

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100		DATE(S) OF INSPECTION 3/6/2018-3/13/2018* FEI NUMBER 3013935808
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ms. Jennifer K. Handsaker, Head Pharmacist		
FIRM NAME Rocky Mountain Pharmacy Inc	STREET ADDRESS 25 N Willson Ave Ste C	
CITY, STATE, ZIP CODE, COUNTRY Bozeman, MT 59715-3580	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Dfug Products	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p> <p>OBSERVATION 1 Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.</p> <p>Specifically, cleaning procedures used between different operations are deficient and lack thoroughness to ensure complete cleaning has occurred.</p>		
<p>OBSERVATION 2 Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.</p> <p>Specifically, (b) (4) water used in the formulation of emollient creams, oral suspensions, and (b) (4) (b) (4) base is not tested for microbiological content by either your firm or the (b) (4) water manufacturer.</p>		
<p>*DATES OF INSPECTION 3/06/2018(Tue), 3/07/2018(Wed), 3/08/2018(Thu), 3/13/2018(Tue)</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nayan J Patel, Investigator	DATE ISSUED 3/13/2018
		<p>Nayan J Patel Investigator Signed By: 2001058019 Date Signed: 03-13-2018 16:13:41</p> <p>X</p>
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
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