was observed on the HEPA filter guard inside the ISO 5 hood
   - Apparent rust was observed where a metal strip outlining the door is peeling up.
   - The corners of the walls were observed to be chipping and cracking.
   - A box cutter with apparent rust on the blade, used to open a bag of (b) (4) stoppers and a

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bag of (b) (4) was placed inside the ISO 5 hood immediately after use during the aseptic filling process.

- Debris was found on the floor under the ISO 5 hood benchtop at the start of the aseptic filling process and consisted of an amber glass vial, a stopper, a (b) (4) and a (b) (4) stopper cap.

This batch was released on 02/18/2022 and (b) (4) vials were distributed to one patient in (b) (4) on 02/23/2022.

b. On 02/16/2022, the technician stated the (b) (4) ISO 8 prep room was clean and ready for compounding use. While the technician was producing bulk Methylcobalamin 1mg/mL, for a sterile injectable drug product, in a (b) (4) glass beaker, batch (b) (4) (finished product batch 02162212A2), the following were observed in the ISO 8 prep room:
   - Apparent residue buildup was observed throughout the countertop where bulk compounding activities were occurring.
   - Apparent residue buildup was observed throughout the floor of the ISO 8 cleanroom.
   - Apparent residue buildup was observed on a white, wire rack located directly over the exposed (b) (4) glass beaker containing bulk Methylcobalamin, during activities using a (b) (4). Your firm uses this (b) (4) to mix and dissolve other API (b) (4) into solution to produce different sterile injectable drug products.

This bulk batch was produced into finished product batch 02162212(b)(4), was quarantined by your pharmacy on 02/17/2022.

c. On 02/15/2022, your pharmacy performed a (b) (4) cleaning of the (b) (4) ISO 5 cleanroom. On 02/16/2022, the technician stated the ISO 5 cleanroom ((b) (4) room) was clean and ready for compounding use. While the technician was producing Methylcobalamin 1mg/mL in 1mL vials, batch 02162212(b)(4) the following were observed in the ISO 5 cleanroom:
   - Apparent debris buildup was observed on the floor of the ISO 5 cleanroom near the door.
   - Apparent rust was observed on the floor under the "ISO 5 hood" benchtop.
   - Apparent rust was observed on the bottom shelf of the "ISO 5 hood" benchtop.

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This finished product batch 02162212(b)(4), produced from bulk batch (b) (4), was quarantined by your pharmacy on 02/17/2022.

d. On 03/10/2022, the technician stated the (b) (4) ISO 7 cleanroom (b) (4) room) was clean and ready for compounding use. While the technician was producing Calcium Chloride 100mg/mL in 30mL vials, batch 03102214(b)(4) the following were observed in the (b) (4) ISO 7 cleanroom:
   - Apparent debris buildup was observed on the floor of the ISO 7 cleanroom near the door.
   - Ceiling has apparent residue build-up around one of the HEPA filters.
   - The seams of the walls along the ceiling appeared to be chipping and cracking.

   This batch is currently pending release for distribution by your pharmacy.

OBSERVATION 4

You had inadequate HEPA filter coverage over the area to which sterile product was exposed.

Specifically,

a. Your (b) (4) airflow "ISO 5 hood", located in your (b) (4) ISO 5 cleanroom (b) (4) room), has a large square light panel in the ceiling measuring approximately 2' x 2' that breaks up the HEPA filter coverage of the benchtop inside the "ISO 5 hood." The light panel is located approximately above the middle section of the benchtop where production of sterile injectable drug product is occurring. For example:
   - On 02/16/2022 your technician placed the syringe on the benchtop under the large light panel, with no HEPA coverage above it, throughout the aseptic filling process for Methylcobalamin 1mg/mL, in 10mL vials, batch 02162212(b)(4). This batch was quarantined by your pharmacy on 02/17/2022.

b. Your ISO 5 hood, located in your (b) (4) ISO 7 cleanroom (b) (4) room), has two rectangular light panels in the ceiling, each measuring approximately 2' x 1', one that breaks up the HEPA filter coverage of the benchtop inside the ISO 5 hood. The light panel that breaks up the HEPA filter coverage is located just outside the center portion of the benchtop where production of sterile injectable drug product is occurring.

