

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA, ORA, OPQO, Pharma Division 1 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 Tel: (973) 331-4900 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 05/28 - 29/2020, 06/01/2020, 06/08/2020, 06/15/2020
	FEI NUMBER 3005734706

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Mr. Stephen S. Laddy, CEO**

FIRM NAME MasterPharm LLC	STREET ADDRESS 115-02 Liberty Avenue
CITY, STATE AND ZIP CODE South Richmond Hill, NY 11419-1902	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

**OBSERVATION 1**

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically,

Approximately (b) (4) Tadalafil 7 mg Capsules, Lot #01-22-2020: 02@19, BUD Date: 7/20/2020 were released, dispensed to patients, and continue to remain on the market despite the confirmed OOS potency testing result of 80.4% (Specification = (b) (4) %) reported for the sub-potent lot.

**OBSERVATION 2**

The ISO classified aseptic processing areas have difficult to clean, particle-generating and visibly dirty equipment and surfaces.

Specifically,

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A) On 06/01/2020 and 06/08/2020, I observed dark black and brownish marks within the lower right corner of the material (b) (4) separating the sterile ISO 5 preparation area and non-sterile ISO 7 preparation area. There is no cleaning regimen for the (b) (4) prior to use. The (b) (4) was used to transfer non-sterile drug product and materials, including filled syringes, (b) (4) and vials for the sterile producing of:

- 1) Morphine Sulfate/Clonidine HCL 10 MG/0.148MG/ML Intrathecal, Quantity Made: (b) (4) Lot #06-01-2020: 66@1, BUD: 06/04/2020
- 2) Hydromorphone HCL/Bupivacaine HCL 12.5 mg/1.25MG/ML Intrathecal, Lot #06-01-2020: 03@3, Quantity Made: (b) (4) BUD: 06/04/2020
- 3) PPC/DC VIAL (Phosphatidylcholine/Deoxycholate) \*FROZEN\* Solution, 50/42MG/ML, Quantity Made: (b) (4) (b) (4), Lot #06-01-2020: 18@2, BUD: 07/16/2020
- 4) Hydromorphone HCL P/F, 6 MG/ML, Quantity Made: (b) (4) Lot #06-01-2020: 81@2, BUD: 06/04/2020

B) Hard-to-reach (b) (4) areas used to enclose the direct compounding areas (DCAs) within the ISO 5 Cleanroom (b) (4) are not cleaned. For example: On 06/08/2020, I observed the lack of cleaning by (b) (6) Sterile Operator, for the upper top half portions of the (b) (4) areas used during the production of:

- 1) Morphine sulfate P/F 10 MG/ML, Lot #06-08-2020: 27@2
- 2) Morphine sulfate P/F 10 MG/ML, Lot #06-08-2020: 30@1
- 3) Fentanyl/Bupivacaine HCL/Clonidine HCL/Baclofen 0.8mg/30mg/0.025mg/0.2MG/ML, Lot #06-08-2020: 16@4
- 4) Morphine Sulfate/Bupivacaine HCL/Clonidine HCL, 4.5/10/0.44MG/ML, Lot #06-08-2020: 81@3

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5) Trimix 1 (Papaverine HCL/Phentolamine Mesylate/Alprostadil) California, 30MG/1MG/10MCG/ML, Lot #06-08-2020: 45@5

C) On 06/08/2020, I observed visible black and brown stains on the ISO 5 Cleanroom (b)(4) ceiling tile stationed directly adjacent to the right of Table 2, direct compounding area (DCA), within Cleanroom (b)(4) used for aseptic processing of sterile drug products, including intrathecal syringes and vials. This tile is located approximately six (6) inches away from the (b) (4) surrounding the DCA.

**OBSERVATION 3**

Non-microbial contamination was observed in your production area.

