DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office, 22215 26th Ave. SE, Suite 210, Bothell, WA 98021 Industry Information: www.fda.gov/oc/industry	09/09/21 to 09/22/21* FEI NUMBER 3011412185

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Kelly M. Shields, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Montana Compounding Pharmacy P.C.	111 N. Higgins Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Missoula, MT 59802	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

You produced highly potent and hazardous drugs without providing adequate containment, segregation, cleaning of utensils and cleaning of personnel to prevent cross-contamination. Specifically, your operations include the preparation of over (b) (4) non-sterile drug products in an approximately (b) (4) period, from (b) (4) to (b) (4).

During this period, you compounded over (b) (4) highly potent drugs such as testosterone, progesterone, and estrogen. For example, "RX# (b) (6) Bi-Est (8:2) - Progesterone - Testosterone 5 - 60 - 2.25 mg/gm (b) (4)". You also compounded over (b) (4) hazardous drugs such as Triiodo-L-Thyronine (T3) and Thyroxine(L) (T4). For example, "RX# (b) (6) Liothyronine Sodium (T3) 1:1000 (0.1%)/(b) (4)".

a) Your firm does not have controls in place to prevent contamination of the drug production area and cross-contamination of other drug products with highly potent and hazardous drugs, such as dedicated or segregated areas. All non-sterile drugs are compounded using (b) (4) work benches. These benches do not allow for the containment of (b) (4) bulk drug substances used to compound these drugs.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Sangeeta M. Khurana	Kenneth O. Gee, Investigator Sangeeta M. Khurana, Investigator	09/22/2021

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b) Your firm does not replace gowns between producing a highly potent and/or hazardous drug product and continuing to compound other drug products.

This is a repeat observation.

*DATES OF INSPECTION
09/09/2021 (Thu), 09/10/2021 (Fri), 09/13/2021 (Mon), 09/14/2021 (Tue), 09/22/2021 (Wed)

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	Sangeeta M. Khurana	Kenneth O. Gee, Investigator Sangeeta M. Khurana, Investigator	09/22/2021

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 judgement, 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."