	CALTH AND HUMAN SERVICES BRUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild	10/23/2017-11/7/2017*
Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	FEI NUMBER 2074359
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Blair W. Galbreath, Director Pharmaceut	ical Services
FIRM NAME	STREET ADDRESS
Dignity Health - Northridge Hospital Medical Center	18300 Roscoe Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Northridge, CA 91325-4105	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 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: $OBSERVATION\ 1$

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically,

Your ISO 7 clean room is currently segregated from outside unclassified air using a plastic strip curtain. This clean room does not have a permanent door to ensure that air from an unclassified area does not enter the clean room. In addition, the absence of a permanent door does not allow the ISO 7 room to maintain an adequate pressure differential to the unclassified area. Within the ISO 7 clean room are ISO 5 classified areas where aseptic processing occurs. For example on 10/27/17, we observed the production of(b) (4) of potassium phosphate and (b) (4) of potassium chloride mixed into a 1000 mL IV bag of 0.9% sodium chloride. This drug had a beyond use date of "930" on "10/28/17".

THIS IS A REPEAT OBSERVATION FROM THE MARCH 2016 INSPECTION.

## **OBSERVATION 2**

Sinks or drains were present in the cleanroom where the ISO 5 classified aseptic processing area was located.

Specifically,

EMPLOYEE(S) SIGNATURE		DATE ISSUED
Uttaniti Limchumroon, Investigator Andrew K Haack, Investigator Taichun Qin, Generic Drug User Fee Amendments (GDUFA)	Ultaniti Linchumreen Investigator Signed (V. Ultaniti Linchumreen - Signed (V. Ultaniti Linchumreen - Signed (11-07-2017 11:01:42	11/7/2017

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INSPECTIONAL OBSERVATIONS

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		EALTH AND HUMAN SERV	ICES	
DISTRICT ADDRESS AND PHONE		DRUG ADMINISTRATION DATE(S) C	F INSPECTION	
19701 Fairchi		10/2	3/2017-11/7/2017	<b>k</b>
Irvine, CA 92		FÉI NUMB		
(949)608-2900	Fax: (949) 608-4417	2074	339	
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED			
	reath, Director Pharmaceu			
FIRM NAME	b 27 4 b 2 d 2 7 2 4 2	STREET ADDRESS	D1_1	
Medical Cente	h - Northridge Hospital	18300 Roscoe	BTAC	
CITY, STATE, ZIP CODE, COUNT		TYPE ESTABLISHMENT INSPECT	ED	301131111111111111111111111111111111111
Northridge, C	A 91325-4105	Producer of S	terile Drug Prod	ıcts
processing. On (b) (4) of pota 0.9% sodium ch  THIS IS A REP  OBSERVATIO The ISO 5 class production area)  Specifically,  Sterile, hazardo this production example, the following the following production area.	ified aseptic processing area wa	an (b) (c) use this sink to of potassium chlorido use date of "930" on the THE MARCH 2016 It is located within a normal at ISO 5-classified (b) d room, located on the oduced within this are	materials to prep o wash her hands pri e mixed into a 1000 '10/28/17". INSPECTION. n-classified room (se	are for aseptic or to producing mL IV bag of gregated (model(b) (4) pharmacy. For
OBSERVATIO Unsealed, loose	ON 4 ceiling tiles were observed in y	your cleanroom.	9(11)365	
	anaranaranan 🗸 bartan baran kanaran bahar	en de reseaux de la comença de la companya de la c		
Specifically,				
In the ISO 7 cl	ean room identified as the IV	room.(b) (4) recessed	l sprinkler heads we	ere observed. A
	een the sprinkler head and the			
the(b) (4)	e alle publications and the state of the sta	O 5 aseptic processing		rinkler is (b) (4)
inc(D) (1)	asea as a 15	o b diseptie processi	as area(b) (1)	10 (-7(-7)
SEE DEVERSE	EMPLOYEE(S) SIGNATURE	westigator		DATE ISSUED 11/7/2017
SEE REVERSE OF THIS PAGE	Uttaniti Limchumroon, In Andrew K Haack, Investig Taichun Qin, Generic Dru Amendments (GDUFA)	ator	Uttarilt Linchunreon investigator Signed By: Uttarilt Linchunreon Signed By: Uttarilt Linchunreon Dale Signed: 11-07-2017 11:01:42	
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DISTRICT ADDRESS AND PHONE	NUMBER	too monantionerin	DATE(S) OF INSPECTION
19701 Fairchi			10/23/2017-11/7/2017* FEINUMBER
Irvine, CA 92	Fax: (949) 608-4417		2074359
(949)000 2300	Edx. (949) 000-4417		
NAME AND TITLE OF INDIVIDUAL			
Blair W. Galb	reath, Director Pharmaceuti	ical Servic	
202000000000000000000000000000000000000	h - Northridge Hospital	1/6/00/03/03/03/03/03/03/03/03/03/03/03/03/	oscoe Blvd
Medical Cente		10300 KO	Dacoe Biva
CITY, STATE, ZIP CODE, COUNT		TYPE ESTABLISHME	
Northridge, C	A 91325-4105	Producer	r of Sterile Drug Products
(b) (4) the(b) (4)	and (h) (1)	lominar fla	w hand both are maintained as a ISO 5
(b) (4) the(b) (4)	and (b) (4)	lammat 110	ow hood, both are maintained as a ISO 5
aseptic processing	ig areas.		
THIS IS A DED	EAT OBSERVATION FROM T	HE MADOU	2016 INSPECTION
	EAT OBSERVATION FROM T	HE WARCH	2010 INSPECTION.
18K	865 24		
OBSERVATIO	N 5	<del>)</del>	
	s designed and/or operated in a w	vay that perm	nits poor flow of personnel.
	<b>o</b>	, , , , , , , , , , , , , , , , , , ,	F
Specifically,			
Your firm does	not have a designated anteroom	for technician	ns to don their gowns prior to entering the
ISO 7 clean roo	m. Technicians enter the ISO 7	clean room v	wearing their street clothing and don their
2000	In this room, on $10/27/17$ , we		The state of the s
		) a 1000 mL I	IV bag of 0.9% sodium chloride. This drug
had a beyond us	e date of "930" on "10/28/17".		
THE IC A DED	EAT ORGERNATION FROM	III MAROU	1 201 C DIGDECTION
THIS IS A REP	EAT OBSERVATION FROM T	HE MARCH	2016 INSPECTION.
OBSERVATIO	N 6		
		cleanrooms	and/or ISO 5 classified aseptic processing
	s were not used in your racinty's	Cicamoonis a	and/or 150 5 classified asceptic processing
area.			
Specifically,			
specificany,			
On 10/27/17, as	s a part of your(b) (4) cleaning	, we observe	ed technician(b) (6) fail to apply the (b) (4)
The way and demand with the Control of			while she was cleaning the interior surface
sporiedar	solution to the interior surface of	view sereem	willie she was eleaning the interior surface
I			
			98
SEE REVERSE	EMPLOYEE(S) SIGNATURE  Uttaniti Limchumroon, Inve	asticator	DATE ISSUED 11/7/2017
OF THIS PAGE	Andrew K Haack, Investigat		Uttanii Limchunwon
1	Taichun Qin, Generic Drug		triveatigator Signed Siy. Uttaniti Limchumroon - S S Date Signed: 11-07-2917 11:01:42
	Amendments (GDUFA)		A STATE OF THE STA

