	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMA G ADMINISTRATION	AND DESCRIPTION OF AN ADDRESS.	4
DISTRICT ADDRESS AND PHO	NE NUMBER	C. HAMILION INCHIN	DATE(S) OF INSPECTION	
6751 Steger			10/26/2015-1/21/2016*	
	H 45237-3097		3003693389	
(513) 6/9-270	13) 679-2700 Fax: (513) 679-2772			4
NAME AND TITLE OF INDIVIDU	IAL TO WHOM REPORT ISSUED	- 1		
Thomas W. Ke	lsey , Regional Director, Pha	rmacy Open	ations	
FIRM NAME		STREET ACCRESS		*
Central Admi	xture Pharmacy Services Inc	8300 Sweet Valley Dr		
	OH 44125-4263	Producer of Sterile Drug Products		
observations, and do observation, or have action with the FDA	observations made by the FDA representative(s) not represent a final Agency determination reg implemented, or plan to implement, corrective representative(s) during the inspection or submatact FDA at the phone number and address about	arding your com action in respons it this information	pliance. If you have an objection re- te to an observation, you may discu-	garding an ss the objection or
OBSERVATION	CTION OF YOUR FIRM WE OBSERVED: ON 1 utensils are not maintained at appro	opriate interv	als to prevent contaminati	ion that would
alter the safety	identity, strength, quality or purity	of the drug r	ars to prevent contaminati	on that would
arter the safety,	identity, suchgain, quanty of purity	or me arug p	i oduct.	x.
Specifically fa	ilure to assure that the (b) (4) (b) (4)			
Specifically, ia		rm for prod	ucing sterile drugs, remove	e reciduals of
ingredients use	d in sterile drug production from pre			
h) (A)	has has been been had been had been had been had been had been been had bee	vious bags (or sterne drugs produced in	lat day. The
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produced by yo	vidual ingredient is added to the (b) ur firm does not use all ingredient or oduct per day on the (b) (4)	nts. Your firm Your firm	n produces approximately m uses(b) (4)	(b) (4)
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	OH 45237~3097		761 NUMBER 3003 693389		
(513) 679-2700 Fax: (513) 679-2772			00000000		
NAME AND TITLE OF INDIVID	JAL TOWNOM REPORT ISSUED				
	lsey , Regional Direct	tor, Pharmacy Ope	rations		
FIRM NAME		STREET ADDRESS			
	Central Admixture Pharmacy Services Inc 8300 Sweet		et Valley Dr		
1.000	OH 44125-4263		of Sterile Drug Prod	anata	
variey view,	On 44125-4205	Producer	of Sterile brug Proc	iucts	
• A medi The onl Em of the • A medi 2. The operform	a fill was performed by emy intervention performed by ployee did not performed by emy did not performed by emy only intervention performed by emy only intervention performed by ed only (b) (4)	ployees (b) (6) and (c) or	For example: n (b) (4) on (b) (4) (b) (4) (b) (4) but performed (6) on (b) (4) on (b) (4)	, bench 1. d interventions , bench mployee performed	
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	n 09/10/15, your firm produ		bags ((b) (4)		
Rx (b) (4), (b) in Cleveland, O		vere produced on pun under pa	bag; Rx (b) (4) #1. On 9/10 bag; Rx (b) (a) bag; Rx (b) (b) (c) p #1 on 09/10/15 to a cubicking list (b) (4) sterility testing results of	4), (b) (6) and stomer located Your firm	
	EMPLOYEE(S) SIGNATURE			DATE ISSUED	
SEE REVERSE	Nicholas L Paulin, In		1/29/20		
OF THIS PAGE	Michael P Sheehan, In		X Nicholas L Paulin Mehala L Ivalin Ivergular Fignethy: Menden L Ovaln C		
FORM FDA 483 (09/88)	PREVIOUS EDITION DESOLETE	INSPECTIONAL OF	SERVATIONS	PAGE 2 OF 4 PAGES	

6751 Steger	DEPARTMENT OF HEAL FOOD AND DRUG	ADMINISTRATION	CLO	
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Cincinnati,	OH 45237-3097 0 Fax: (513)679-2772	TEI NUMBER		
NAME AND TITLE OF INDIVIDU	ML TO WHOM REPORT ISSUED			
	lsey , Regional Director, Pha	rmacy Operation	5	
Central Admi	Central Admixture Pharmacy Services Inc 8300 Sw		eet Valley Dr	
A second second second second	OH 44125-4263	Producer of Sterile Drug Products		
	/15, eight days after you distributed a product is to be administered.	the product. Your	firm has no limitat	ion on when
	sonnel engaged in the processing of	drug products is no	ot appropriate for th	ne duties they
room and ISO 5 covers their ent eyebrows expos face shield. Th (b.) Firm person sterile compour	s employees do not wear eye protect b hoods. During the inspection, we do ire head with the exception of an op- sed and uncovered to the environment ese employees were observed produ- national (b) (4) adding ISO 7 clean room and for proce- ent identified that the (b) (4)	observed employee ening which leaves nt. These employe cing sterile produc	s wearing a sterile he their eyes, eyelashes do not wear any ts underneath the IS	nood which es and goggles or a GO 5 hoods.
OBSERVATIO				
Aseptic process produce aseptic Specifically, (b)			-	
Aseptic process produce aseptic Specifically, by your facility is 1 *DATES OF II 10/26/2015(Mo	(4) a non-sterile detergent, not sterilized prior to use.	used for cleaning f d),10/29/2015(Thu	loors in the classifi	ed areas of

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 6751 Steger Drive 10/26/2015-1/21/2016* Cincinnati, OH 45237-3097 3003693389 (513) 679-2700 Fax: (513) 679-2772 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Thomas W. Kelsey , Regional Director, Pharmacy Operations STREET ADDRESS Central Admixture Pharmacy Services Inc 8300 Sweet Valley Dr CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Valley View, OH 44125-4263 Producer of Sterile Drug Products 1/21/2016 X Michael P Sheehan Michael P.Sheeban Signed by: Michael P. Sheehan -S EMPLOYEE(6) SIGNATURE DATE ISSUED

SEE REVERSE OF THIS PAGE

Nicholas L Paulin, Investigator Michael P Sheehan, Investigator

X Nicholas L Paulin

1/21/2016

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