





**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

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%

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator	Christopher R Czajka Investigator Signed By: Christopher R. Czajka Date Signed: 09-19-2019 12:47:51 X	DATE ISSUED 9/19/2019

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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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