DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DA	TE(S) OF INSPECTION		
22215 26th Ave SE, Suite 210		/17-7/21; 7/25-7/26; 7/31; 8/1/2017		
Bothell, WA 98021 (425) 302-0340	FE	INUMBER		
Industry Information: www.fda.gov/oc/industry	3	013436443		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED				
TO: Scott D. Herzog, PharmD, Chief Operating Officer, V				
FIRM NAME	STREET ADDRESS			
Kelley-Ross Compounding Pharmacy	805 Madison St, #702	805 Madison St, #702		
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INS	PECTED		
Seattle, WA 98104	Producer of Sterile and N	on-Sterile Drug Products		
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRE OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETER OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMEN OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURIN YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE N	MINATION REGARDING YOUR COMPLIAN T CORRECTIVE ACTION IN RESPONSE G THE INSPECTION OR SUBMIT THIS INF	CE. IF YOU HAVE AN OBJECTION REGARDIN TO AN OBSERVATION, YOU MAY DISCUSS	IG AN	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:				
OBSERVATION 1				
Equipment, materials, and/or supplies are not disi	nfected prior to entering the a	septic processing areas.		
squipment, materials, and or suppressive not als	intering the intering the u			
Specifically, on 7/17/2017 a non-sterile plastic bag containing in-process materials, containers and closures used for the production of Tri-Mix (Prost/Pap/Phent 10 mcg/30 mg/1 mg/mL) injectable, Lot number (b) (6) were placed directly into the ISO-5 (b) (4) biological safety cabinet (BSC), Serial Number (b) (4) without adequate disinfection or sanitation of the outer surface.				
OBSERVATION 2				
The ISO-classified areas have difficult to clean, p	article-generating, or visibly of	lirty equipment.		
Specifically, on 7/17/2017 during the production of Tri-Mix (Prost/Pap/Phent 10 mcg/30 mg/1 mg/mL) injectable. Lot number (b) (6) : A) Apparent residue was observed on the metal HEPA filter screens installed in the ceiling of the ISO 7 Prep Area and ISO 7 Anteroom.				
B) After being wiped with a non-sterile paper tow		, apparent res	idue	
was observed on the exterior surface of the (b) (4		ocated in the (b) (4)		
(b) (4) , Serial Number (b) (4)	, used for weighing in-pro	ocess non-sterile drug materials	in	
the ISO 7 Prep Area.		Add Continuation P	0000	
		Add Continuation P	aye	
AM	ENDMENT 1			
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (	Print or Type) DATE ISSUED		
REVERSE OF THIS PAGE Oul P. C/S Can	Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator	8/2/2017		
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVAT	IONS Page 1 o	FA	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECT	ΓΙΟΝ			
22215 26th Ave SE, Suite 210 7/1		7/21; 7/25 <b>-7/26</b> ; 7/31; 8/1/2017			
Bothell, WA 98021 (425) 302-0340	FEINUMBER				
Industry Information: www.fda.gov/oc/industry	3013436443				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED					
TO: Scott D. Herzog, PharmD, Chief Operating Officer, Vice P	resident				
FIRM NAME					
Kelley-Ross Compounding Pharmacy	805 Madison St, #702				
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED				
Seattle, WA 98104	Producer of Sterile and Non-Sterile Drug	g Products			
the bottom of a glass window installed between the ISO 7 Anteroom and ISO 7 Positive Pressure Room.           OBSERVATION 3           ISO-5 classified areas were not certified under dynamic conditions.					
Specifically,					
A) From 6/2/2017 to 7/19/2017 72 sterile drug produc	ts were made; however, certification of	of the following units			
expired on 06/2017:	in t ( , i + 1)     ( h) ( 4 ) 1	and the New Constant			
	binet, Serial Number (b) (4)	ocated in the Negative			
Pressure Room; and		i i a p ta			
ii. The ISO-5 (b) (4)	, Serial Number (b) (4) loc	ated in the Positive			
Pressure Room.					
B) An in situ air pattern analysis (smoke study) of the following has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions: i. The ISO-5 (b) (4) biological safety cabinet, Serial Number (b) (4) located in the Negative Pressure Room; and					
ii. The ISO-5 (b) (4)	, Serial Number (b) (4) loc	ated in the Positive			
Pressure Room.					
