

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

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 08/27/2015 - 09/30/2015*
	FEI NUMBER 3003348498

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ms. Suja Alum, Pharmacist-In-Charge

FIRM NAME Pharmacy Creations	STREET ADDRESS 540 Route Ten West
CITY, STATE, ZIP CODE, COUNTRY Randolph, NJ 07869	TYPE ESTABLISHMENT INSPECTED Producer of 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 WE OBSERVED:

OBSERVATION 1

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically, there is lack of potency and sterility assurance for non-preserved sterile preparations in that beyond use dates, up to 180 days, are assigned without supporting testing. Examples of products include:

Sterile Product Name	Strength	Units	Unit Volume	Beyond Use Date
Preservative Free Triamcinolone Acetonide/Moxifloxacin HCl/Vancomycin Injection (ophthalmology)	15/1/10 mg/mL	(b) (4) units	1 mL	180 days
Dexamethasone-Moxifloxacin HCl Injection (ophthalmology)	1/5 mg/mL	(b) (4) units	1 mL	180 days
Povidone Iodine Ophthalmic Solution	5 %	(b) (4) units	1 mL	180 days
Hyaluronidase Bovine Single Dose Vial (ophthalmology)	175 U/mL 300 U/mL	(b) (4) units (b) (4) units	2 mL 2 mL	180 days 180 days
Vancomycin Injection (ophthalmology)	10 mg/mL	(b) (4) units	1 mL	180 days
Phentolamine/Papaverine/Prostaglandin E1 Injection (urology)	0.5/10/0.005 mg/mL 1/15/0.01 mg/mL 1/15/0.02 mg/mL	(b) (4) units (b) (4) units (b) (4) units	0.5 mL 0.5 mL 0.5 mL	180 days 180 days 180 days
Heparin Sodium/Lidocaine HCl Bladder Irrigation Solution - Prefilled Syringes (urology)	3,300 units/mL 13.25 mg/mL	(b) (4) units	20 mL	180 days

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Helen Verdell, Investigator <i>Helen Verdell</i> Michael R. Klupal, Investigator <i>Michael R. Klupal</i>	DATE ISSUED 09/30/2015
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OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, non-viable particulate monitoring is limited to (b) (4) during the certification of the ISO-5 (b) (4). There is no periodic monitoring of non-viable particulates during the aseptic fill process of batches that may include up to (b) (4) units.

In addition, daily viable monitoring including surface monitoring, settling plates, and personnel monitoring is not performed.

OBSERVATION 3

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

Specifically, your endotoxin reduction study for vials is inadequate in that there is no scientific justification for (b) (4).

Additionally;

a.) No recovery studies were performed to determine if a known quantity of endotoxin could be recovered from the vials.

b.) The (b) (4)

c.) The vials were then (b) (4). The vials were subsequently sent to an outside laboratory for sterility and endotoxin testing.

d.) No signed protocol or report was generated for this study. There is no established acceptance criteria, no discussion of the results, or documentation of any deviations that may have occurred during the study. Only the laboratory testing results were provided showing passing results for each of the sample vials.

* DATES OF INSPECTION:
08/27/2015(Thu), 08/28/2015(Fri), 08/31/2015(Mon), 09/02/2015(Wed), 09/03/2015(Thu), 09/28/2015(Mon), 09/30/2015(Wed)

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