Deroit District Office: 1/14/19 - 1/18/19, 28/2019 200 River Place, Suite 5000 Datroit, MI 48207 1/14/19 - 1/18/19, 28/2019 201 Sith, 303-3100 Protocol, Suite 5000 Datroit, MI 48207 3011967886 Industry Information: www.fda.gav/de/industry 3011967886 201 Reveal AD THE DE MONDULT, Yow More REPORT IS ESSUED 102 E. Water St. CD:stationing LLC 102 E. Water St. CTV, STATE AND 2P 600E 102 E. Water St. Description of the Reveal Station of the Provide Station of Production and process control procedures are not followed in the execution of production and process control procedures are not followed in the execution of production and process control procedures are not followed in the execution of production and process control functions. Specifically, a. Your firm failed to follow the formula worksheet for the compounding of Vancomycin HCI USP 1mg/0.1ml lot no. 0302018. Fer the worksheet instructions the specified pH range should be (b) (4). Newever the reported pH value for this lot was 6.97. This lot was associated wit	1				
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300 River Place, Suite S000 Detroit, M1 48207 FFT NUMBER 301 (31) 303-1010 Processing Place Pl	DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	_	
(13) 303-100 Fax(313)393-8139 FEINAMER Industry Information: www.fdl.gw/doc/industry 3011967886 Industry Information: www.fdl.gw/doc/industry 301196786 Industry Information: wwwww	Detroit District Office:		1/14/19 - 1/18/19, 2/8/20	019	
Industry Information: www.indugerviewGAREPORT IS ISSUED TO: Raymond R. Carlson, Owner PRAMAGE RC Outsourcing LLC STREET ADDRESS RC Outsourcing LLC TY FRO FESTALLSHKENT INSPECTED Outsourcing LLC TY FRO FESTALLSHKENT INSPECTED Outsourcing LLC TY FRO FESTALLSHKENT INSPECTED OUTS OBSERVATION AND DO THE FRAME OF PLAT NOT PREVENTION OF YOUR FACILITY. THEY ARE INSPECTIONAL DesErvision, AND DO NOT HEPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AND GUESTING DESERVATION, AND DO NOT HEPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AND GUESTING OUTSON THAT THE YOU HEPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AND GUESTING DESERVATION, AND DO NOT HEPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AND GUESTING OUTSON ACTION WITH HE YOW HEPRENTITURG) DURING THE HAPPENTING DURING			FEI NUMBER	_	
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ORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 1 of 5	OF THIS FITTULY BUCK	Robert M. Barbosa		02/08/2019	
FACE FOR 3	FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	NSPECTIONAL OBSERV	ATIONS	Page 1 of 5	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
Detroit District Office:	1/14/19 - 1/18/19, 2/8/2019			
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	FEI NUMBER			
	3011967886			
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED				
TO: Raymond R. Carlson, Owner				
FIRM NAME	STREET ADDRESS			
RC Outsourcing LLC	102 E. Water St.			
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED			
Lowellville, OH 44436-1117	Outsourcing Facility			
-Cefuroxime 1mg, 1ml syringe & 10ml vial, (45 day BU -Moxifloxacin 1.5mg, 0.1ml/1ml syringe, (45 day BUD) -Vancomycin 1mg, 2mg, & 25mg, 1ml syringe & 15ml				
OBSERVATION 3 There is a failure to thoroughly review any unexplained distributed.	discrepancy whether or not the batch has be	en already		
Specifically, Your firm failed to conduct an investigation for the 70 s 1, 2017 and December 31, 2018. Syringe defect categor -bent needle -dull needle -clogged needle -stuck plunger -empty syringe		between Apri		
OBSERVATION 4 Testing and release of drug product for distribution do satisfactory conformance to the identity and strength of		ation of		
Specifically, Your firm did not conduct identity and strength (poten- produced at your facility:	cy) testing of each lot for the following drug	g products		
-Cefuroxime Img				
-Moxifloxacin 1.5mg				
-Vancomycin 1mg				
-Vancomycin 2mg				
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED		
SEE REVERSE OF THIS PAGE Lite-Il. Buster	Robert M. Barbosa	02/08/2019		
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	NSPECTIONAL OBSERVATIONS	Page 2 of		

	T OF HEALTH AND HUMAN SERVICES D AND DRUG ADMINISTRATION		
ISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTIO	N	
Detroit District Office:	1/14/19 - 1/18/19, 2	2/8/2019	
300 River Place, Suite 5900 Detroit, MI 48207	FEINUMBER	FEINUMBER	
(313) 393-8100 Fax:(313)393-8139	3011967886		
Industry Information: www.fda.gov/oc/industry IAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	5011707000		
ro: Raymond R. Carlson, Owner	STREET ADDRESS		
RC Outsourcing LLC	102 E. Water St.		
