

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 9/9/2019-9/19/2019* FEI NUMBER 3010504654
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samih N. Botros, Pharmacist-in-Charge

FIRM NAME Tower Pharmacy and Compounding	STREET ADDRESS 26732 Crown Valley Pkwy, Suite 101
CITY, STATE, ZIP CODE, COUNTRY Mission Viejo, CA 92691-6306	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

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

Specifically,

- a) On 09/12/19, I observed the use of a (b) (4) set with a worn inner (b) (4) surface in the compounding of Testosterone 0.1% Gel batch 17350, for the fulfillment of prescription (b) (6). Later the same day, I observed that (b) (4) set cleaned with commercial dishwashing detergent and warm tap water and left to dry on a soiled mat made from an absorbent cloth material. Your Pharmacist-in-Charge (PIC) stated that this (b) (4) set is not product-dedicated and may potentially be used in the compounding of any high-risk drug product at the firm, including but not limited to formulations incorporating Dehydroepianrosterone (DHEA), Estriol, Estradiol, Estrone, Progesterone, and Testosterone. Your PIC also stated that your firm has not taken any actions to ensure that this cleaning method prevents the transfer of APIs from one compounded drug product to another via the abrasions on the (b) (4) inner surface.
- b) On 09/12/19, I observed the use of a metal spatula with an unsealed wood handle in the compounding of Testosterone 0.1% Gel batch 17350, for the fulfillment of prescription (b) (6). Later the same day, I observed that spatula cleaned with commercial dishwashing detergent and warm tap water and left to dry on a soiled mat made from an absorbent cloth material. Your PIC stated that this spatula is not product-dedicated and may potentially be used in the compounding of any high-risk drug product at the firm, including but not limited to formulations incorporating DHEA, Estriol, Estradiol, Estrone, Progesterone, and Testosterone. Your PIC also stated that your firm has not taken any actions to ensure that this cleaning method prevents the transfer of APIs from one compounded drug product to another via the porous handle on the spatula.
- c) On 09/10/19 and 09/12/19, I observed your PIC perform compounding of the following high-potency and non-high-potency drug products with his beard protruding below the bottom of the face mask he wore during compounding:

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	Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 09-19-2019 12:47:51 X	

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- 09/10/19: Diltiazem 2% Ointment, batch 17344, for the fulfillment of prescription (b) (6)
- 09/12/19: Testosterone 0.1% Gel, batch 17350, for the fulfillment of prescription (b) (6)

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

- a) Your firm routinely uses (b) (4) in the compounding of (b) (4) which is then incorporated into compounded drug products that are used to fill patient prescriptions. I observed the following while reviewing your firm's compounding logs:
- (b) (4) batch (b) (4), prepared 06/01/19, was used in the compounding of Lidocaine-Tetracaine 23-7% Gel batch 17152 on 06/01/19, Benzocaine-Lidocaine-Tetracaine 20-8-4% Gel batch 17154 on 06/01/19, Testosterone in (b) (4) batch (b) (4) on 06/07/19, Testosterone in (b) (4) batch (b) (4) on 06/10/19, Testosterone in (b) (4) batch (b) (4) on 06/14/19, Benzocaine-Lidocaine-Tetracaine 20-8-4% Gel batch 17186 on 06/15/19, and Benzocaine-Lidocaine-Tetracaine 5-10-5% Gel batch 17193 on 06/19/19.
 - (b) (4) batch (b) (4), prepared 06/27/19, was used in the compounding of Testosterone in (b) (4) batch (b) (4) on 06/28/19, Lidocaine-Tetracaine 23-7% Gel batch 17209 on 06/29/19, and Benzocaine-Lidocaine-Tetracaine 20-6-4% Gel batch 17210 on 06/29/19.
 - (b) (4) batch (b) (4), prepared 07/03/19, was used in the compounding of Benzocaine-Lidocaine-Tetracaine 5-10-5% Gel batch 17223 on 07/04/19, Testosterone in (b) (4) batch (b) (4) on 07/10/19, Testosterone in (b) (4) batch (b) (4) on 07/11/19, Benzocaine-Lidocaine-Tetracaine 20-6-6% Gel batch 17186 on 07/13/19, and Lidocaine 30% batch 17260 on 07/26/19.
 - (b) (4) batch (b) (4), prepared 08/14/19, was used in the compounding of Testosterone in (b) (4) batch (b) (4) on 08/14/19, and Benzocaine-Lidocaine-Tetracaine 20-8-4% Gel batch 17310 on 08/22/19.
 - (b) (4) batch (b) (4), prepared 08/29/19, was used in the compounding of Baclofen-Lidocaine-Ketoprofen 2-2-5% Gel batch 17329 on 08/29/19, Benzocaine-Lidocaine-Tetracaine 20-8-4% Gel batch 17330 on 08/30/19, Benzocaine-Lidocaine-Tetracaine 5-10-5% Gel batch 17331 on 08/30/19, Testosterone in (b) (4) batch (b) (4) on 09/03/19, and Testosterone in (b) (4) batch (b) (4) on

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09/07/19.

