DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	08/26/2015 - 09/29/2015* FEI NUMBER 3001779702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Anthony Grzib, R.Ph., Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Wedgewood Village Pharmacy, Inc.	405 Heron Drive Suite 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Swedesboro, NJ 08085-1749	Producer of Sterile and Non-Sterile Drug Products

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:

For the processing of sterile and non-sterile human and veterinary drug products that are distributed throughout the US and Puerto Rico, such as Tri-Mix Standard (PPP) 5.88 mcg/18mg/0.6/mg/ml in AQ vehicle Injection 5ml (Batch ID 000-00414351, Use By 6/22/16); 40 mg Propranolol Capsules (Batch ID 000-00427987 Use by 11/29/15); Omeprazole 2 mg/ml Oral Suspension (Batch ID 000-00491229 Use by 11/29/15):

OBSERVATION 1

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

Specifically, your previous FDA inspection in 2/2013 cited a lack of raw material and finished product testing. Your firm did not fully implement corrective and preventative actions. You continue to formulate your drug products without verifying that you are receiving valid certificates of analysis (C of As). You have not fully qualified your suppliers by periodically having a lot of the Active Pharmaceutical Ingredient (API) analyzed and you are not performing at least one unique identity test to assure that there were no product label mix-ups by the supplier. Your firm only tests a small percentage of your finished products for potency.

In 6/2013 your firm recalled veterinary drug products that your firm prepared and labeled as containing Trimeprazine (as Tartrate) 5mg/capsule (e.g. Batch ID 200-20120620 Use By 615/13) that did not contain the API Trimeprazine Tartrate USP. You only detected the problem with the Trimeprazine Tartrate API because the API manufacturer's C of A included a retest date of July 2013 and you wanted to extend the shelf life for your inventory balance of this lot of API. You had two contract laboratories analyze the API and both confirmed that the API was not Trimeprazine Tartrate USP. One of the laboratories determined that it was actually tartaric acid.

OBSERVATION 2

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

Specifically, your environmental monitoring of cleanroom operations is not generating enough data to be statistically

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significant to provide assurance that your cleanroom is operating in a continuous state of control. By your estimates your firm's cleanroom is processing approximately 20 batches of drug product a day (from 10 to about 1500 units per batch). For example:

(A) Your environmental monitoring of cleanroom operators is limited to monitoring their gloved hands once every six months. Your procedures also do not require the operator's gowning attire to be monitored. Your operator's arms repeatedly enter the critical ISO-5 area to aseptically manipulate sterile drug products. Their upper bodies periodically lean into the ISO-5 area to clean and sanitize the laminar flow hood and to suspend drug products and components from the overhead hooks.

(B) You only monitor the cleanroom air quality for non-viable particles once every six months, as part of your re-certification program for your laminar flow hoods and the HEPA filters in the ceiling.

(C) You only monitor the cleanroom air quality for viable air particle counts and cleanroom contact surfaces for microbial contamination once a month.

OBSERVATION 3

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

Specifically,

(A) Your media fills performed to evaluate whether sterile drugs and sterile components can be aseptically processed are not factoring in complex operations or worse-case conditions.

(B) Your smoke studies performed to evaluate whether the design and set-up of your aseptic processing operations create turbulence in the unidirectional HEPA filtered airflow and potentially compromising the sterile drug processing operations were not performed under fully dynamic conditions, which simulated complex aseptic processes.

OBSERVATION 4

Clothing of personnel engaged in the processing and packing of drug products is not appropriate for the duties they perform.

Specifically, your cleanroom gowning procedure potentially compromises the integrity of the sterile gowns used to form a barrier between the cleanroom operators and the ISO 5 critical work area where sterile drug products are aseptically manipulated in HEPA filtered laminair flow hoods. Your operators wash and sanitize their hands but then they handle the outsides of the sterile gowns (and sleeves) with their bare hands. Then they don a pair of sterilized gloves.

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OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm failed to fully investigate and document the decisions and corrective actions taken after a storm abruptly shut down power for two days in June 2015. You had work in-process when the power went out, your cleanrooms lost ventilation and their positive pressure gradient, and your refrigerators and freezers warmed to ambient temperature with drug substances, work-in-process materials, and finished drug products inside them.

OBSERVATION 6

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, after the previous FDA inspection in 2/2013, your firm initiated a program to assure that your cleaning procedures were effectively removing the drug residue from multi-use equipment prior to using that equipment to process the next drug product. Your protocol (plan) based primarily on drug solubility and total organic carbon (TOC) analysis did not address a number of critical parameters, e.g. the potency of certain drug products if left on equipment in trace amounts, the effectiveness of the swab recovery method and the meaningfulness of the data collected. A final report summarizing whether the plan was effective was not completed or could not be located. A plan was not established for periodic monitoring of cleaning effectiveness.

*** DATES OF INSPECTION:**
08/26/2015(Wed), 08/27/2015(Thu), 08/28/2015(Fri), 08/31/2015(Mon), 09/01/2015(Tue), 09/02/2015(Wed), 09/08/2015(Tue), 09/09/2015(Wed), 09/10/2015(Thu), 09/11/2015(Fri), 09/18/2015(Fri), 09/29/2015(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Russell J. Glapion, Investigator Russell Glapion	09/29/2015