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
	FEI NUMBER 3014522595

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David L. Reed, President / Owner

FIRM NAME	STREET ADDRESS
Reed Pharmacy, Inc.	118 South Broadway
CITY, STATE, ZIP CODE, COUNTRY Sterling, KS 67579	TYPE ESTABLISHMENT INSPECTED 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

SEE REVERSE OF THIS PAGE	Robert J Ham, Investigator		9/27/2018

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
	FEI NUMBER 3014522595
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED David L. Reed, President / Owner	
FIRM NAME Reed Pharmacy, Inc.	STREET ADDRESS 118 South Broadway
CITY, STATE, ZIP CODE, COUNTRY Sterling, KS 67579	TYPE ESTABLISHMENT INSPECTED Producer of Nonsterile Drugs

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 distibuted 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

SEE REVERSE OF THIS PAGE	Robert J Ham, Investigator		9/27/2018

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 FEI NUMBER 3014522595
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
David L. Reed, President / Owner	
FIRM NAME Reed Pharmacy, Inc.	STREET ADDRESS 118 South Broadway
CITY, STATE, ZIP CODE, COUNTRY Sterling, KS 67579	TYPE ESTABLISHMENT INSPECTED Producer of Nonsterile Drugs

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.

SEE REVERSE OF THIS PAGE	Robert J Ham, Investigator		9/27/2018