#### DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 8/6/2018-8/15/2018\* 250 Marquette Ave, Ste. 600 FEINUMBER Minneapolis, MN 55401 3005070479 (612) 334-4100 Fax: (612) 334-4134 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kevin R. Dillon, Chief Pharmacy Officer FIRM NAME STREET ADDRESS Mayo Clinic Pharmacy 21 2nd St Sw TYPE ESTABLISHMENT INSPECTED CITY, STATE, ZIP CODE, COUNTRY Rochester, MN 55905-0001 Producer of Sterile and Non-Sterile 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 WE OBSERVED: OBSERVATION 1

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.

Specifically,

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.

### **OBSERVATION 2**

Non-microbial contamination was observed in your production area.

Specifically,

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	DEPARTMENT OF HEAL	TH AND HUM	IAN SERVICES	
443	FOOD AND DRU	G ADMINISTRATI	TION	
DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600			DATE(S) OF INSPECTION 8/6/2018-8/15/2018*	
Minneapolis,		FEINUMBER		
(612)334-4100 Fax: (612)334-4134			3005070479	
NAME AND TITLE OF INDIVIDUA	I TO WHOM DEPORT ISSUED			
SECTION OF SECTION	on, Chief Pharmacy Officer			
FIRM NAME		STREET ADDRESS		
Mayo Clinic E	Clinic Pharmacy 21 2nd			
Rochester, M		Products	r of Sterile and Non-Sterile	
#R1419080718, adjacent to the b) On 8/10/2018	we observed rust on the wheels of (b) (4) ISO 5 hood.	the cart location (b) (4) ISO	cin B 0.15% ophthalmic solution, lot cated inside the clean room (ISO 7)  5 hood, we observed duct tape attached to	
The state of the s	ing your (b) (4) cleaning of your (b) (4) disinfectant inside the ISO 5 classi	A. W. S. Land Hell Lin (2001) (1915) (1916) (1917)	ods, we observed the operator use a non with sterile wipes.	
그렇게 하게 되는 생각이 있었다면 가능하게 되었는데, 이번 때 아니다.			overage of the item being disinfected were	
Specifically,				
	rrent procedure, SOP 7.012 Sporici	ide Hood Cl	et time of (b) (4) minutes in order to eliminate leaning - (b) (4) Cleaning, states that the contact time of (b) (4)	
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Tenzin Jangchup, Investigat James K Ireland, Investigat		Terron Jangdrup Terron Jangdrup Terron Jangdrup Terron Jangdrup Seyned By Terron Jangdrup - 85 Date Seynes: 08-15-2018 09-22-24	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
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Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	<b>БЕГИЦИВЕК</b> 3005070479					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Kevin R. Dillon, Chief Pharmacy Officer						
FIRM NAME	STREET ADDRESS					
Mayo Clinic Pharmacy	21 2nd St Sw					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Rochester, MN 55905-0001	Producer of Sterile and Non-Sterile					
	Products					
	,					

# **OBSERVATION 5**

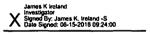
No endotoxin testings are done for multi-dose products which are not produced with a preservative to ensure product sterility.

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)



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