For example:

- On 02/14/2022 your technician placed an opened bag of (b) (4) stoppers on the benchtop under the rectangular light panel, with no HEPA filter coverage above it, and proceeded to use these stoppers to cap vials containing sterile injectable drug product Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch 02142220(b)(4). This batch of (b) (4) and (b) (4) ((b) (4) vials pulled for testing) was released on 02/18/2022 and (b) (4) vials were distributed to two patients in (b) (4) and (b) (4) as of 02/28/2022.
- On 02/22/22 your technician placed the syringe and (b) (4) on the benchtop under the rectangular light panel inside the ISO 5 hood, with no HEPA filter coverage above it, during the aseptic filling process for Methylcobalamin 10mg/mL in 10mL vials, batch 02222207(b)(4). This batch of (b) (4) vials ((b) (4) pulled for testing) was released on 03/02/2022, and (b) (4) vials were distributed to 34 patients in (b) (4) states as of 03/09/2022.
- On 02/23/2022 your technician placed exposed, empty sterile vials on the benchtop under the rectangular light panel inside the ISO 5 hood, with no HEPA filter coverage above it, during the second half of the aseptic filling process for Semaglutide/Cyanocobalamin 5mg/0.2mg/mL in 2mL vials, batch 02232210(b)(4). Your technician used approximately (b) (4) of these exposed, empty sterile vials unprotected by HEPA air to fill with the sterile injectable drug product. This batch of (b) (4) vials ((b) (4) pulled for testing) was released on 03/01/2022 and (b) (4) vials were distributed to 282 patients in (b) (4) states as of 03/10/2022.

OBSERVATION 5

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

a. On 02/14/2022, the technician entered the (b) (4) ISO 7 cleanroom ((b) (4) room), which contains the ISO 5 hood, from the ISO 7 anteroom with ungloved hands (exposed skin). The technician donned sterile gloves while inside the ISO 7 cleanroom. The technician then proceeded to produce sterile injectable drug product Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch 02142220(b)(4). This batch of (b) (4) vials and (b) (4) vials was released on 02/18/2022 and (b) (4) vials were distributed to two patients in (b) (4) and (b) (4) as of 02/28/2022.

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b. On 02/16/2022, the technician's mask was not covering their nose in the (b) (4) ISO 8 prep room while producing Methylcobalamin 1mg/mL in a (b) (4) glass beaker, batch (b)(4) (finished product batch 02162212(b)(4), a sterile injectable drug product. This bulk batch, used to make finished product batch 02162212 was quarantined by your pharmacy on 02/17/2022.

c. On 02/16/2022, the technician entered the (b) (4) ISO 5 cleanroom (b) (4) room) from the ISO 7 anteroom with ungloved hands (exposed skin) and then placed the sealed pack of sterile gloves on the "ISO 5 hood" benchtop, opened the pack and donned the sterile gloves. The technician sprayed the benchtop in a few spots with sterile (b)(4), wiped the benchtop with a (b) (4) wipe, then proceeded to produce sterile injectable drug product Methylcobalamin 1mg/mL in 10mL vials, batch 02162212(b)(4). This batch of (b)(4) vials was quarantined by your pharmacy on 02/17/2022.

d. On 03/10/2022, in the (b) (4) ISO 7 cleanroom (b)(4) room) during sterile production of Calcium Chloride 100mg/mL in 30mL vials, batch 03102214(b)(4) the technician changed their sterile gloves twice, exposing skin, with exposed sterile injectable drug products in the ISO 5 hood. This batch is currently pending release for distribution by your pharmacy.

OBSERVATION 6

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

a. For the following batches of sterile injectable drug products, your technicians were observed continuing to use the (b)(4) (used to simultaneously (b) (4) the compounded solution and fill the vials) after the tip of the (b) (4) touched their gloved hands and the benchtop inside the ISO 5 hood:
   - Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch 02142220(b)(4) (Observed on 02/14/2022), the batch of (b)(4) vials and (b)(4) vials was released on 02/18/2022 and 30mL x 24 vials were distributed to two patients in (b) (4) and (b) (4) as of 02/28/2022.
   - Methylcobalamin 1mg/mL in 10mL vials, batch 02162212(b)(4) (Observed on 02/16/2022), the batch of (b)(4) vials were quarantined by your pharmacy on 02/17/2022.

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- Methylcobalamin 10mg/mL in 10mL vials, batch 02222207(b)(4) (Observed on 02/22/2022), the batch of (b)(4) vials was released on 03/02/2022, and (b)(4) vials were distributed to 34 patients in (b)(4) states as of 03/09/2022.
- Semaglutide/Cyanocobalamin 5mg/0.2mg/mL in 2mL vials, batch 02232210(b)(4) (Observed on 02/23/2022), the batch of (b)(4) vials was released on 03/01/2022 and (b)(4) vials were distributed to 282 patients in (b)(4) states as of 03/10/2022.