- b) Your firm routinely uses (b) (4) in the compounding of (b) (4), which is then incorporated into compounded drug products that are used to fill patient prescriptions. I observed the following while reviewing your firm's compounding logs:
- (b) (4) batch (b) (4), prepared 06/07/19, was used in the compounding of Testosterone 1% Gel batch 17164 on 06/07/19, Testosterone 0.2% Gel batch 17165 on 06/07/19, Estradiol 2mg/gm batch 17173 on 06/10/19, Progesterone 150mg/gm batch 17174 on 06/10/19, Testosterone 1% Gel batch 17175 on 06/10/19, Testosterone 2% Gel batch 17179 on 06/11/19, Testosterone 3% Gel batch 17196 on 06/21/19, and Testosterone 1% Gel batch 17197 on 06/21/19.
 - (b) (4) batch (b) (4), prepared 07/02/19, was used in the compounding of Testosterone 75mg/gm batch 17213 on 07/02/19, Testosterone 1% Gel batch 17219 on 07/03/19, Testosterone 1% Gel batch 17225 on 07/05/19, Testosterone 1% Gel batch 17230 on 07/09/19, Progesterone 150mg/gm batch 17236 on 07/11/19, Estradiol 2mg/gm Cream batch 17237 on 07/11/19, and Testosterone 0.25% Gel batch 17246 on 07/16/19.
 - (b) (4) batch (b) (4), prepared 07/17/19, was used in the compounding of Testosterone 45% Cream batch 17249 on 07/17/19, Testosterone 1% Gel batch 17258 on 07/26/19, and Testosterone 0.4% Gel batch 17265 on 07/31/19.
 - (b) (4) batch (b) (4), prepared 08/06/19, was used in the compounding of Testosterone 1% Gel batch 17274 on 08/06/19, Progesterone 1% Gel batch 17279 on 08/08/19, Progesterone 150mg/gm batch 17280 on 08/08/19, Estradiol 2mg/gm batch 17281 on 08/08/19, Testosterone 1% Gel batch 17284 on 08/09/19, Testosterone 1% Gel batch 17285 on 08/12/19, Testosterone 1% Gel batch 17290 on 08/14/19, Testosterone 1% Gel batch 17305 on 08/20/19, Testosterone 3% Gel batch 17318 on 08/27/19, and Testosterone 0.25% Gel batch 17319 on 08/27/19.
 - (b) (4) batch (b) (4), prepared 09/07/19, was used in the compounding of Testosterone 2% Gel batch 17342 on 09/07/19, and Testosterone 1% Gel batch 17348 on 09/10/19.
- c) Your firm routinely uses (b) (4) in the compounding of (b) (4), which is then incorporated into compounded drug products that are used to fill patient prescriptions. I observed the following while reviewing your firm's compounding logs:
- (b) (4) batch (b) (4), prepared 06/06/19, was used in the compounding of Hydroquinone-Retinoic Acid-Kojic Acid-Hydrocortisone 8-0.025-4-1% batch 17162 on 06/07/19.
 - (b) (4) batch (b) (4), prepared 07/10/19, was used in the compounding of Hydroquinone-Fluocinolone-Retinoic Acid 6-0.01-0.05% batch 17234 on 07/10/19, and Kojic Acid-Niacinamide 5-10%

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batch 17240 on 07/11/19.

- (b) (4) batch (b) (4), prepared 07/25/19, was used in the compounding of Triple Bleaching Cream batch 17259 on 07/26/19, Tranexamic Acid 5% batch 17263 on 07/31/19, Kojic Acid-Hydroquinone-Niacinamide 5-5-10% batch 17271 on 08/02/19, Hydroquinone-Tretanoin-Fluorocinolone 6-0.05-0.01% batch 17276 on 08/06/19, and Hydroquinone-Kojic Acid-Vitamin E 12-5-5% batch 17282 on 08/08/19.

***DATES OF INSPECTION**

9/09/2019(Mon), 9/10/2019(Tue), 9/11/2019(Wed), 9/12/2019(Thu), 9/17/2019(Tue), 9/19/2019(Thu)

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