DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 Tel: (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	06/17/19-06/18/19, 07/01/19-07/02/19, 07/09/19, 07/16/19, 07/25/19
	FEI NUMBER 3010924627

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Teresa Malanda, RPh, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
Mandell's Clinical Pharmacy	7 Cedar Grove Ln, Suite 24
CITY, STATE AND ZIP CODE Somerset, NJ 08873-1331	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:

1. The ISO 5 classified area is located within a non-classified room (segregated production area).

Specifically,

The ISO-5 classified laminar flow (b) (4) (LF(b) (4) (Model (b) (4), for aseptic filling of sterile fertility drug products is located within a non-classified room which is not HEPA filter equipped to prevent risk of contamination. On 06/18/19, we observed water dripping from an 8 feet high ceiling vent that is approximately15 feet away from the ISO-5 classified LF(b) (4) in the non-classified room . There is no assurance that the lower quality air from unclassified room does not contaminate the environment when the(b) (4) is opened (b) (4) for cleaning, disinfection and to replace the(b) (4)

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Niketa Patel Nancy M. Espinal	Niketa Patel, Investigator Nancy M. Espinal, Investigator	07/25/2019

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Somerset, NJ 08873-1331	Producer of sterile and non-sterile drug products

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

Specifically,

A. No media fill was performed for the ISO-5 classified LF(b) (4)(model (b) (4) located in the unclassified room.

B. The firm performs media fill (b) (4) to support aseptic filling practices in the ISO-5 biological safety cabinet (BSC) (Model (b) (4)) located in the ISO-7 production room. The media fills are performed using a total of (b) (4) ((b) (4) to be tested). This does not represent the most challenging condition, in that the firm produces batches which range in size from (b) (4) vials.

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3. Non-depyrogenated equipment was used in sterile drug production.

Specifically,

The firm does not depyrogenate the (b) (4) that comes into direct contact during mixing of drug components in the ISO-7 production room. On 07/16/19, the pharmacist was observed using a (b) (4) the production of the Progesterone 50mg/ml in oil injection per the formula (b) (4)

4. Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

A. The ready to use sterile sporicidal ((b) (4) is not used to clean the ISO-5 BSC (located within the ISO-7 production room) and ISO-5 LF (b) (4) (located in an unclassified room).

B. The ready to use sterile sporicidal ((b) (4) is used (b) (4) to clean the ISO- 7 rooms (production and ante). The manufacturer's label states that (b) (4) of contact time is effective for microbial control. However, the firm does not have a specific length of time for which personnel are required to leave the sporicidal on contact surfaces within the rooms.

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5. You produced highly potent drugs without providing adequate cleaning of work surface and cleaning of utensils to prevent cross-contamination.

Specifically,

The firm does not use deactivating and decontaminating agent to eliminate the cross contamination of glass item and (b) (4) hood that is used for multiple drug products.

A. The firm's glass items (beakers, graduate cylinders, stirring rods, vials etc.) that are used throughout the compounding process for multiple drug products are cleaned using antibacterial hand-wash soap and tap water. Prior to the next use, the glass items are rinsed with sterile water and then depyrogenated.

B. The firm uses household antibacterial cleaner (b) (4) and sterile (b) (4) to clean the (b) (4) hood (b) (4) each (b) (4) is weighed and put into solutions.

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