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED		
Lowellville, OH 44436-1117	Outsourcing Facility		
-Vancomycin 25mg			
In addition, the following tests were also obser	ved not having been performed:		
Testing for pH of each lot was not performed for facility:	or the following sterile injectable drug product	produced at y	
-Cefuroxime Img			
Testing for subvisible particulate of each lot war produced at your facility:	as not performed for the following sterile inject	able drug pro	
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg	as not performed for the following sterile inject	able drug pro	
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg			
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg	as not performed for the following sterile inject for the following sterile drug products produce		
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed			
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg			
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed -Cefuroxime 1mg			
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed -Cefuroxime 1mg -Moxifloxacin 1.5mg			
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg	for the following sterile drug products produce		
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg ***THIS IS A REPEAT OBSERVATION***	for the following sterile drug products produce		
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produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg ***THIS IS A REPEAT OBSERVATION*** OBSERVATION 5	for the following sterile drug products produce	d at your faci	
produced at your facility: -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg Sterility testing of each lot was not performed -Cefuroxime 1mg -Moxifloxacin 1.5mg -Vancomycin 1mg -Vancomycin 2mg ***THIS IS A REPEAT OBSERVATION*** OBSERVATION 5 The accuracy, sensitivity and reproducibility of Specifically, EMPLOYEE(S) SIGNATURE	for the following sterile drug products produce	d at your faci	
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	FOOD AND DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
Detroit District Office:	1	/14/19 - 1/18/19, 2/8/2019	
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139		FEI NUMBER	
Industry Information: www.fda.gov/oc/industry		3011967886	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUE	D		
TO: Raymond R. Carlson, Owner	1		
RC Outsourcing LLC	STREET ADDRESS 102 E. Water St.		
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INS	PECTED	
Lowellville, OH 44436-1117	Outsourcing Facility		
intended use in the sterility testing of Dexar Phenylephrine 2.5%. Further, the in-house s	5.		
OBSERVATION 6 Aseptic processing areas are deficient regar	ding the system for monitoring envi	ronmental conditions.	
Specifically,			
Active air sampling is not performed daily	during production activities.		
**THIS IS A REPEAT OBSERVATION*	**		
OBSERVATION 7 Specific identification tests are not conduct report of analysis.	ed on components that have been ac	ccepted based on the suppliers	
Specifically.			
Your does not perform on identity test on a following bulk API's are used in the produc			
-Moxifloxacin Hydrochloride USP -Dexamethosone Sodium Phosphate USP -Tobramycin Sulfate USP -Phenylephrine Hydrochloride USP -Vancomycin Hydrochloride USP			
OBSERVATION 8			
obobitinition	EMOLOVEEVEN MANE AND TITLE		
EMPLOYEE(S) SIGNATURE SEE	EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
Detroit District Office:	1/14/19 - 1/18/19, 2/8/2	019		
300 River Place, Suite 5900 Detroit, MI 48207	FEI NUMBER			
(313) 393-8100 Fax:(313)393-8139	3011967886			
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	5011207880			
TO: Raymond R. Carlson, Owner				
FIRM NAME	STREET ADDRESS			
RC Outsourcing LLC	102 E. Water St.			
CITY, STATE AND ZIP CODE	102 E. Water St. TYPE OF ESTABLISHMENT INSPECTED			
Lowellville, OH 44436-1117	Outsourcing Facility			
You compound drugs that are essentially a copy of one		a of continue		
 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a 				
component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.				
Examples of compounded drug products that are essent -Dexamethasone 400 mcg/0.1 mL syringe for injection -Moxifloxacin 0.150 mg/0.1 mL syringe for injection -Vancomycin 1 mg/0.1 mL syringe for injection -Vancomycin 2 mg/0.1 mL syringe for injection -Vancomycin 25 mg/mL – 10 mL dropper		s include;		
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED		
PAGE June M. Butter	Robert M. Barbosa	02/08/2019		
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