	TH AND HUMAN SERVICES G ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild	9/9/2019-9/19/2019*
Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	FEI NUMBER 3010504654
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Samih N. Botros, Pharmacist-in-Charge	
FIRM NAME	STREET ADDRESS
Tower Pharmacy and Compounding	26732 Crown Valley Pkwy, Suite 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mission Viejo, CA 92691-6306	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,

- set with a worn inner (b) (4) surface in the a) On 09/12/19, I observed the use of a (b) (4) 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.
- 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.
- 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:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Christopher R Czajka,	Investigator	Christopher R Czajka Investigator Signed By: Christopher R. Czajka X Date Signed: 00-19-2019 12:47:51	DATE ISSUED 9/19/2019
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVA	TIONS	PAGE 1 of 4 PAGES

		ALTH AND HUMAN SERVIC	ES		
DISTRICT ADDRESS AND PHONE NU	FOOD AND DRUG ADMINISTRATION HONE NUMBER  FOOD AND DRUG ADMINISTRATION DATE(S) (		E(S) OF INSPECTION		
19701 Fairchild			19-9/19/2019*		
Irvine, CA 9263			4654		
(949)608-2900 I	Fax: (949)608-4417	301000	1001		
NAME AND TITLE OF INDIVIDUAL TO	WHOM REPORT ISSUED				
	s, Pharmacist-in-Charge				
Tour Pharmagy	and Compounding	street ADDRESS 26732 Crown Val	low Dkwy Cuito	101	
CITY, STATE, ZIP CODE, COUNTRY	and compounding	TYPE ESTABLISHMENT INSPECTED	rey rkwy, Suite	. 101	
Mission Viejo,	CA 92691-6306	Compounding Pharmacy			
09/12/19: T  OBSERVATION  You used a non-ph	estosterone 0.1% Gel, batch 1735  2 narmaceutical grade component	0, for the fulfillment of p	rescription(b) (6)		
Specifically,					
following while  (b) (4) 23-7% Gel 1 06/01/19, To (b) (4) on 06 Tetracaine 2 batch 17193  (b) (4) (b) (4) Benzocaine  (b) (4) Lidocaine-Ton 07/10/19 20-6-6% Ge  (b) (4) (b) (4) (c) (4) (d) (d) (d) (d) (e) (e) (e) (f) (f) (f) Ketoprofen	batch (b) (4), prepared 06/2 batch 17152 on 06/01/19, Benzocaestosterone in (b) (4) batch 5/10/19, Testosterone in (b) (4) batch 17186 on 06/13 on 06/19/19.  batch (b) (4), prepared 06/2 batch (b) (4) on 06/28/19, Lidocae-Lidocaine-Tetracaine 20-6-4% Gestach (b) (4), prepared 07/05 batch (b) (4), prepared 08/18 batch 17186 on 07/13/19, and Lestach 17186 on 07/13/19, and Lestach (b) (4), prepared 08/19 batch (b) (4) on 08/14/19, and Batch (b) (4), prepared 08/20-2-2-5% Gel batch 17329 on 08/29/28/30/19, Benzocaine-Lidocaine-Testach 17329 on 08/29/28/30/19	ing logs: 01/19, was used in the coaine-Lidocaine-Tetracain (b) (4) on 06/07/19, Tebatch (b) (4) on 06/1 5/19, and Benzocaine-Li 07/19, was used in the coaine-Tetracaine 23-7% Cel batch 17210 on 06/29 03/19, was used in the coaine-Tetracaine 23 on 07/04/19, Testoste ch (b) (4) on 07/11/19, Bidocaine 30% batch 1720 04/19, was used in the coenzocaine-Lidocaine-Tetracaine-Tetracaine-Tetracaine-Tetracaine-Tetracaine-Tetracaine-Tetracaine-Tetracaine-Tetracaine-Lidocaine-Tetracaine-Lidocaine-Tetracaine-Lido	mpounding of Lidocate 20-8-4% Gel batestosterone in (b) (4) 4/19, Benzocaine-L docaine-Tetracaine mpounding of Tester fiel batch 17209 on (7) 4/19. Impounding of Benzocaine-Lidocaine in (b) (4) mpounding of Tester fiel batch 17209 on (7) 4/19. Impounding of Tester fiel batch 17209 on (8) 60 on 07/26/19. Impounding of Tester fiel batch 17331 on 08/30 mpounding of Backetine-Tetracaine 20-8-atch 17331 on 08/30	caine-Tetracaine ch 17154 on batch idocaine- 5-10-5% Gel osterone in 06/29/19, and cocaine- batch (b) (4) ne-Tetracaine osterone in el batch 17310 ofen-Lidocaine4% Gel batch	
	PLOYEE(S) SIGNATURE hristopher R Czajka, Inve	stigator	Christopher R Czajka Investigator Signed By: Christopher R Czajka X - Date Signed: 09-19-2019 12:47:51	DATE ISSUED 9/19/2019	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE I	NSPECTIONAL OBSERVATI	ONS	PAGE 2 of 4 PAGES	