OBSERVATION 4 Environmental monitoring was not performed in your aseptic processing areas. Specifically, gloved fingertip sampling was not performed by Operator in from 10/17/2014 to 6/27/2017. Per your sampling schedule, sterile drug production operators are required to perform gloved fingertip sampling every (b) (4)					
AMENDMENT 1 Add Continuation Page					
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SEE REVERSE OF THIS PAGE BLOYEE(S) SIGNATURE BLOYEE(S) SIGNATURE F. C.L.S. BLOYEE(S) SIGNATURE F. C.L.S.	EMPLOYEE(S) NAME AND TITLE (Print or Type) Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator	DATE ISSUED 8/2/2017			
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	Page 2 of 4			

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
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22215 26th Ave SE, Suite 210 Bothell, WA 98021		7/17-7/21; 7/25-7/26; 7/31; 8/1/2017			
(425) 302-0340		43			
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED					
TO: Scott D. Herzog, PharmD, Chief Operating Officer, Vice Pr	resident				
FIRM NAME	FIRM NAME STREET ADDRESS				
Kelley-Ross Compounding Pharmacy	805 Madison St, #702				
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED				
Seattle, WA 98104	Producer of Sterile and Non-Steril	e Drug Products			
OBSERVATION 5 Sporicidal agents are not used in your facility's cleanroom. Specifically, your (b) (4) cleaning procedures require the use of a (b) (4) solution and non-sterile $^{(b) (4)}$ $^{(b) (4)}$ . The concentration of each batch of the (b) (4) solution is not verified prior to use and a disinfectant efficacy study has not been conducted for this solution. The (b) (4) solution and non-sterile (b) (4) is applied on (b) (4) basis to the following:					
A) The exterior surfaces of the ISO-5 (b) (4)	biological safety cabinet, Se	erial Number			
(b) (4) .		<i>10</i>			
B) The exterior surfaces of the ISO-5 (b) (4)	, S	erial Number (b) (4) .			
C) The floors, walls and ceilings of the Sterile Drug Production Room.					
OBSERVATION 6					
Media fills were not performed that closely simulate as	septic production operations inco	orporating, as appropriate,			
worst-case activities and conditions that provide a challenge to aseptic operations.					
Specifically, A) Media fills have not been performed for Operators to simulate sterile drug production operations in the ISO-5 (b) (4) biological safety cabinet (BSC), Serial Number (b) (4) . From 4/17/2017 to current, the ISO-5 (b) (4) BSC has been designated as the primary unit for performing sterile drug production and approximately (b) (4) sterile drug products have been made.					
<ul> <li>B) From 4/9/2014 to 6/17/2016 Operator add did not perform a high-risk media fill recertification test every (b) (4) per SOP 8.090 "Evaluation of Compounding Personnel for Aseptic Technique and Manipulation Procedures". Operator was designated as a responsible sterile drug production operator. In addition, Operator performed recertification on 6/17/2016 with a (b) (4)</li> </ul>					
AMENDMENT 1 Add Continuation Page					
		Participation and the second second			
SEE REVERSE OF THIS PAGE BUILT P. CLS	EMPLOYEE(S) NAME AND TITLE (Print or Type Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator	<ul> <li>DATE ISSUED</li> <li>8/2/2017</li> </ul>			
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	NSPECTIONAL OBSERVATIONS	Page 3 of 4			

OBSERVATION 7         Non-microbial contamination was observed in your production area.         Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:         A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6) , the following was observed in the (b) (4) , Serial Number (b) (4) :          i. Apparent dried white residue in the airfoil holes;         ii. Apparent dried buildup in the center of the air filter screen; and         iii. Apparent staining and buildup on the (b) (4)         balance used to weigh in-process non-sterile drug materials.         B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4)	DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
Bothell, WA 98021 (22), 302-0340       TELNUMBER 3013436443         Industry Information: www.fda.gov/oc/industry MARE ARD TILE OF INDURDAL. TO WHOM REPORT IS ISSUED TO: SociD. Herzog, PharmD, Chief Operating Officer, Vice President TRIM MARE       STREET ADDRESS         Kelley-Noss Compounding Pharmacy       805 Madison St, 4702       Compounding Pharmacy         0.70, Stork ARD 2002E       Type of ESTRALEMENT INSPECTED         Seattle, WA 98104       Producer of Sterile and Non-Sterile Drug Products         (b) (d)       Test Kit that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016.         OBSERVATION 7       Non-microbial contamination was observed in your production area.         Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:         A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , the following was observed in the (b) (4)         ii: Apparent dried white residue in the airfoil holes; ii: Apparent dried white residue in the (b) (4)       balance used to weigh in-process non-sterile drug materials.         B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4)       .         (b) (4)       , Serial Number (b) (6)       .         (c) (d)       , Serial Number (b) (6)       .         (c) (d)       , Serial Number (b) (6)       .         (c) (d)       , Serial Number (b) (6)	DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF IN		N			