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		ALTH AND HUMAN SERV	ICES	
DISTRICT ADDRESS AND PHONE			FINSPECTION	
19701 Fairchi			3/2017-11/7/2017*	
Irvine, CA 92		2074		
(949)608-2900	Fax: (949) 608-4417	2074		
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED			
[1] 경영 [1] 10 [1	reath, Director Pharmaceut			
FIRM NAME		STREET ADDRESS		
750 6	h - Northridge Hospital	18300 Roscoe	Blvd	
Medical Cente		TYPE ESTABLISHMENT INSPECT	FD	
Northridge, C		0.15.19001000000000000000000000000000000	terile Drug Produ	cts
				2 COMMET A
of the (b) (4)	. When in ope	eration, the view scr	een is an interior surf	ace of the area
that is maintaine	ed as ISO 5 and is where aseptic	processing of drugs of	occurs.	
OBSERVATIO		Q 7	S	
Materials or sup	plies were not disinfected prior t	o entering the asepti	c processing areas.	
500 8000 80 ANN 1 81 1				
Specifically,				
		V <u>20020</u> 01 18 18 18		n 1880 1884 1
On 10/24/17, w	e observed an IV bag of 5% I	Dextrose, vials of	Heparin and a pacl	kage of sterile
presaturated wi	pes being moved into the pass	-through chamber of	of the ISO 5(b) (4)	
	e ISO 7 clean room without being			an moving the
items onto (b) (			prior to disinfecting	
	were used to produce 500 mL	of Hengrin 500 u		
"10/25".	were used to produce 500 mil	of fieparm, 500 u	mis/mic with a DOD	01 1030 OII
10/23 .				
OBSERVATIO	IN 9			
		as ICO 5 alossified a		
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ents and cleaning wipes used in the	le 180 3 classified a	septic processing area	as were not
sterile.				
C .C 11				
Specifically,				
0 10/07/17	1 1 1 1 1 1 (b) (6)	11. 11. 4 C		100 5 (b) (4)
On 10/27/17, v	we observed technician (b) (6) use	e non-sterile lint-fr	ee wipes within the	150 5 (b) (4)
	during cleaning.			
	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2			
THIS IS A REP	EAT OBSERVATION FROM T	THE MARCH 2016	INSPECTION.	
0.0000000000000000000000000000000000000	NAT O			
OBSERVATIO	)N 9			
1				
	EMPLOYEE(6) SIGNATURE	7100	i	DATE ISSUED
SEE REVERSE	Uttaniti Limchumroon, Inv		1 22	11/7/2017
OF THIS PAGE	Andrew K Haack, Investiga		Ultaniii Limchumroon Investigator Signed By: Ultaniii Limchumroon -	
	Taichun Qin, Generic Drug	user Fee	X S Date Signed: 11-07-2017 11:01:42	
	Amendments (GDUFA)			
			TO THE STATE OF TH	CHOCK SECURITIES
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERV	ATIONS	PAGE 4 OF 6 PAGES

