

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 8/30/16 to 9/20/16*
	FEI NUMBER 3011412185

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Roy G. Calcagno, Owner

FIRM NAME Montana Compounding Pharmacy P.C.	STREET ADDRESS 111 N. Higgins Ave
CITY, STATE AND ZIP CODE Missoula, MT 59802	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-sterile Drug Products

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 (I) (WE) OBSERVED:

**OBSERVATION 1**

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Specifically,

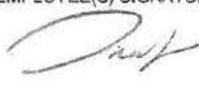
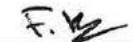
a. (b) (4) brand (b) (4) (b) (4) lot “(b) (4)” is used as a component in non-sterile drug products such as (b) (4), oral suspensions, and intranasal drug preparations. This non-pharmaceutical grade (b) (4) for drug production is dispensed from a 5-gallon water bottle through a drinking water dispenser spigot in the employee break room. A representative example of non-pharmaceutical grade (b) (4) used in the formulation of drugs is (b) (4) (b) (4) that is given a beyond use date (BUD) of 180 days in ambient storage temperature. (b) (4) is intended to be used as a preservative in the formulation of drugs such as Oxytocin nasal spray. Oxytocin nasal spray is assigned BUD of 90 days in refrigeration. This is a repeat observation.

b. Non-pharmaceutical grade (b) (4) markers are used as a component in non-sterile drug capsule production. After encapsulation of a drug product, a (b) (4) marker is applied directly on each capsule to make a distinguished marking. No control is in place to prevent the marker material from penetrating to the drugs.

**OBSERVATION 2**

Vermin was observed in your production area. Specifically,

On 8/30/2016, a fly was noted hovering over the in-process drug (b) (4) mixture and hovering over the production area during the process and capsule filling of Thyroid USP 16.25mg capsule, lot 08302016:49@3. This fly was observed directly on a drug container, production work table and lab coat, street pants, hair and face of the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type) Tracy K. Li, Consumer Safety Officer Farhana Khan, Consumer Safety Officer	DATE ISSUED 09/20/2016
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operator during production.

OBSERVATION 3

Non-microbial contamination was observed in your production area. Specifically,

One section of the dust covered louver blades of the HVAC system was missing over the production area. Uncontrolled airflow from this missing louver section would allow for undesired particulates into uncovered, weighed (b) (4) active pharmaceutical ingredients and components for production.

OBSERVATION 4

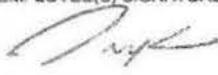
Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. Specifically,

There is no dedicated area for production and cleaning of such area prior to drug production. On 8/30 and 8/31/2016, no cleaning of the work surfaces were done prior to the weighing and staging of components and mixing of drug products during the production of Thyroid USP 16.25 mg capsule, lot 08302016:49@3 Estradiol 2 mg Capsule, lot 08302016:15@5. This production work station is a shared space for (b) (4) and (b) (4).

OBSERVATION 5

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

An unlabeled and reusable syringe reported to be used multiple times to draw contents from a component, (b) (4) (b) (4) for production of drug products was observed secured to the container with a

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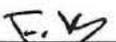
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rubber band. (b) (4) is formulated with non-pharmaceutical grade (b) (4) (b) (4). There was no label on the syringe to prevent a mix-up in using the dispensing aid for different components. There is no control on the number of uses or duration a syringe is used. Securing a syringe to a component, to be re-used to draw contents from the component, is a common practice at the firm as identical syringes were observed to be secured with a rubber band to various containers. This is a repeat observation.

**\*DATES OF INSPECTION**  
 8/30/2016 (Tue), 8/31/2016 (Wed), 9/01/2016 (Thu), 9/02/2016 (Fri), 9/19/2016 (Mon), 9/20/2016 (Tue)

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