FOOD AND DRING ADMINISTRATION  1300 River Place, Suite 5900  Detroit, Mi 48207  (313) 393-8100 Fax: (313) 393-8139  Elizabeth A. Prokopik, Corporate Counsel  Finance Processor Country  Noblesville, IN 46060-3303  Producer of Sterile Drug 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 plat to implement, corrective action in reports to an observation, you may discuss the objection action with the PDA representative(s) during the inspection to FDA at the address above. If you have an operating an observation, or have implemented, or plat to implement, corrective action in response to an observation, you may discuss the objection action with the PDA representative(s) during the inspection or solution in the information to FDA at the address above. If you have any questions, please contact TDA at the plane number and address above.  DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:  OBSERVATION 1  Asceptic processing areas are deficient regarding the system for monitoring environmental conditions.  Specifically,  i. Environmental monitoring is not performed at least daily during drug production in the critical areas to evaluate the quality of the asceptic processing environment and assess whelf asceptic conditions are maintained.  a. Non-viable particulate monitoring is performed in the asceptic processing areas every (b)(4)  b. Active viable air monitoring is performed in the asceptic processing areas every (b)(4)  (b)(4)  d. Personnel fingertip monitoring is performed in the asceptic processing areas every (b)(4)  (b)(4)  d. Personnel fingertip monitoring is performed for (b)(4)  Environmental monitoring excursions are not investigated. Management indicated Rooms (b)(4)  and the anteroom are classified as ISO 6. According to SOP Environmental Control and (b)(4)  D	7.100 - 0.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00 - 1.00		ALTH AND HUMAN SERVI	CES	Angers and the state of the sta	
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Elizabeth A. Prokopik , Corporate Counsel  Finance successing recess counses  Finance successing from Care Pharmacy, Inc.  Finance successing  Roblesville, IN 46060-3303  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 reparding 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 action with the FDA representative(s) during the inspection or sometime 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  Asceptic processing areas are deficient regarding the system for monitoring environmental conditions.  Specifically,  i. Environmental monitoring is not performed at least daily during drug production in the critical areas to evaluate the quality of the asceptic processing environment and assess wheth asceptic conditions are maintained.  a. Non-viable particulate monitoring is performed in the asceptic processing areas (b)(4)  (b)(4)  b. Active viable air monitoring is performed in the asceptic processing areas every (b)(4)  (b)(4)  c. Viable surface monitoring is performed in the asceptic processing areas every (b)(4)  d. Personnel fingertip monitoring is performed in the asceptic processing areas every (b)(4)  and the anteroom are classified as ISO 6. According to SOP Environmental Control and		48207		FEI NUMBER		
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Pharmakon Long Term Care Pharmacy, Inc.  14460 Getz Rd, Suite 200  Tregerous 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 reparding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, or have implemented. Or plan to implement, corrective action in response to an observation, or have implemented.  DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:  DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:  OBSERVATION 1  Asceptic processing areas are deficient regarding the system for monitoring environmental conditions.  Specifically,  i. Environmental monitoring is not performed at least daily during drug production in the critical areas to evaluate the quality of the asceptic processing environment and assess whelf asceptic conditions are maintained.  a. Non-viable particulate monitoring is performed in the asceptic processing areas every (b)(4)  b. Active viable air monitoring is performed in the asceptic processing areas every (b)(4)  (b)(4)  c. Viable surface monitoring is performed in the asceptic processing areas every (b)(4)  (b)(4)  d. Personnel fingertip monitoring is performed in the asceptic processing areas every (b)(4)  (b)(4)  Environmental monitoring excursions are not investigated. Management indicated Rooms (b)(4)  and the anteroom are classified as ISO 6. According to SOP Environmental Control and	NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED				
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OF THE BACE   Fmily I Orban Investigator				l v	5/11/2016	
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 6 PAGE	FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE II	NSPECTIONAL OBSERVAT	TIONS	PAGE 1 OF 6 PAGES	

RESS AND PHONE NUMBER	JU MUNITUM INTERNAL	DATE(S) OF INSPECTION			
	8	4/18/2016-5/11/2016*			
t, MI 48207 393-8100 Fax:(313)393-8139		3011756326			
E OF INDIVIDUAL TO WHOM REPORT ISSUED					
eth A. Prokopik , Corporate Counse		All			
kon Long Term Care Pharmacy, Inc.	223 202024 400029 340029	REETADDRESS 4460 Getz Rd, Suite 200			
P CODE, COUNTRY		TYPE ESTABLISHMENT (NSPECTED			
ville, IN 46060-3303	Producer	Producer of Sterile Drug Products			
No data was provided to support that the environmental monitoring surface and for Management stated this incubator is management.	FUs were reconciled incubator fingertip san aintained bet	used to incubate media fill containers and imples is qualified for its intended use.  tween (b)(4). In addition, there was no			
	f drug produ	acts is not appropriate for the duties they			
inadequate in that protective gowns, factorized aseptic processing are not sterile. In additionable neck skin exposed, as well as personal of during the aseptic processing of Amikao	ce masks, she dition, the cu clothing. For cin 400 mg/	noe covers, and hair nets worn during arrent gowning method leaves facial and r example, gowning worn as observed (100 ml (Rx No. (b) (6) Invanz 500			
	FOOD AND DRIVERS AND PHONE NUMBER FOR Place, Suite 5900  The Place 5900  The Place, Suite 5	The producer of the processing of drug producer of the processing are not sterile. In addition, the cuneck skin exposed, as well as personal clothing. For during the aseptic processing of Amikacin 400 mg/mg/100 ml (Rx No. [b) (6)] and Gentamicin 240 mg/100 ml (Rx No. [b) (6)]			

