

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
New Jersey District Office 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 Ph: (973)331-4900 Fax: (973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov		09/13/2021-11/18/2021*
Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		FEI NUMBER
		3013505558
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED		
Ms. Shawn DeAntonio, Pharm D, Pharmacist in Charge		
TO: FIRM NAME	STREET ADDRESS	
Ideal Specialty Apothecary, Inc. dba Ideal Pharmacy	2333 Morris Ave, Suite B101	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Union, New Jersey 07083	Compounding Pharmacy	

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**  
(Repeat Observation)

**ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions.**

The smoke studies for the (b) (4), approximately (b) (4) each, conducted (b) (4), during the (b) (4) certifications (last performed on 01/27/2021 and 07/15/2021), were not performed under routine dynamic conditions. Although the certification report states smoke studies were done under “dynamic conditions”, videos provided indicate that smokes studies were not performed under dynamic operational conditions. The videos show a technician passing smoke, with (b) (4). Components such as repeater pump, stir plate, beakers, vials, (b) (4), tubing, or sterile wipes, used during Medroxyprogesterone acetate (MPA) or Hydroxyprogesterone caproate (HPC) compounding were not placed in the (b) (4) during the smoke study. In addition, the videos indicate that no pharmacy representative was present simulating routine operations within the (b) (4) during the smoke study.

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	Helen Verdel S <small>Digitally signed by Helen Verdel -S Date: 2021.11.18 09:46:33 -05'00'</small>	Janet Rajan S <small>Digitally signed by Janet Rajan -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Janet Rajan -S, o.9.23.2.15020000.100.1, #200376185 Date: 2021.11.18 09:38: 3 -05'00'</small>	Helen Verdel, Investigator Janet A. Rajan, Investigator

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**OBSERVATION 2**

(Repeat Observation)

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

Specifically, the media fill lot size is (b)(4) vials however a routine batch of Hydroxyprogesterone caproate (HPC) may be as many as approximately (b)(4) vials. Equipment such as the hot plate or stir plate, used during HPC compounding, are not included in the media fill simulation. In addition, routine processes such as changing the needles and (b)(4) every (b)(4) and foiling the vials, post filling, outside the (b)(4) in the unclassified segregated compounding area, are not included during the media fill simulations.

**OBSERVATION 3**

(Repeat Observation)

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

Specifically, the ISO-5 (b)(4), used for compounding of sterile Medroxyprogesterone acetate (MPA) and Hydroxyprogesterone caproate (HPC), is operating at (b)(4) (b)(4) to the surrounding unclassified segregated compounding area (SCA). In addition, sterile Ophthalmic Solution Tobramycin 14 mg/mL (Compounded on 10/12/2021) was compounded in the (b)(4) held at (b)(4) to the surrounding unclassified SCA; however, none of the ingredients used in compounding Tobramycin were hazardous. Tobramycin was also not (b)(4) or (b)(4) post filling. Additionally, the viable environmental monitoring test conducted on 01/07/2020, 04/02/2020 and 07/28/2020 isolated the following microbial growth in the

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	<p>Helen Verdel -S</p> <p>Digitally signed by Helen Verdel -S Date: 2021.11.18 09:47:00 -05'00'</p> <p>Janet Rajan -S</p> <p>Digitally signed by Janet Rajan -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Janet Rajan -S, o=D, ou=2342-19200300.100.1, 1.2.840.10203.1.1.1 Date: 2021.11.18 09:39:13 -05'00'</p>	<p>Helen Verdel, Investigator</p> <p>Janet A. Rajan, Investigator</p>	11/18/2021



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TO: FIRM NAME Ideal Specialty Apothecary, Inc. dba Ideal Pharmacy	STREET ADDRESS 2333 Morris Ave, Suite B101
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CITY, STATE, ZIP CODE, COUNTRY Union, New Jersey 07083	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy
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unclassified SCA and in the ISO-5 (b) (4) of the (b) (4) :

Date	Location	Total Colony Forming Units (CFU's)
01/07/2020	Ambient Unclassified SCA	9 Bacterial CFU's on (b) (4) Plate: 2 CFU's of Bacillus, 1 CFU of Gram negative rods, 5 CFU's of Micrococcus, 1 CFU of Staphylococcus Coagulase (-)
04/02/2020	ISO-5 (b) (4) of (b) (4)	2 Bacterial CFU's from (b) (4) Swab A: 1 CFU of Micrococcus, 1 CFU of Staphylococcus Coagulase (-)
07/28/2020	Ambient Unclassified SCA	3 Fungal CFU's on (b) (4) Plate: 1 CFU of Alternaria, 2 CFU's for Cladosporium

**OBSERVATION 4**

**The final containers/closures used for drug products intended to be sterile were not maintained to ensure that drug products intended to be sterile maintain sterility.**

Specifically, during filling operations, for both Hydroxyprogesterone caproate (HPC) and Medroxyprogesterone acetate (MPA), the stopper on the 2 mL, 13 mm sterile empty, stoppered, crimped, and sealed glass vials, is punctured with the (b) (4) needles. Aseptically processed HPC vials are foiled immediately, post filling, outside the (b) (4), in the unclassified segregated compounding area (SCA) during which the HPC vials with punctured stoppers, are exposed to non-sterile conditions of the SCA. Once MPA is filled, the 2 mL vials with punctured stoppers, are (b) (4) in the (b) (4) which is corroded, with what appeared to be rust. (b) (4) (b) (4) MPA vials are transferred to non-sterile bins in the storage room that is not temperature and relative humidity monitored or controlled; these vials with punctured stoppers are exposed to non-sterile conditions of the storage bins. MPA vials are foiled with sterile foils (based on the Pharmacist in Charges availability) in the unclassified/uncontrolled dispensing area (under stained ceiling and air vent/diffuser). While awaiting foiling, the MPA vials with punctured stoppers, are exposed to the non-sterile storage bins for an unknown period of time.