(425) 302-0340       FEI NUMBER         Industry Information: www.fda.gov/co/industry       3013436443         NME AND TITE CONTROL ON WOM REPORT IS USED       3013436443         TO: SoutD. Herzog, PharmD, Chief Operating Officer, Vice President       805 Madison St, #702         FRIM MAKE       STREET ADDRESS         Kelley-Roos Compounding Pharmacy       805 Madison St, #702         GTY, STATE AND ZIP CODE       TYPE OF ESTABLESHMENT INSPECTED         Scattle, WA 98104       Producer of Sterile and Non-Sterile Drug Products         (b) (4)       Test Kit that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016.         OBSERVATION 7       Non-microbial contamination was observed in your production area.         Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:       A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , the following was observed in the (b) (4)         ii. Apparent dried buildup on the (b) (4)       balance used to weigh in-process non-sterile drug materials.         B) A crack approximately ½ inch by 6 inches was observed on the light shield installed in the (b) (4)       .         ii. Apparent dried white residue in the airfoil holes; and ii. Apparent dried wist residue on the interior celling surface of the hood.       .         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       .       . </td <td></td> <td></td> <td>26; 7/31; 8/1/2017</td>			26; 7/31; 8/1/2017			
Industry information: www.ida.gov/ce/industry Wide XM Child Continuation: Www.ida.gov/ce/industry Try: SociD D. Herzog, Pharmb, Chief Operating Officer, Vice President FIRM NAME Kelley-Roos Compounding Pharmacy 805 Madison St, 4702 City, STATE AND ZP CODE Seattle, WA 98104 Producer of Sterile and Non-Sterile Drug Products (b) (4) Test Kit that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016. OBSERVATION 7 Non-microbial contamination was observed in your production area. Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room: A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6) the following was observed in the (b) (4) Serial Number (b) (4) i. Apparent dried buildup in the center of the air filter screen; and ii. Apparent dried buildup in the center of the air filter screen; and ii. Apparent dried white residue in the (b) (4) A crack approximately ½ inch by 6 inches was observed on the light shield installed in the (b) (4) Apparent dried white residue in the (b) (4) Apparent dried white residue in the (b) (4) Apparent dried white residue on the infroil holes; and Apparent dried white residue in the (b) (4) Apparent dried white residue in the (b) (4) Apparent dried white residue on the infroil holes; and Apparent dried white residue in the (b) (4) Apparent dried white residue in the (b) (4) Apparent dried white residue in the (b) (4) Apparent dried white residue on the infroi holes; and Apparent dried white residue on the infroi holes; and Apparent dried white residue in the airfoil holes; and Apparent dried white residue in the airfoil holes; and Apparent dried white residue on the infroi ceiling surface of the hood. D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6) Apparent dried white residue in the airfoil holes; and Apparent dried white residue in the airfoil holes; and Apparent dried white residue on the interfoir ceiling surface of the hood. D) During the production						
FIFM NAME       STREET ADDRESS         Kelley-Ross Compounding Pharmacy       805 Madison St, #702         City, STATE AND ZIP GODE       Producer of Sterile and Non-Sterile Drug Products         (b) (4)       Test Kit that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016.         OBSERVATION 7       Non-microbial contamination was observed in your production area.         Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:       A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6) , the following was observed in the (b) (4)       .         Apparent dried white residue in the airfoil holes;	Industry Information: www.fda.gov/oc/industry					