		IEALTH AND HUMAN SERVICE DRUG ADMINISTRATION	S	nic i manufettic es e e
DISTRICT ADDRESS AND PHONE		DATE(S) OF INSE	PECTION	
19701 Fairchi			017-11/7/2017*	
Irvine, CA 92		FEI NUMBER 2074359	van de la companie d Na companie de la companie de	- 200,-02
(949)608-2900	Fax: (949) 608-4417	20/4553		
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED			
	reath, Director Pharmaceu			
FIRM NAME	h - Northridge Hospital	STREET ADDRESS 18300 Roscoe Bly	.a	
Medical Cente	1000	16300 ROSCOE BIV	ď	
CITY, STATE, ZIP CODE, COUNT		TYPE ESTABLISHMENT INSPECTED	2 - 211 100 1230 - 11200 1	
Northridge, C	A 91325-4105	Producer of Ster	ile Drug Produ	cts
Specifically,	ed in aseptic processing were of			
cover the hair o (b) (4) of "1400" on "10	e observed technician (b) (6) to be not the back of her head while so laminar flow hood. With ha 0/27".  observed this same technician and ISO 5 (b) (4)	she aseptically processed iir exposed, she processed	drug products indiffractor IX completed by the desired the desired by the desired	side the ISO 5 ex with a BUD ISO 5(b) (4)
	N 10 production areas surrounding the overhangs without adequate and		c processing area of	contained
specifically,				
On 10/23/17 an	d on 10/27/17, we observed a	ledge on the operator's	right hand side,	adjacent to the
(b) (4)		that contained a visible	e build-up of dust	t. This ledge is
adjacent to the	b) (4)		for cleaning. Or	10/27/17, we
	of potassium chloride and(b	(4) of notassium pho	formula seminarian and a seminaria	
] [ [ [ [ [ [ [ [ [ [ [ [ [ [ [ [ [ [ [	dium chloride produced in thi	s(b) (4) . This drug had	a beyond use da	ic 01 930 0n
"10/28/17".				
				<del>vonoviuse</del> n vii
-	THE OVER ON COMMENTS	ACCURATE CONTROL OF THE PARTY O	200 200 000	DATE ISSUED
SEE REVERSE OF THIS PAGE	Uttaniti Limchumroon, In Andrew K Haack, Investig Taichun Qin, Generic Dru Amendments (GDUFA)	ator	Uttarall Limchunroon Investigater Signed By: Uttariti Limchunroon - Signed By: Uttariti Limchunroon - Dete Signed: 11-07-2017 11:01:42	11/7/2017
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATI	ONS	PAGE 5 OF 6 PAGES

## DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 10/23/2017-11/7/2017\* FEI NUMBER 19701 Fairchild Irvine, CA 92612-2445 2074359 (949)608-2900 Fax: (949)608-4417 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Blair W. Galbreath, Director Pharmaceutical Services Dignity Health - Northridge Hospital 18300 Roscoe Blvd Medical Center CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Northridge, CA 91325-4105 Producer of Sterile Drug Products \*DATES OF INSPECTION 10/23/2017(Mon), 10/24/2017(Tue), 10/27/2017(Fri), 11/02/2017(Thu), 11/07/2017(Tue)



EMPLOYEE(S) SIGNATURE		DATE ISSUED
Uttaniti Limchumroon, Investigator Andrew K Haack, Investigator	Uttanti Limshumroon	11/7/2017
Taichun Qin, Generic Drug User Fee Amendments (GDUFA)	Investigator Signed By: Ultaniti Limchumroon - Signed Signed: 11-07-2017 11:01:42	