It is routine practice for your technician's to (b)(4) unscrew the (b) (4) from the tip of the syringe, place it on the benchtop and re-screw it to the syringe once it is refilled numerous times throughout the aseptic filling process.

b. On 02/14/2022, while your technician was producing sterile injectable Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch 02142220(b)(4), we observed your technician only sanitizing their gloved hands once they were already inside the ISO 5 hood; never prior to re-entering the ISO 5 hood. Additionally, prior to starting production, your technician retrieved a chair from the (b) (4) ISO 5 cleanroom, brought it into the (b) (4) ISO 7 cleanroom and using their gloved hands wiped the chair with a (b) (4) cloth sprayed with sterile (b)(4) Your technician proceeded to enter the ISO 5 hood with their gloved hands and began compounding activities without first sanitizing the gloved hands.

c. On 02/16/2022, while your technician was producing the bulk solution for Methylcobalamin 1mg/mL, batch (b)(4) (finished product batch 02162212(b)(4), we observed your technician touching a keyboard and mouse with gloved hands and did not sanitize the gloved hands before continuing compounding activities.

d. On 02/16/2022, while your technician was producing sterile injectable Methylcobalamin 1mg/mL in 10mL vials, batch 02162212(b)(4), your technician did not wipe down the packaged syringe and packaged (b) (4) with your sterile (b)(4) prior to introduction in the "ISO 5 hood."

e. On 03/10/2022, while your technician was producing the bulk solution for Calcium Chloride 100mg/mL, batch (b)(4) (finished product batch 0310221(b)(4), we observed your technician touching a mouse with their right gloved hand and did not sanitize the gloved hand before continuing compounding activities inside the unclassified (b) (4) hood, located in the unclassified (b)(4) prep room. Additionally, we

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observed the technician touching the inside of a trash can with gloved hands while pushing garbage down contained inside the trash can and did not sanitize the gloved hands before continuing compounding activities inside the unclassified (b) (4) hood.

f. On 03/10/2022, while your technician was producing sterile injectable Calcium Chloride 100mg/mL in 30mL vials, batch 03102214(b)(4) your technician did not wipe down the vial crimping tool or the bag of non-sterile foil seals (which was being stored on the floor in the ISO 7 cleanroom) with your sterile (b)(4) prior to introduction in the ISO 5 hood. Additionally, we observed the technician reach into the ISO 5 hood with gloved hands to grab a (b) (4) and did not sanitize the gloved hands prior to entering the ISO 5 hood.

OBSERVATION 7

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically,

a. In your (b) (4) ISO 7 cleanroom ((b)(4) room), the ISO 5 hood is constructed with (b) (4) panels hanging from the ceiling to separate the ISO 5 hood from the ISO 7 cleanroom environment. Currently, there are gaps between the (b) (4) panels spread out across the length of the ISO 5 hood benchtop measuring approximately 0.5 inch, 1.0 inch and 1.5 inches. Additionally, there is a large gap between the bottom of the (b) (4) panels and the top of the ISO 5 hood benchtop, measuring approximately 2 feet. You have not evaluated the gaps to ensure lesser quality ISO 7 air is not entering the higher quality air in the ISO 5 hood environment. Your pharmacy has been routinely producing sterile injectable drug products inside this ISO 5 hood since March 3rd, 2021.

b. In your (b) (4) ISO 7 cleanroom ((b)(4) room), the ISO 5 hood is constructed with (b) (4) panels hanging from the ceiling to separate the ISO 5 hood from the ISO 7 cleanroom environment. Currently, there is a gap measuring approximately 1 inch between two (b) (4) panels located approximately over the center

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Suite 4-930 Cincinnati, OH 45202 513-322-0700	02/14/2022 – 02/17/2022, 02/22/2022, 02/23/2022, 03/10/2022, 03/14/2022
	FEI NUMBER 3012315020
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Blake E. McLeod, Pharmacist-in-Charge	
FIRM NAME TMC Acquisition LLC dba Tailor Made Compounding	STREET ADDRESS 200 Moore Drive
CITY, STATE, ZIP CODE, COUNTRY Nicholasville, KY 40356-8512	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

of the ISO 5 hood benchtop where sterile production occurs. Additional gaps measuring approximately 0.5 inch were located at the top of the (b) (4) panels near the ceiling. Furthermore, there is a large gap between the bottom of the (b) (4) panels and the top of the ISO 5 hood benchtop, measuring approximately 2 feet. You have not evaluated the gaps to ensure lesser quality ISO 7 air is not entering the higher quality air in the ISO 5 hood environment. Your pharmacy has been producing sterile injectable drug products inside this ISO 5 hood since 03/08/2022.

