

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

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	DATE(S) OF INSPECTION 2/12/2019-2/22/2019*
	FEI NUMBER 1456985

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tony L. Jones, President/Pharmacist-In-Charge

FIRM NAME John's Pharmacy Inc.	STREET ADDRESS 102 E Harrison St
CITY, STATE, ZIP CODE, COUNTRY Sullivan, IL 61951-2002	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drugs

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

Specifically,

(b) (4) water produced by your (b) (4) system, (b) (4) has never been tested for microbial quality, nor are maintenance records maintained for (b) (4) (b) (4). This (b) (4) water is used in production of several drug products and bulk (b) (4), which is also used in the production of drug products. For example, the following prescriptions for drug products were produced with this (b) (4) water:

- (b) (4) 10mg/mL suspension for Rx # (b) (6) on 01/15/2019
- Chlorpromazine 100mg/mL liquid for Rx # (b) (6) on 11/26/2018

OBSERVATION 2

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Constantin Y Philopoulos, Investigator	Constantin Y Philopoulos Investigator Signed by Constantin M. Philopoulos-S Date Signed 02-22-2019 09:53:10 X _____	DATE ISSUED 2/22/2019

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Specifically,

Work surfaces and drug product production equipment, such as spatulas, mortars/pestles, beakers, an (b) (4) mortar/pestle, balances, and capsule filling machines, are not rinsed with qualified (b) (4) (b) (4) water and/or with appropriate sanitizing agents after cleaning with a (b) (4) cleaner agent or (b) (4) soap/hot water, respectively. For example, only (b) (4) soap/hot water was observed to be used to clean and rinse production equipment/utensils after production of the following prescription drug products:

- Zonisamide 10mg/mL suspension for Rx # (b) (6) on 02/13/2019
- Triamcinolone Acetonide 0.025% medicated Cerave cream for Rx # (b) (6) on 02/13/2019

Additionally, a (b) (4) cleaning agent spray was observed to be used in wiping the counter top and balance surfaces before and after production of each of these prescription (Rx) drug products.

***DATES OF INSPECTION**

2/12/2019(Tue), 2/13/2019(Wed), 2/22/2019(Fri)

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