	DEPARTMENT OF HEAL FOOD AND DRUG			
DISTRICT ADDRESS AND PHON			DATE(S) OF INSPECTION	
550 Main Stre			12/27/2022-1/10/2023*	
Cincinnati, C			FEI NUMBER 3006419237	
(313)322-0700	22-0700 Fax: (513) 679-2772			
NAME AND TITLE OF INDIVIDUA	IL TO WHOM REPORT ISSUED	· · · · · · · · · · · · · · · · · · ·		***************************************
	te, Vice President			
FIRM NAME		STREET ADDRESS		
CITY, STATE, ZIP CODE, COUNT	na Solutions Inc	1500 Bull Lea Rd Ste 250		
Lexington, KY		Manufacturer		
observations, and do observation, or have action with the FDA	observations made by the FDA representative(s) not represent a final Agency determination regainplemented, or plan to implement, corrective representative(s) during the inspection or submatted FDA at the phone number and address about	arding your cor action in respon it this informat	npliance. If you have an objuste to an observation, you m	ection regarding an any discuss the objection or
	TION OF YOUR FIRM WE OBSERVED:			
OBSERVATIO		3117		1 0 11 1
The responsibility	ities and procedures applicable to the	e quality co	ontrol unit are not ful	ly followed.
The following of	leficiencies are related to the stabili	ty batches	of (b) (4)	(b) (4)
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FDA inspection	:		0,	
Specifically,				
complete. Your	C-100033 on Sterility Testing requires analyst repeatedly marked the interithe the initial review.			
B) Vour analyst	failed to enter Active Viable Air (AVA	V cample a	ad tima durina Facina	
	lity testing of stability batches as req			
() Your test met	hod MTM0213-003 00 requires use of	f (h) (1)		and your analyst
C) Your test method MTM0213-003.00 requires use of (b) (4) and your analyst failed to follow the SOP. This was not identified during the initial review.				
D) Your analyst o	over(b) (4) the EM and Bio-burde			red duration. This was
not identified during the initial review.				
	EMPLOYEE(S) SIGNATURE			DATE ISSUED
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OF THIS PAGE	Paranthaman SenthamaraiKann	an, Inves	tigator Habee Dalo	neeb-S e: 3.01.10
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL	OBSERVATIONS	PAGE 1 of 4 PAGES