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OF THIS PAGE

Robert M Barbosa, Investigator

Emily J Orban, Investigator Bei Y He, Investigator

EMPLOYEE(S) SIGNATURE

Emily 3 Orban Emy 3 Orban Investigator Signed by: Emily 3, Orban-6 DATE ISSUED

5/11/2016

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	FOOD AND DRUG ADMINISTRAT		DATE(S) OF INSPECTION		
	r Place, Suite 5900		4/18/20	)16-5/11/2016*	
Detroit, MI	, MI 48207 93-8100 Fax:(313)393-8139		3011756	326	
(212) 232-014	30 Fax: (313/393-6139	8.			29
NAME AND TITLE OF INDIVIOU	AL TO WHOM REPORT ISSUED				Maria Assay
	Prokopik , Corporate Counsel				
FIRM NAME	THE PER AND ANY CONTRACTOR OF THE ANY	STREET ADDRESS			
Pharmakon Lor	ng Term Care Pharmacy, Inc.		etz Rd, Suite 200		
	IN 46060-3303	Producer of Sterile Drug Products			ucts
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.  Specifically,  The following aseptic practice was observed:  While exiting the ISO 6 Room the operator was observed to use gowned elbow and forearm to activate the door mechanism leading into the ISO 6 anteroom. After this, gowned forearm and elbow were observed making contact with the ISO 5 laminar flow hood work surface during aseptic operations.  The above example was observed during processing of Arnikacin 400mg/100ml for Rx No. (b) (6) Invanz 500mg/100ml for Rx No. (b) (6) and Gentamicin 240mg/100ml for Rx No. (b) (6) on 4/18/16.					
·	ON 4 ing areas are deficient regarding the oduce aseptic conditions.	system for	cleaning	and disinfecting	the room and
ISO 5 ar operatio includin (b)(4)	eaning using sterile (b)(4) to clean to diso 6 areas (b)(4) nal days. For example, (b)(4), g Ampicillin Sulbactam, Cefazolin, Similarly, from 4/16/16 to 4/17 ed; however, (b)(4) cleaning was not	aseptic pro asterile dr and Cefepi (16, (b)(4)) steri	ocessing i rug produc me; <mark>(b)(4)</mark> ile drug pr	s not documented cts were aseptical cleaning was not	d for all lly processed documented otically
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SHONATURE  Robert M Barbosa, Investigat  Emily J Orban, Investigator  Bei Y He, Investigator	tor		, Systyacii X Emily 3 Orban Petry 3 Orba Peresigator Stand by: Emily 3, Orban = 5	DATE ISSUED 5/11/2016

INSPECTIONAL OBSERVATIONS

PAGE 3 OF 6 PAGES

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

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DISTRICT ADDRESS AND PHO	NE NUMBER	DATE(S) OF INSE		214700	
300 River PL Detroit, MI	ace, Suite 5900	4/18/20 FEINUMBER	16-5/11/2016*		
	40207 00 Fax: (313)393-8139	3011756	3326		
NAME AND TITLE OF INDIVIDU	ALTO WHOM REPORT ISSUED				
Elizabeth A.	Prokopik , Corporate Counse	el			
FIRM NAME		STREET ADDRESS			
Pharmakon Long Term Care Pharmacy, Inc.		14460 Getz Rd, Suite 200			
Noblesville,	IN 46060-3303	Producer of Ster	ile Drug Produ	icts	
iii. On 4/18 (b) (6) (b) (6)	rile sanitizing agents are used tion of the aseptic processing areas (b)(4) in the ISO 5 and IS/16, prior to and during the aseptic Invanz 500 mg/100 ml (Rx No.), the operator was observed (b)(was allowed to dry.	O 6 areas.  processing of Amikac  (b) (6) and Gentan	ed by your firm inc ein 400 mg/100 m nicin 240 mg/ 100	l (Rx No. ) ml (Rx No.	
OBSERVATION Aseptic process the aseptic conductor Specifically,	ing areas are deficient regarding s	ystems for maintaining	any equipment u	sed to control	
(b)(4) are checked documents before 3 ii. In additional observed	ked and documented by operators ntation of (b)(4) pressure checks wa	ently monitored. Curre (b)(4) as recorded in the (b)(4) the anteroom on the a	ently, such pressur  Additional  Record of Room  djoining wall to R	re differentials lly, no Pressure Log Room <sup>(5)(6)</sup> was	
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Robert M Barbosa, Investigator  Emily J Orban, Investigator  Bei Y He, Investigator		S/1/2016  X Emily J Orban  Emily J Orban  Investigator  Stoned by LEM' J. Orban -S	DATE ISSUED 5/11/2016	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATIO		PAGE 4 OF 6 PAGES	

