

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134		DATE(S) OF INSPECTION 8/6/2018-8/15/2018* FBI NUMBER 3005070479			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kevin R. Dillon, Chief Pharmacy Officer					
FIRM NAME Mayo Clinic Pharmacy		STREET ADDRESS 21 2nd St Sw			
CITY, STATE, ZIP CODE, COUNTRY Rochester, MN 55905-0001		TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile 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 WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.</p> <p>Specifically,</p> <p>During the certification by your third-party contractor on 10/30/2017, there were 73 CFUs found in the viable air sample inside your (b) (4) ISO 5 compounding hood and no identification of the CFUs were done and no evaluation of drug impact were conducted at the time.</p>					
<p>OBSERVATION 2</p> <p>Non-microbial contamination was observed in your production area.</p> <p>Specifically,</p>					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Tenzin Jangchup, Investigator James K Ireland, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> <div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -35 Date Signed: 08-15-2018 09:23:24 X </div> </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Tenzin Jangchup, Investigator James K Ireland, Investigator	<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -35 Date Signed: 08-15-2018 09:23:24 X </div>
EMPLOYEE(S) SIGNATURE Tenzin Jangchup, Investigator James K Ireland, Investigator	<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -35 Date Signed: 08-15-2018 09:23:24 X </div>				
DATE ISSUED 8/15/2018					

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134		DATE(S) OF INSPECTION 8/6/2018-8/15/2018* FEI NUMBER 3005070479			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kevin R. Dillon, Chief Pharmacy Officer					
FIRM NAME Mayo Clinic Pharmacy		STREET ADDRESS 21 2nd St Sw			
CITY, STATE, ZIP CODE, COUNTRY Rochester, MN 55905-0001		TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Products			
<p>a) On 8/7/2018, during the sterile production of an amphotericin B 0.15% ophthalmic solution, lot #R1419080718, we observed rust on the wheels of the cart located inside the clean room (ISO 7) adjacent to the (b) (4) ISO 5 hood.</p> <p>b) On 8/10/2018, during the (b) (4) cleaning of the (b) (4) ISO 5 hood, we observed duct tape attached to a power cord on the front right side of the (b) (4) ISO 5 hood.</p>					
<p>OBSERVATION 3 Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.</p> <p>Specifically,</p> <p>On 8/10/18, during your (b) (4) cleaning of your (b) (4) ISO 5 hoods, we observed the operator use a non sterile chemical disinfectant inside the ISO 5 classified hoods with sterile wipes.</p>					
<p>OBSERVATION 4 Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.</p> <p>Specifically,</p> <p>The sporicidal agent used in your ISO 5 area requires a contact time of (b) (4) minutes in order to eliminate spores. Your current procedure, SOP 7.012 Sporicide Hood Cleaning - (b) (4) Cleaning, states that the sporicide is applied (b) (4), with a total wet contact time of (b) (4) application.</p>					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Tenzin Jangchup, Investigator James K Ireland, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -SS Date Signed: 08-15-2018 09:23:24 </div> <div style="font-size: 2em; font-weight: bold; margin-top: 5px;">X</div> </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Tenzin Jangchup, Investigator James K Ireland, Investigator	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -SS Date Signed: 08-15-2018 09:23:24 </div> <div style="font-size: 2em; font-weight: bold; margin-top: 5px;">X</div>
EMPLOYEE(S) SIGNATURE Tenzin Jangchup, Investigator James K Ireland, Investigator	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -SS Date Signed: 08-15-2018 09:23:24 </div> <div style="font-size: 2em; font-weight: bold; margin-top: 5px;">X</div>				
FORM FDA 483 (09/08)		INSPECTIONAL OBSERVATIONS			
<small>PREVIOUS EDITION OBSOLETE</small>		PAGE 2 of 3 PAGES			

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

DISTRICT ADDRESS AND PHONE NUMBER

250 Marquette Ave, Ste. 600
Minneapolis, MN 55401
(612) 334-4100 Fax: (612) 334-4134

DATE(S) OF INSPECTION

8/6/2018-8/15/2018*

FEI NUMBER

3005070479

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kevin R. Dillon, Chief Pharmacy Officer

FIRM NAME

Mayo Clinic Pharmacy

STREET ADDRESS

21 2nd St Sw

CITY, STATE, ZIP CODE, COUNTRY

Rochester, MN 55905-0001

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile and Non-Sterile
Products

OBSERVATION 5

No endotoxin testings are done for multi-dose products which are not produced with a preservative to ensure product sterility.

Specifically,

On 8/7/2018, we observed the production of amphotericin B 0.15% ophthalmic solution, lot #R1419080718, was produced without an addition of a preservative and labeled with a beyond use date of seven days refrigerated with no testing of endotoxin conducted.

***DATES OF INSPECTION**

8/06/2018(Mon), 8/07/2018(Tue), 8/08/2018(Wed), 8/09/2018(Thu), 8/10/2018(Fri), 8/15/2018(Wed)

X James K Ireland
Investigator
Signed By: James K. Ireland -S
Date Signed: 08-15-2018 09:24:00

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Tenzin Jangchup, Investigator
James K Ireland, Investigator

X Tenzin Jangchup
Investigator
Signed By: Tenzin Jangchup -S
Date Signed: 08-15-2018 09:23:24

DATE ISSUED

8/15/2018