DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT OFFICE ADDRESS AND PHONE NUMBER			DATE(S) OF INSPECTION		
250 Marquette Ave, Ste 600			07/23, 24, 26, 30/2018		
Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134			FEI NUMBER		
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED			920		
TO: Stephen G.	Anderson, Owner	ETREET ADDRESS			
CITY, STATE AND ZI		165 19th St S, Ste 102 TYPE OF ESTABLISHMENT INSPECTED			
Sartell, MN 563		Producer of non-sterile 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) (WE) OBSERVED:					
DONING AN INSPEC	TION OF TOOK FIRM (I) (WE) OBSERVED.				
OBSERVATI	ON 1				
You produced beta-lactam drugs and highly potent drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination. Specifically,					
Specificany,					
a. Your firm p	produced the following batches of ceftazi	dime:			
Batch 03201710@12 on 10/04/2017, using (b) (4)hood #1					
Batch 232018	301@11 on 01/23/2018, using (b) (4) ho	od #2			
Batch 15201805@20 on 05/16/2018, using (b) (4)hood #1					
Ceftazidime powder was mixed with other powder excipients and encapsulated. These batches were produced without adequate inactivation of the drug in the work area and on equipment used. Batch records for 03201710@12 and 15201805@20 indicate that(b) (4) and(b) (4) were used during cleaning, while the batch record for 23201801@11 indicates that only (b) (4) was used during cleaning. Pharmacist-In-Charge(b) (6) stated to me that the batches were made with equipment dedicated to non-hazardous drug products and thus cleaning would have been performed with only (b) (4) (b) (6) stated that the batch records indicating that (b) (4) was used during cleaning were inaccurate.					
			7.00	d Continuation Page	
SEE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or T)	(pe)	DATE ISSUED	
REVERSE OF THIS PAGE	Charles L. Zhou - S Direction of the Comment of the	Charles L. Zhou, Investigator		07/30/2018	

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(612) 334-4100 Fax: (612) 334-4134	FEI NUMBER				
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	3012360920				
TO: Stephen G. Anderson, Owner FIRM NAME					
	STREET ADDRESS				
W & C Apothecary dba The Apothecary	165 19th St S, Ste 102				
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED				
Sartell, MN 56377-2567	Producer of non-sterile drugs				
-Batch 05201806@16, progesterone 275 mg capsule, vb. On 07/26/2018, I observed the production of batch 2 (b) (4) hood #1. After production of this batch, pharm (b) (4) solution to the hood, immediately wiped it upminute contact time, and applied (b) (4) ATR 100 mg/g gel, was the next batch produced after the solution of this batch, pharm (b) (4) solution to the hood, immediately wiped it upminute contact time, and applied (b) (4) ATR 100 mg/g gel, was the next batch produced after the solution of this batch, pharm (b) (4) solution to the hood, immediately wiped it upminute contact time, and applied (b) (4)	23201807@22, progesterone/testosterone 50 nacy tech ^{(b) (6)} applied (b) (4), therefore not leaving the (b) (4) for a (b) and allowed that to sit. Batch 26201807@batch 23201807@22.	0/1 mg troche in (4)			
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OF THIS PAGE	Charles L. Zhou, Investigator	07/30/2018			