DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
You produced highly potent drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

On 02/24/21, I observed an employee perform compounding of multiple lots of non-sterile hazardous human drug products, some of which utilized product-contact metal stir axles that were cleaned with only and expired solution between lots of different products. The first hazardous compounded drug product lot manufactured at your firm on was Estradiol 0.5mg/Estriol 0.5mg/gm vaginal cream, lot 02242021@1, during which a metal stir axle was used in the blending of the in-process ointment and was in contact with the product throughout the blending process. The stir axle was cleaned using only a bottle of solution, lot # with the expiration date of 10/19. The same day, your firm manufactured Estriol vaginal cream 2mg/0.5mg, lot 02242021@3 in the same hazardous compounding room using potentially the same stir axle.

*DATES OF INSPECTION
2/23/2021(Tue), 2/24/2021(Wed), 2/26/2021(Fri), 3/01/2021(Mon), 3/03/2021(Wed)
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 judgment, 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."