	F HEALTH AND HUMAN SERVICES ND DRUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild	DATE(s) OF INSPECTION 9/9/2019-9/19/2019*
Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417	FEINUMBER 3010504654
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Samih N. Botros, Pharmacist-in-Charge	е
FIRM NAME	STREET ADDRESS
Tower Pharmacy and Compounding	26732 Crown Valley Pkwy, Suite 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mission Viejo, CA 92691-6306	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 compo	
	7/19, was used in the compounding of Testosterone 1% Gel
	2% Gel batch 17165 on 06/07/19, Estradiol 2mg/gm batch
	gm batch 17174 on 06/10/19, Testosterone 1% Gel batch 17175
기계에 가는 옷을 먹는 것이다면 하는 가장을 되어 가고 있으면 가장 하는 아니라 하는 것이다. 그렇게 하는 것이다. 그렇게 하는 것이다. 그렇게 하는 것이다. 그렇게 하는 것이다.	5.1명 (C. T.), '라마마마마마 (C. B.) (C. B.), '라마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마마
1942년 전경 경우 프랑지엄 (1977년 1914년 - 1912년 - 1914년 - 1917년 1917년 - 1	17179 on 06/11/19, Testosterone 3% Gel batch 17196 on
06/21/10 and Testasterone 1% Gal hatch	17107 on 06/21/10

- (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%

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Christopher R Czajka,	Investigator	Clussoppher R Czajka Investigator Signet Byr, Christopher R. Czajka S Date Signad: 09-19-2019 12-47:51	DATE ISSUED 9/19/2019
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSER	EVATIONS	PAGE 3 of 4 PAGE

	DEPART		TH AND HUMAN ADMINISTRATION			
DISTRICT ADDRESS AND PHO		POOD AND DRUG	DA	ATE(S) OF INSPECTION		
19701 Fairch				9/9/2019-9/19/2019*		
Irvine, CA 9			1580	FEI NUMBER 3010504654		
(949) 608-290	Fax: (949) 608-4417			0010001001		
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Samih N. Bot:	ros, Pharmacist-in-	-Charge	I american	18		
	cy and Compounding		26732 Crown Valley Pkwy, Suite 101		101	
CITY, STATE, ZIP CODE, COUN			TYPE ESTABLISHMENT I			
Mission Viej	o, CA 92691-6306		Compoundin	g Pharmacy		
• (b) (4) Cream by Hydroque 6-0.05-0 on 08/08	atch 17259 on 07/26/19, inone-Niacinamide 5-5-1.01% batch 17276 on 08//19.	Tranexamic A 0% batch 172	eid 5% batch 1 71 on 08/02/19	, Hydroquinone	9, Kojic Ac -Tretanoin-I	id- Fluorocinolon
DATES OF I 0/09/2019(Mon	<b>NSPECTION</b> ), 9/10/2019(Tue), 9/11	1/2019(Wed)	, 9/12/2019(T	hu), 9/17/2019	(Tue), 9/19	7/2019(Thu)
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() Silver	2000 mg - 100 mg - 10			_1/2		
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ORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INS	PECTIONAL OBS	ERVATIONS		PAGE 4 of 4 PAGES

INSPECTIONAL OBSERVATIONS

FORM FDA 483 (09/08)