OBSERVATION 8

You produced hazardous drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

a. On 02/16/2022 in the (b) (4) ISO 8 prep room, your technician was observed spraying sterile (b)(4) onto a (b) (4) wipe to wipe apparent residue off the opening of the (b)(4) glass beaker and proceeded to use it to compound the bulk solution for drug product Methylcobalamin 1mg/mL, batch (b)(4) (finished product batch (b) (4) The beaker had already been cleaned and (b) (4) and was identified as ready-to-use by the technician at the time the apparent residue was detected. The technician identified the apparent residue as possible residual Testosterone. Your pharmacy uses this (b)(4)) beaker size to also compound the following sterile injectable drug products:
   - Testosterone Cypionate/Enanthate/Propionate 80/80/40mg
   - Vitamin B-Complex
   - NAD+ 200mg/mL
   - Semaglutide/Cyanocobalamin 2mg/0.4mg/mL
   - Semaglutide/Cyanocobalamin 5mg/0.2mg/mL
   - GAC 25mg/100mg/250mg/mL
   - GOAL Injectable
   - Methylcobalamin 10mg/mL
   - Methylcobalamin 1mg/mL
   - Methylene Blue 10mg/mL

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- BCAAs (Leucine/Iso-Leucine/Valine) 10mg/10mg/5mg/mL
- Dexpanthenol 250mg/mL
- Glutathione 200mg/mL PF Injectable
- Methionine/Inositol/Choline B12 + Carnitine 10mg/40mg/1mg/100mg/mL
- Myers Cocktail 4mg/0.8mg/1mg/0.4mg/8mg/0.04mg/mL
- Nandrolone Decanoate 200mg/mL

b. On 02/23/2022 in the (b)(4) unclassified prep room, apparent residue build-up was observed on a non-dedicated glass flask and (b)(4) non-dedicated (b)(4) . Additionally, on 03/10/2022 in the unclassified (b)(4) prep room, apparent residue build-up was observed for a second time on a non-dedicated glass flask being stored in a cabinet. These glass flasks and (b)(4) are used to perform (b)(4) of drug products prior to aseptic filling operations. The pieces were all identified as being clean and ready-to-use by your QA/QC Manager. The residue on the inside of the glass flask observed on 02/23/2022 and 03/10/2022 was identified as possible residual Testosterone. The apparent white residue build-up observed on 03/10/2022 on (b) (4) was unable to be identified by your pharmacy. The (b) (4) is the last step in the (b)(4) process before the drug product enters the glass flask. Your pharmacy uses the glass flasks and (b) (4) to (b)(4) in the unclassified prep room the following sterile injectable drug products:
   - All Testosterone products
   - All Estradiol products
   - Sermorelin/Glycine 2000mcg/5mg/mL
   - Sermorelin 2000mcg/mL
   - Ascorbic Acid 500mg/mL

c. Additionally, to clean all utensils and glassware used in sterile and non-sterile compounding, your pharmacy is using a non-pharmaceutical grade detergent that may leave residues or not be adequately rinsed from the utensils and glassware that come into direct contact with drug products.

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OBSERVATION 9

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

Specifically,

a. On 02/14/2022, while your technician was producing Calcium Chloride 100mg/mL in 5mL and 30mL vials, batch (b)(4), your technician left the (b) (4) ISO 7 cleanroom (b)(4) room) with exposed sterile injectable product vials on the ISO 5 hood benchtop, walked through the ISO 7 anteroom and into the (b) (4) ISO 5 cleanroom (b) (4) room) to grab a bag of stoppers. Your technician was observed bringing the bag of stoppers into the ISO 7 cleanroom without wiping the bag down and using the stoppers to complete production of the batch.

b. On 02/16/2022, while your technician was producing Methylcobalamin 1mg/mL in 10mL vials, batch 02162212(b)(4) your technician held the door to the (b) (4) ISO 5 cleanroom ((b) (4) room) open and grabbed a blue plastic bin off a metal shelfing rack in the ISO 7 anteroom. Your technician was observed placing this blue plastic bin on the "ISO 5 hood" benchtop without sanitizing it first. There is no material (b)(4) going from the ISO 7 anteroom into the ISO 5 cleanroom and your Pharmacy is using the blue plastic bin in absence of one. Additionally, your technician opened the door to the ISO 5 cleanroom a second time with exposed sterile injectable product vials on the benchtop and entered the (b) (4) ISO 7 cleanroom (b)(4) room) through the ISO 7 anteroom to obtain a (b)(4) test apparatus, which your technician then brought into the ISO 5 cleanroom.