	DEPARTMENT OF HEAD FOOD AND DRU	LTH AND HUMAN SI IG ADMINISTRATION	ERVICES		
DISTRICT ADDRESS AND PHONE NUMBER		DATE	DATE(S) OF INSPECTION		
300 River Pl Detroit, MI	lace, Suite 5900		4/18/2016~5/11/2016* FEINUMBER		
	00 Fax: (313)393-8139	P27555	11756326		
NAME AND TITLE OF INDIVIDU	JAL TO WHOM REPORT ISSUED		Win. (0.0000) Max	3 100 000	
	Prokopik , Corporate Counse				
Pharmalcon I o	ng Town Care Phases I-	14460 Cota	pd	COLOR TOTAL STATE	
Pharmakon Lo	ng Term Care Pharmacy, Inc.	14460 Getz	Rd, Suite 200	7	
Noblesville,	IN 46060-3303	Producer of	Sterile Drug Pro	oducts	
Invanz 500mg/ 4/18/16.	100ml for Rx No. (b) (6) and Ge	ntamicin 240mg	/100ml for Rx No.	(b) (6) on	
The operations	relating to the processing of penicil lrug products for human use.	lin are not perfo	rmed in facilities sep	parate from those	
Specifically,					
cephalosporin on the control of the	e not been established for the separa drug products from those for all other are dedicated to handling cephalosp products were processed:	er human drug p orin drug produc	roducts. Your firm h	as (b)(4) hoods,	
OBSERVATION The responsibile Specifically,	ON 7 ities and procedures applicable to the	ne quality contro	ol unit are not fully fo	ollowed.	
SOP Compound	ding Sterile Preparations Guideline	s states	(b)(4)		
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\$ 00 B	ALL COLD PATRICULAR TO THE SECOND STATE OF	examinations w	ere not observed, no	r are they	
documented for	each finished drug product.				
	T			200000000000000000000000000000000000000	
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	Robert M Barbosa, Investiga		V	DATE ISSUED 5/11/2016	
	Robert M Barbosa, Investiga Emily J Orban, Investigator		X Emily J Orban		
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	DEPARTMENT OF HEAI FOOD AND DRU	TH AND HUMAN SER G ADMINISTRATION	VICES		
DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900			DATE(S) OF INSPECTION		
Detroit, MI		FEINUM			
	00 Fax: (313)393-8139	3013	1756326		
NAME AND TITLE OF INDIVIDU	JAL TO WHOM REPORT ISSUED	L		-	
Elizabeth A.	Prokopik , Corporate Counsel				
FIRM NAME	7001 SS 1001 110	STREET ADDRESS	W _ W W W W W	_	
Pharmakon Lo	ng Term Care Pharmacy, Inc.		4460 Getz Rd, Suite 200		
Noblesville,	IN 46060-3303	Producer of S	roducer of Sterile Drug Products		
W		0	47	mana	
			25		
OBSERVATION	ON 8	W. O. W. C.	A CONTRACTOR AND A CONT		
	tten testing program designed to ass	ess the stability c	haracteristics of drug products.		
Specifically,					
Documentation	was not provided to support beyond	l nea datae accion	ed to sterile draw products. For		
	z 500mg/100ml (Rx No. (b) (6) i	Philippe pridition and critical reality file and contract	[2018년 18일 시간 시간 경기를 가득했다면 되었다면 사람들은 말이 되었다면 하다. 그리고 그리고 하는데 사람들이 되었다면 하는데 가입니다. 그리고 그렇게 되었다면 하는데 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그	10	
	insert from the manufacturer states			IU	
		ane product is our		042090	
*DATES OF I	NSPECTION				
4/18/2016(Mor	),4/19/2016(Tue),4/20/2016(Wed),4	1/21/2016(Thu),5	/10/2016(Tue),5/11/2016(Wed)		
	5/11/2016 5/11/2016				
X Robert M Barbosa	X Bei Y He	¥			
Robert M Barbosa Investigator	Bel Y He Invastigator				
Signed by: Robert M. Barbosa -S	Signed by: BeTY, He -5				
			9		
	EMPLOYEE(S) SIGNATURE	AND	DATE ISSUED	_	
SEE REVERSE	Robert M Barbosa, Investigat	or	shupon 5/11/2016		
OF THIS PAGE	Emily J Orban, Investigator	78180000 E 1	X Emily J Orban		
	Bei Y He, Investigator		Evely J Cothan Investigation Signed by: Evely J. Orban -5		
***	E 11-8895	-999	- Aug 52 mild 57 April 3		

INSPECTIONAL OBSERVATIONS

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