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	Janet Rajan -S Digitally signed by Janet Rajan -S DN: c, US, o, U.S. Government, ou, HHS, ou, FDA, ou, People, cn, Janet Rajan -S, o, S, 2342-19200300-100.1, 1.2003076195 Date: 2021.11.18 09 39 47 -05 00'		



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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Ms. Shawn DeAntonio, Pharm D, Pharmacist in Charge		
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**OBSERVATION 5**

**Non-microbial contamination was observed in your compounding area.**

Specifically, the following was observed:

- A. The interior of the (b) (4) and (b) (4) trays used to sterilize equipment used for compounding of Medroxyprogesterone acetate (MPA) and Hydroxyprogesterone caproate (HPC), MPA bulk suspension prior to filling and (b) (4) of MPA is corroded, with what appeared to be rust despite a comment at the end of the page of the service report for the (b) (4) (Performed on 12/04/2020) which states "it is suggested that tray holder be replaced due to corrosion". In addition, the stainless steel carts staged in the unclassified compounding area are corroded (with what appeared to be rust); sterile (b) (4) bottles and fiber drum containers of MPA Active Pharmaceutical Ingredient (API) are stored on the stainless steel cart. Containers of MPA API are stored underneath corroded (with what appeared to be rust) shelves.
- B. The (b) (4), located in the unclassified segregated compounding area, are placed on wooden planks (hard to clean surface), to stabilize the (b) (4) staged on the corroded (with what appeared to be rust) stainless steel carts. The (b) (4) are used to sterilize equipment, bulk suspension, and (b) (4) product.
- C. Discoloration was observed on the ceiling HEPA filters in the unclassified segregated compounding area, where aseptically processed HPC vials are foiled and where the ISO-5 (b) (4) is located.
- D. The ceiling above the benchtop in the general dispensing area where (b) (4) Medroxyprogesterone acetate (MPA) vials are foiled is stained brown and has a yellow, cream like substance protruding. The air diffuser/vent on the ceiling above the benchtop is also heavily corroded, with what appeared to be rust. During foiling of MPA the punctured stoppers on the vials are exposed to the ceiling and air vent/diffuser.

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**OBSERVATION 6**

**Vermin was observed present in areas immediately adjacent to your compounding area.**

Specifically,

- A. On 09/21/2021, a green/yellow live insect, approximately 1 inch, was observed flying in the general dispensing area where vials of sterile Medroxyprogesterone acetate (MPA) (intramuscular parenteral drug) are foiled with sterile foils on the benchtop. Sterile MPA vials are foiled after the product has been (b) (4). During foiling, the punctured stopper on the vials of MPA finished product, is exposed to the unclassified dispensing area. The dispensing area is also where non-hazardous non-sterile drugs are compounded.
- B. On 10/18/2021, we also observed 3 dead black insects that appeared to be flies in the bathroom. The bathroom is adjacent to the storage room where sterile MPA finished product is stored; the bathroom is also approximately 8 feet from the general dispensing area where (b) (4) MPA vials are foiled.

**OBSERVATION 7**

**Your firm compounded drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the compounding environment and product.**

Specifically, the compounding room, that is not currently in use, was constructed between April and September 2020, with installation occurring between June and September 2020. The Compounding Record Documentation (CRD) for all sterile products compounded for 2020-2021 indicates that (b) (4) of (b) (4) 125 mg/0.05 mL Sterile Intravenous Injection was repackaged, (b) (4) Lots of Medroxyprogesterone acetate (MPA) and (b) (4) Lots of Hydroxyprogesterone caproate (HPC) were compounded between April 2020 and September 2020. In addition, approximately (b) (4) non-sterile drugs were also compounded and dispensed between September 2019 and September 2021.

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	Helen Verdel -S Digitally signed by Helen Verdel -S Date: 2021.11.18 09:48:13 -05'00'	Janet Rajan -S Digitally signed by Janet Rajan -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Janet Rajan -S, o=32342-15202300-100-1-1, ou=2003076185 Date: 2021.11.18 09:40:57 -05'00'	Helen Verdel, Investigator  Janet A. Rajan, Investigator

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**\*DATES OF INSPECTION**

09/13/2021(Mon), 09/15/2021(Wed), 09/17/2021(Fri), 09/21/2021(Tue), 09/24/2021(Fri),  
 09/28/2021(Tue), 09/29/2021(Wed), 10/04/2021(Mon), 10/12/2021(Tue), 10/18/2021(Mon),  
 11/02/2021(Tue), 11/18/2021(Thu)

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	Helen Verdell Digitally signed by Helen Verdell -S Date: 2021.11.18 09:48:35 -05'00' -S	Janet Rajan Digitally signed by Janet Rajan -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Janet Rajan -S, o.S.2342.1920000.100.1, 1.2000076195 Date: 2021.11.18 09:41:38 -05'00' S	Helen Verdell, Investigator Janet A. Rajan, Investigator