Specifically,

A) On 06/08/2020, I observed rust-like and reddish brown material on the heel of the sanitizer dispensing unit within the ISO 7 anteroom directly connected to ISO 5 Cleanroom (b)(4)

B) On 05/28/2020, I observed the following deficiencies within the ISO 7 hazardous non-sterile production room:

1) Visible white product residue directly on shelves used to store hazardous API and inactive ingredients within the ISO 7 hazardous non-sterile production room. This is in spite of the room being last used and cleaned on 05/27/2020 as per the Director of Pharmacy Operations and cleaning log of the production area.

2) Chipped and chipping metallic coating directly on top of a flammable container used to store alcohol-based materials used within the ISO 7 hazardous non-sterile production room.

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C) On 05/28/2020, I observed chipped and chipping coating/paint material as well as brown stains on the (b) (4) near product contact surfaces used to (b) (4) non-sterile preparation creams, including: Benzocaine, Lidocaine, Tetracaine 20/10/10% cream, 05-28-2020 00@1, BUD: 08/26/2020.

**OBSERVATION 4**

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

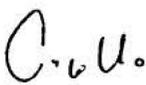
Non-dedicated work surfaces and utensils, including mortar pestles, mixing spoons, spatulas, and glassware, are shared for production operations between hazardous and non-hazardous non-sterile drug products. In addition, you do not use deactivating agents for removal of hazardous ingredients on shared utensils. This includes the following drug products, which were prepared and produced using the hazardous non-sterile production room:

A) Non-sterile preparation of Mitomycin (b) (4) 0.4 MG/ML solution, Lot Number: 05-27-2020: 10@1, BUD: 07/11/2020, Date Made: 05/27/2020

B) Production of Formula 82 M Minoxidil/Tretinoin/Fluocinolone Acetonide 5/0.01%/0.01% Solution, Lot #: 05-27-2020: 40@10, BUD: 11/22/2020, Date Made: 05/27/2020

C) Production of HCG Sublingual Mini 400 IU Troche, (b) (4) each, Qty: (b) (4) Lot #: 01-14-2020: 44@3, BUD: 05/16/2020, Date Made: 01/14/2020

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D) Production of Formula 82 M Minoxidil/Tretinoin/Fluocinolone Acetonide 5/0.01%/0.01% Solution, Lot #: 01-14-2020: 42@16, BUD: 07/07/2020, Date Made: 01/14/2020

E) Production of Formula 82 D ((b) (4)) Minoxidil/Tretinoin/Fluocinolone Acetonide/Dutasteride 5/0.01/0.01/0.75%, Lot #: 01-14-2020: 04@9, BUD: 07/07/2020, Date Made: 01/14/2020

**OBSERVATION 5**

ISO-5 classified areas were not certified under dynamic conditions.

Specifically,

Unidirectional airflow was not verified under operational conditions. For example:

A) Smoke studies conducted within the ISO Class 5 areas are inadequate. The studies did not include evaluation of constant unidirectional HEPA air flow for sterile drug product solutions being (b) (4) using a (b) (4)

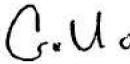
B) The smoke study videos, Dated: 03/26/2020, representing (b) (4) of vials and syringes did not include the transfer of starting materials into the ISO Class 5 areas to demonstrate unidirectional airflow away from sterile product under dynamic conditions.

**OBSERVATION 6**

There is a lack of adequate personnel sampling.

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A) On 06/08/2020, (b) (6) Sterile Operator, was observed to spray his gloved hands with (b) (4) spray immediately before fingertip personnel monitoring.

B) The same sterile operator was observed to quickly and lightly touch the (b) (4) plates with his fingertips and thumbs as opposed to slowly rolling each fingertip and thumb on the (b) (4) surface with adequate pressure to ensure recovery of potential microbes.

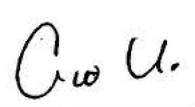
**OBSERVATION 7**

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

Specifically,

There is no gauge which measures the pressure differentials of airflow between the ISO 7 hazardous negative pressure room, which houses the ISO 5 (b) (4) and the ISO 7 anteroom used for gowning.

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