DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	2/15/2022-2/18/2022
	FEI NUMBER 3016774626

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brandi M. Chane-Lee, Owner/Certified Pharmacy Technician

FIRM NAME	STREET ADDRESS
Davis City Pharmacy Inc.	111 Trinity St
CITY, STATE, ZIP CODE, COUNTRY Weatherford, TX 76086-3358	TYPE 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 WE OBSERVED:
OBSERVATION 1

You produced highly potent drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

a) Your firm routinely compounds potent and/or hazardous non-sterile drug products (creams and capsules) containing hormones such as Progesterone or Testosterone on a counter top without procedures/systems in place to ensure containment and proper segregation of potent/hazardous drugs as well as to prevent cross contamination.
Approximately (b) (4) lots of non-sterile drug products containing Progesterone and approximately (b) (4) lots of non-sterile drug products containing Testosterone were produced from 8/15/2021 to 2/16/2022.

On 2/15/2022, we observed the non-sterile technician weigh out Testosterone (b) (4) Lot (b) (4) a potent and potentially hazardous drug substance to prepare a non-sterile compounded cream on an open counter top designated for non-sterile non-hazardous and hazardous compounding activities in the firm's compounding lab.

b) On 2/15/2022, I observed the non-sterile technician spill a small amount of Testosterone (b) (4) during the preparation of a cream. We observed (b) (6) wipe down the spill with (b) (4), (b) (4) using a paper towel and resume compounding operations. There is no scientific justification and/or assurance that the (b) (4) used is adequate to inactivate or decontaminate the hazard spill to prevent cross contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Patty P Kaewussdangkul, Investigator Steven A Brettler, Investigator	DATE ISSUED 2/18/2022

X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 02-18-2022 12: 7:01

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c) Your firm uses (b) (4) a commercially available non-pharmaceutical grade liquid detergent to clean and sanitize equipment dedicated to the production of potent/hazardous drugs. There is no scientific justification and/or assurance that the cleaning agents used to clean and sanitize equipment is appropriate to inactivate, decontaminate and/or remove the potent/hazardous drug substances from the equipment. Furthermore, the use of (b) (4) is not as effective as using (b) (4) to achieve adequate disinfection. In addition, the manufacturer of the (b) (4) recommends that it is used as a solvent for gums, shellac and essential oils.

OBSERVATION 2

Unsealed, loose ceiling tiles were observed in your non-sterile "compounding lab".

Specifically,

On 2/15/2022, exposed blue wires were observed hanging in plain sight from a loose unsealed ceiling tile of the non-sterile "compounding lab" during the preparation of your non-sterile Testosterone Cream 2%, 20mg, Lot #2002152022 with a beyond use date of 03/15/2022.

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

Your firm failed to conduct appropriate tests to determine the identity and strength of each active ingredient in the following non-sterile drug products prior to release and distribution:

- RX (b) (6) : Benzocaine 20%, Lidocaine 10%, Tetracaine 10%
  Lot #09302021, BUD:10/30/2021.

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- RX (b) (6) : Benzocaine 20%, Lidocaine 10%, Tetracaine 10%
  Lot #20101002012022, BUD: 08/01/2022.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm failed to establish microbial specifications for your finished non-sterile compounded drug products to assure that it meets the appropriate standards for microbial quality. The firm failed to perform testing/evaluate the following non-sterile drug products for microbial limits and objectionable organisms:

- Benzocaine 20%, Lidocaine 10%, Tetracaine 10%, Lot #09302021, BUD: 10/30/2021.
- Benzocaine 20%, Lidocaine 10%, Tetracaine 10%, Lot #20101002012022, BUD: 08/01/2022.

OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Your firm's production records (formula worksheets) for Benzocaine 20%, Lidocaine 10%, Tetracaine 10% cream, Lot #09302021 and Lot #20101002012022 are deficient because they do not contain the following information:

- Order of mixing ingredients
- Step by step instructions
- Procedures to ensure proper blending of particles

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- Equipment not identified used in the production of the compounded drug product.
- Settings for the (b) (4) used to mix (b) (4) and (b) (4) are not identified.

X Steven A Brettler
Investigator
Signed By: Steven A. Brettler -S
Date Signed: 02-18-2022 12:47:52

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	Patty P Kaewussdangkul, Investigator Steven A Brettler, Investigator X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 02-18-2022 12: 7:01	2/18/2022

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."