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OTY, STATE AND 2P CODE Seattle, WA 98104       TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products         (b) (4)       Test Kit that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016.         OBSERVATION 7 Non-microbial contamination was observed in your production area.         Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:         A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)         i. Apparent dried white residue in the airfoil holes;         ii. Apparent dried buildup in the center of the air filter screen; and         iii. Apparent staining and buildup on the (b) (4)         (b) (4)         (b) (4)         (c) The following was observed in the (b) (4)         (c) The following was observed in the (b) (4)         (c) The following was observed in the (b) (4)         (c) The following was observed in the (b) (4)         (d) Apparent dried white residue in the airfoil holes; and         (d) Apparent dried white residue in the airfoil holes; and         (d) Apparent dried residue on the interior ceiling surface of the hood.         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)         (d) In the manufacture of non-sterile drug products.         AMENDMENT 1       Add Continuation Page         Apprent dried residue on the interior ceiling surface of the MP						
Seatel, WA 98104       Producer of Sterile and Non-Sterile Drug Products         (b) (4)       Test K it that expired on 6/18/2016, prior to the 14-day read of the media plates conducted on 7/1/2016.         OBSERVATION 7       Non-microbial contamination was observed in your production area.         Specifically, the following was observed on 7/21/2017 in the Non-Sterile Drug Production Room:       A) After cleaning and during the production of Nifedipine 0.2% Ointment, Lot Number (b) (6), the following was observed in the (b) (4), Serial Number (b) (4)       It is Apparent dried white residue in the airfoil holes;         ii. Apparent dried white residue in the airfoil holes;	Kelley-Ross Compounding Pharmacy	805 Madison St, #702				
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following was observed in the (b) (4)       . Serial Number (b) (4)       :         i. Apparent dried white residue in the airfoil holes;       ii. Apparent dried buildup in the center of the air filter screen; and       iii. Apparent dried buildup on the (b) (4)       balance used to weigh in-process non-sterile         drug materials.       B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4)       (b) (4)         (b) (4)       , Serial Number (b) (4)       .         C) The following was observed in the (b) (4)       Hood, Serial Number (b) (4)         i. Apparent dried white residue in the airfoil holes; and       .         ii. Apparent dried residue on the interior ceiling surface of the hood.       D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were observed on the top surface of the <sup>(0)(4)</sup> light fixtures installed above (b) (4)       hoods and stored chemicals used in the manufacture of non-sterile drug products.         AMENDMENT 1         Add Continuation Page         SEE         PREDE         EMPLOYEE(S) SIGNATURE         Control Control of Nifedipine 0.2% Ointment, Lot Number (b) (4)         Add Continuation Page         Add Continuation Page         Add Continuation Page         Add Continuation Page <td>Specifically, the following was observed on 7/21/2017</td> <td>7 in the Non-Sterile Drug Production Ro</td> <td>om:</td>	Specifically, the following was observed on 7/21/2017	7 in the Non-Sterile Drug Production Ro	om:			
iiii. Apparent staining and buildup on the (b) (4)       balance used to weigh in-process non-sterile drug materials.         B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4)       (b) (4)         (b) (4)       , Serial Number (b) (4)       .         C) The following was observed in the (b) (4)       Hood, Serial Number (b) (4)       .         i. Apparent dried white residue in the airfoil holes; and       Hood, Serial Number (b) (6)       .         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       . apparent dust particles were observed on the top surface of the (b) (4)       hoods and stored chemicals         Used in the manufacture of non-sterile drug products.       Add Continuation Page       Add Continuation Page         SEE       EMPLOYEE(S) SIGNATURE       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         SEE       Gerard P. De Leon, Investigator       8/2/2017	following was observed in the (b) (4) , Serial Number (b) (4) :					
drug materials.         B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4)         (b) (4)       , Serial Number (b) (4)         (b) (4)       , Serial Number (b) (4)         (c) The following was observed in the (b) (4)       Hood, Serial Number (b) (4)         i. Apparent dried white residue in the airfoil holes; and       Hood, Serial Number (b) (4)         ii. Apparent dried residue on the interior ceiling surface of the hood.       D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were observed on the top surface of the (b) (4)         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were observed on the top surface of the (b) (4)       hoods and stored chemicals used in the manufacture of non-sterile drug products.         AMENDMENT 1         Add Continuation Page         SEE       EMPLOYEE(S) SIGNATURE         Gerard P. De Leon, Investigator         %2/2017	ii. Apparent dried buildup in the center of the air filter	screen; and				