Descriptions from written specifications, test procedures and laboratory mechanisms are not recorded and justified.  Specifically,  A) Your test method TM-0213-007 for identity by FTIR of finished drug product (b) (4) requires identification and comparison of wave numbers of both standard and test samples, however analytical results of all of the finished in the comparison or identification.  B) Your SOP PHL-LEX-SOP-MQC-100076 on data review requires all data to be reviewed within (b) (4) and (b) (4) showed (b) (4) are required by your SOP.  Deservation 3  EE REVERSE OF THIS PAGE  BAIL THE PAGE  RATE BAGE  RA		DEPARTMENT OF HEAD				
Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772  SIMON MY Scholte, Vice President  Simon W Scholte, Vice President  Simon W Scholte, Vice President  STORY MANUFACTURE  Firamal Pharma Solutions Inc  STORY MANUFACTURE  E) The Result of Analysis for sterility testing of (b) (4)  Deviations from written specifications, test procedures and laboratory mechanisms are not recorded and justified.  Specifically,  A) Your test method TM-0213-007 for identity by FTIR of finished drug product (b) (4)  requires identification and comparison of wave numbers of both standard and test samples, however analytical results of all membranes of identification.  B) Your SOP PHL-LEX-SOP-MQC-100023 for (b) (4)  are derived just from visual observation without wave number comparison or identification.  B) Your SOP PHL-LEX-SOP-MQC-100023 for (b) (4)  are derived just from visual observation without wave number comparison or identification.  B) Your SOP PHL-LEX-SOP-MQC-100023 for (b) (4)  are derived just from visual observation without wave number of both standard and test samples, however analytical results of all microbial assay which requires removal of (b) (4)  are derived just from visual observation without wave number of both standard and test samples, however analytical results of all microbial assay which requires removal of (b) (4)  are derived just from visual observation without wave number of both standard and test samples, however analytical requires removal of (b) (4)  are derived just from visual observation without wave number of both standard and test samples, however analytical requires removal of (b) (4)  are derived just from visual observation without wave number of both standard and test samples, however analytical requires requires identification.  B) Your SOP PHL-LEX-SOP-MQC-100023 for (b) (4) setting describes procedure for (b) (4) in however analytical requires removal of (b) (4)  are derived just from visual observation without wave number of the first processing and suitable looks are derived just fro	The second control of the second			DATE(S) OF INSPECTION		
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550 Main Stre			DATE(S) OF INSPECTION 12/27/2022-1/10/2023*	
Cincinnati, (			12/2//2022-1/10/2023* FEI NUMBER	
	513)322-0700 Fax: (513)679-2772		3006419237	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED	***************************************		
	lte, Vice President			
FIRM NAME		STREET ADDRESS	_	
Piramal Phari	na Solutions Inc	1500 Bull Lea Rd Ste 250 TYPE ESTABLISHMENT INSPECTED		
Lexington, K		Manufacturer		
Specifically,				
60 :8:19	(b) (d)		50	
	ed to transfer <sup>(b) (4)</sup> for drug formulation			n a box labeled a
(b) (4)	loses. The hose was found unwrapped	and lacking	(b) (4) date and status.	
B) Your <b>(b) (4)</b>	labeled released were stored a	long with u	nlaheled (b) (4) having unk	nown release an
15/0	he manufacturing area.	IOUP MICH O	mascica (3) (1) naving unk	nown release all
(E 95)	s <del>o≡</del> s:			
	ent wash room number 1814 in the o		acturing area had hoses th	at lacked cleanin
status and identi	ty. These hoses were used for <sup>(b) (4)</sup> was	hing.		
D) Vour outornal	(b) (4) washer connected to the (b) (	1)	had at a the control of the desired	
			had standing water on the	washer floor to
approximately 12	2 hours during media fill batch (b) (4)	on (D) (4	)	
OBCEDIA	NAT 4			
OBSERVATIO	5073/00 MT 2	0.1		4
Laboratory reco	ords do not include the initials or sig	nature of th	ne person who performs ea	ach test.
Specifically,				
specifically,				
A\\/		¥		
	logy sample receiving logbook is incor			tials of the perso
who initiated the	test and the person who reviewed the	e results at n	nore than 15 instances.	
B) Your (b) (4	log book does not record sample en	try for (b) (4)	on at least two instances in	cluding Decembe
14th and 24th.	Jag aren dese net recers cample en	017 101	on at icast two mistances m	cidding Decembe
C) Your chemist	ry lab notebook recording (b) (4)	resu	ılts for (b) (4)	lacks initials an
signature of the	person who performed the test and th	e second pe	rson who reviewed the resu	lts.
	<b>_</b>			
APP DE /	EMPLOYEE(S) SIGNATURE		1	DATE ISSUED
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	TH AND HUMAN SERVICES ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street	DATE(S) OF INSPECTION  12/27/2022-1/10/2023*
Cincinnati, OH 45202	FEI NUMBER 3006419237
(513)322-0700 Fax: (513)679-2772	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Simon W Scholte, Vice President	
FIRM NAME Piramal Pharma Solutions Inc	STREET ADDRESS
CITY, STATE, ZIP CODE, COUNTRY	1500 Bull Lea Rd Ste 250  TYPE ESTABLISHMENT INSPECTED
Lexington, KY 40511-1267	Manufacturer
OBSERVATION 5 Each lot of components was not appropriately identi approved or rejected.  Specifically, Your firm stored substances labeled quarantine and reflammable cabinets in the receiving area.	ified as to its status in terms of being quarantined, released along with unlabeled substances in the same
OBSERVATION 6 Complaint records are deficient in that they do not in Specifically, Your complaint (b) (4) related to empty (b) (4) completely investigated to include review of operator's to the specific of	of (b) (4) mg (b) (4) (lot:(b) (4) was not

 $12/27/2022(Tue),\ 12/28/2022(Wed),\ 12/29/2022(Thu),\ 12/30/2022(Fri),\ 1/04/2023(Wed),\ 1/05/2023(Thu),\ 1/06/2023(Fri),\ 1/10/2023(Tue)$ 

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The observations of objectionable conditions and practices listed on the front of this form are reported:

- 1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
- 2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."