c. On 02/16/2022, while your technician was producing the bulk solution for Methylcobalamin 1mg/mL, batch (b)(4) (finished product batch 02162212(b)(4)), we observed your technician leave the (b) (4) ISO 8 prep room and enter an unclassified room used for non-sterile compounding. Your technician re-entered the ISO 8 prep room and continued compounding activities without changing their garb or sanitizing their gloved hands.

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OBSERVATION 10

Environmental monitoring was not performed in your aseptic processing areas.

Specifically,

According to your firm's QA/QC Manager, Environmental Monitoring (i.e., surface samples) is conducted by your vendor every (b)(4), but (b) (4). Therefore, results are not representative of the aseptic processing environment making the results unreliable. Additionally, your pharmacy is currently incubating (b)(4) plates for an (b)(4) period that could (b)(4) the plates out making results inconclusive. (b)(4) plates are being incubated for approximately (b)(4) at (b)(4) and then for approximately (b)(4) at (b)(4), for (b)(4) total incubation time.

OBSERVATION 11

ISO 5 classified areas were not adequately certified under dynamic conditions to demonstrate unidirectional airflow.

Specifically,

Smoke studies in the (b) (4) ISO 7 cleanroom and (b) (4) ISO 5 cleanroom showed air turbulence within the (b) (4) airflow ISO 5 hood environment with smoke raising up in the ISO 5 hood and lingering as well as spreading out over the ISO 5 hood benchtop. Additionally, the (b) (4) (b) (4) ISO 5 cleanroom certification performed in January 2022 did not meet air changes per (b) (4) (ACH) recommendations of (b) (4) ACH to maintain the ISO 5 environment; result for the cleanroom was 57 ACH.

Your pharmacy's drug products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

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OBSERVATION 12

Media fills are not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

Your pharmacy's media fill dated 02/09/2022, conducted in the (b) (4) ISO 7 cleanroom (b) (4), and media fill dated 02/28/2022, conducted in the (b)(4) ISO 7 cleanroom (b) (4) fails to closely simulate current aseptic operations. The media fills were conducted with only (b)(4) vials. Per your firm's batch size range of (b)(4) vials, the average batch size for sterile injectable drug products is approximately (b)(4) vials. Prior to 01/05/2022, your pharmacy was only using (b)(4) vials during media fills. After this date, your pharmacy increased media fills to (b)(4) vials. Then on 02/15/2022 and per SOP 7.008 "Media Fill for High Risk Compounding", version 3, your pharmacy increased media fills to (b)(4) vials, only (b)(4) of the approximate average batch size of (b)(4) vials and is still using this batch size for media fills presently.

OBSERVATION 13

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

a. On 02/22/23, your pharmacy produced sterile injectable drug product Methylcobalamin 10mg/mL, batch number 02222207 (b)(4), using (b) (4), batch number (b) (4), for parenteral use. The COA for (b) (4) specifically states, "Product not intended for Parenteral use." This Methylcobalamin batch of (b)(4) vials pulled for testing) was released and (b)(4) vials were distributed to patients in (b) (4) states as of 03/09/2022. In total, your pharmacy used this batch of (b) (4) to produce (b)(4) batches of drug products ((b)(4) sterile injectable drug products and (b)(4) nasal spray drug products), out of which (b)(4) batches have been released and distributed to patients.

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b. On 02/23/2022, your pharmacy produced two batches of sterile injectable drug product Semaglutide/Cyanobalamin 5mg/0.2mg/mL in 2mL vials, batches 02232210(b)(4) and 02232202(b)(4), using (b) (4), batch number (b) (4), for parenteral use on patients. The commercial invoice and packing slip that accompanied the shipment of the (b) (4) batch states "PEPTIDES USED FOR RESEARCH & DEVELOPMENT – PHARMACEUTICAL DRUG DISCOVERY". These batches of finished product were released on 03/01/2022 and 02/28/2022 and completely distributed (greater than (b)(4) as of 03/10/2022 and 03/08/2022 respectively. Additionally, according to your pharmacy's QA/QC Manager, your pharmacy has depleted this entire batch of (b)(4) of (b) (4) to produce sterile injectable drug products for patient use.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."