B) A crack approximately ¼ inch by 6 inches was observed on the light shield installed in the (b) (4) (b) (4) , Serial Number (b) (4) . C) The following was observed in the (b) (4) Hood, Serial Number (b) (4) i. Apparent dried white residue in the airfoil holes; and ii. Apparent dried residue on the interior ceiling surface of the hood. D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6) , apparent dust particles were observed on the top surface of the <sup>(b) (4)</sup> light fixtures installed above (b) (4) hoods and stored chemicals used in the manufacture of non-sterile drug products. AMENDMENT 1 Add Continuation Page MENDMENT 1 Add Continuation Page Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator 8/2/2017	iii. Apparent staining and buildup on the (b) (4)	balance used to weigh in	-process non-sterile			
(b) (4)       , Serial Number (b) (4)         C) The following was observed in the (b) (4)       Hood, Serial Number (b) (4)         i. Apparent dried white residue in the airfoil holes; and       Hood, Serial Number (b) (4)         ii. Apparent dried residue on the interior ceiling surface of the hood.       D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were observed on the top surface of the <sup>(b) (4)</sup> light fixtures installed above (b) (4)       hoods and stored chemicals used in the manufacture of non-sterile drug products.         AMENDMENT 1       Add Continuation Page         REVERSE OF THIS       EMPLOYEE(S) SIGNATURE       EMPLOYEE(S) SIGNATURE       EMPLOYEE(S) SIGNATURE         REVERSE OF THIS       EMPLOYEE(S) SIGNATURE       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         Barrier De Leon, Investigator Kenneth O. Gee, Investigator       8/2/2017       8/2/2017	drug materials.					
i. Apparent dried white residue in the airfoil holes; and         ii. Apparent dried residue on the interior ceiling surface of the hood.         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were         observed on the top surface of the (b) (4) light fixtures installed above (b) (4)       hoods and stored chemicals         used in the manufacture of non-sterile drug products.       Add Continuation Page         AMENDMENT 1       Add Continuation Page         REVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE Continue       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         SEE PEVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE Continue       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         SEE PEVERSE OF THIS       Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator       8/2/2017	B) A crack approximately <sup>1</sup> / <sub>4</sub> inch by 6 inches was observed on the light shield installed in the (b) (4) (b) (4) , Serial Number (b) (4) .					
i. Apparent dried white residue in the airfoil holes; and         ii. Apparent dried residue on the interior ceiling surface of the hood.         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were         observed on the top surface of the (b) (4) light fixtures installed above (b) (4)       hoods and stored chemicals         used in the manufacture of non-sterile drug products.       Add Continuation Page         AMENDMENT 1       Add Continuation Page         REVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE Continue       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         SEE PEVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE Continue       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         SEE PEVERSE OF THIS       Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator       8/2/2017	() The following was observed in the $(h)$ $(A)$	Hood Serial Number (b)	(4)			
ii. Apparent dried residue on the interior ceiling surface of the hood.         D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were hoods and stored chemicals used on the top surface of the <sup>(b) (4)</sup> light fixtures installed above (b) (4)       hoods and stored chemicals used in the manufacture of non-sterile drug products.         AMENDMENT 1       Add Continuation Page         REVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE       EMPLOYEE(S) NAME AND TITLE (Print or Type)       DATE ISSUED         SEE OF THIS PAGE       Gerard P. De Leon, Investigator Kenneth O. Gee, Investigator       8/2/2017						
D) During the production of Nifedipine 0.2% Ointment, Lot Number (b) (6)       , apparent dust particles were hoods and stored chemicals used in the manufacture of non-sterile drug products.         AMENDMENT 1       Add Continuation Page         REVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE         Between the set of the formation of the set						
SEE     EMPLOYEE(S) SIGNATURE     EMPLOYEE(S) NAME AND TITLE (Print or Type)     DATE ISSUED       SEE     Gerard P. De Leon, Investigator     Gerard P. De Leon, Investigator     8/2/2017	observed on the top surface of the <sup>(b) (4)</sup> light fixtures installed above (b) (4) hoods and stored chemicals					
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