

**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 4/9/2018-4/18/2018*
	FEI NUMBER 3014332926

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shar Shahrzad Bahri Eshraghi, Owner

FIRM NAME Medlife Pharmacy and Compounding	STREET ADDRESS 6644 Irvine Center Dr
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CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92618-2117	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drugs
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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:
PRODUCTION**

OBSERVATION 1

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm assigns BUD for the drug products produced at your firm with no stability program conducted for the product. For example, you produced Dexamethasone Sodium Phosphate 24mg/mL 10ml/vial (RX #s (b) (6) and (b) (6) - lot #s 3398, 31292, 3260, 3222, 3693, 3511- between (b) (4) and (b) (4)) and assigned one month expiration date at room temperature with no stability data to support one month stability at room temperature.

OBSERVATION 2

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your firm does not have adequate separation or other control systems to ensure preventing cross-contamination of non-potent product and potent products. Your firm produces all drug products in your firm's only hood, using the same balance ((b) (4)) and mixed use containers and utensils. For example, your worksheet shows that your firm produced opioid, hormones, and non-potent products in the same hood using the shared equipment and utensils.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Yasamin Ameri, Chemist/Biologist Taichun Qin, Generic Drug User Fee Amendments (GDUFA)	DATE ISSUED 4/18/2018
	X Yasamin Ameri Chemist/Biologist Signed By: 2011685859 Date Signed: 04-18-2018 12:52:31 <i>Taichun Qin</i>	

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically, Dexamethasone Sodium Phosphate 24mg/ml produced by your firm from (b) (4) to (b) (4) were not manufactured to be sterile as required.

OBSERVATION 4

Records are not kept for the maintenance, cleaning, sanitizing and inspection of equipment.

Specifically, your firm does not always have cleaning records showing cleaning after production of each lot of drug products. Between January 2018 to April 2018, your firm produced (b) (4) drug products to include; opioid, hormones, and non-potent drug products inside your facility's only laminar flow hood (b) (4). Your cleaning log shows that you performed (b) (4) cleaning at the (b) (4); however, cleaning activities and line clearance between the batches of drug produced are not always recorded on the formula worksheet.


OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, your firm does not perform a microbial test required to determine the microbial limit for any of the drug products produced at your firm (e.g. Dexamethasone Sodium Phosphate 24mg/mL).

OBSERVATION 6

The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

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Specifically, your firm has not validated the mixing process and does not perform examination of the mixed drug products to ensure uniformity and homogeneity of the manufactured drug products. Your examination is limited to visual verification. (e.g. Lidocaine 23% Tetracaine 7%).

OBSERVATION 7

Each lot of a component liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically, your firm uses (b) (4), in formulation and production of drug products with no microbial analysis to ensure that it meets the quality of the water required for production of non-sterile drug products.

OBSERVATION 8


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

Specifically, your firm does not perform any testing on the finished product to ensure they meet the potency required by the formulation. For example, you produced Lidocaine 23% Tetracaine 7%; and released it for use with no testing to ensure the product has the required potency.

EQUIPMENT

OBSERVATION 9

The calibration of instruments is not done at suitable intervals.

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Specifically, your firm uses equipment which are either never been calibrated or have expired calibration. For example, you use micro-analytical balance (no eq. id) to weight the drug substances (e.g Dexamethasone Sodium Phosphate) and excipients for producing drug products with expired calibration; and three thermometers (no eq. id) which never calibrated; for monitoring the temperature of (b) (4) refrigerators and a freezer that store raw materials (bulk substances and excipient), and finished drug products.

OBSERVATION 10

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm uses only tap water for both washing and final rinse of containers and utensils which are used for production of drug products produced at your firm.

***DATES OF INSPECTION**

4/09/2018(Mon), 4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 4/16/2018(Mon), 4/17/2018(Tue), 4/18/2018(Wed)

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