

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

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115		9/24/2018 – 9/27/2018	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER	
David L. Reed, President / Owner		3014522595	
FIRM NAME	STREET ADDRESS		
Reed Pharmacy, Inc.	118 South Broadway		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Sterling, KS 67579	Producer of Nonsterile 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

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable identity, strength, quality, and purity at the time of use.

Specifically,


You have not performed stability studies and consequently do not have data to support the expiration date assigned to your finished drug product LET (Lidocaine, Epinephrine, Tetracaine) topical solution. You stated the customer may store it refrigerated for 6-months. You have produced LET topical solution four times since 02/2017. LET topical solution is indicated for anesthesia of lacerations, to include children.

OBSERVATION 2

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically,

You incorporate food grade Sodium Metabisulfite, lot # (b) (4) into your finished drug product LET (Lidocaine, Epinephrine, Tetracaine) topical solution. The Sodium Metabisulfite does not have an

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expiration date and you can not determine how long you have used it. You do not have scientifically justified data to support this product meets release or stability requirements.

OBSERVATION 3

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

Specifically,

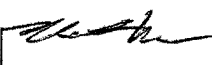
You do not test any of your drug products quality, strength or purity before they are released. You have produced and distributed the following products: LET (Lidocaine, Epinephrine, Tetracaine) topical solution; Eucerin / TMC 0.1% Cream 1:1 (Triamcinolone, Eucerin); Canker Sore Rinse (Nystatin, Prednisone, Diphenhydramine, Tetracycline) and others since 07/2018.

OBSERVATION 4

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,

You clean your product contact compounding surfaces with botanical cleaner and / or soap and water. You do not have scientific justification ensuring these direct product contact surfaces are free from

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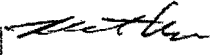
contamination prior to use. Products made utilizing these surfaces include but are not limited to Eucerin / TMC 0.1% Cream 1:1 (Triamcinolone, Eucerin); Triple Nipple Ointment (Nystatin, Betamethasone, Mupirocin); etc.

OBSERVATION 5

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing.

Specifically,

You do not have production records which require elements such as the order of introduction of each component, descriptions of containers and closures used, weighing of components, in-process steps or inspections of your product(s). Products made without records include but are not limited to LET (Lidocaine, Epinephrine, Tetracaine) topical solution.

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