	F HEALTH AND HUMA ND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	}	8/16/2022-8/26/2022* FEI NUMBER	
LOGAVIIIO, IID 2000,		3004081307	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			
Pankaj Vijay Shitole, Senior Directo			
FIRM NAME	STREET ADDRESS	T146 G 102 L G 105	G 107 L G
Cipla Limited	The second secon	L146, S-103 to S-105, 7 to L-147/1/2/3, L-1	
		-116, Verna Industria	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHME		
Verna, Salcette, Goa, 403722 India	Drug Man	ufacturer	
This document lists observations made by the FDA represent observations, and do not represent a final Agency determinated observation, or have implemented, or plan to implement, confaction with the FDA representative(s) during the inspection of questions, please contact FDA at the phone number and additional contents of the phone number and additional contents.	tion regarding your com rective action in respon or submit this information	pliance. If you have an objection r se to an observation, you may disc	egarding an uss the objection or
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED OBSERVATION 1 Aseptic processing areas are deficient regardi		monitoring environmenta	l conditions.
 The environmental monitoring of the contaminants in critical areas will be distributed to the US market. 			nsure microbial products
From August 2018-January 2019 there were rejected due to environmental monitoring excursions from the filling of the saseptic filling machines. Lines are used for manufacturing Suspension for the US market and solution for the US market. The following batches were rejected during this time period:			
Control of the Contro		(b) (4)	
Batch CFU/swab recovered from from from from from from from from	illing (b) (4)		filling machine,
• Batch (b) (4) Solution, (c) (4) filling machine, (d) CFU/swab recovered from fil (b) (4) mber 23, 2018.			
SEE REVERSE OF THIS PAGE Teresa I Navas, Investig Drug Cadre Jonah S Ufferfilge, Inv	lgator - Dedica	Justin A Boyd Investigator Investigator Difference of the Society	B/26/2022
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL O	BSERVATIONS	PAGE 1 of 11 PAGES

DEPARTMENT OF HE FOOD AND D	ALTH AND HUMAN RUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032 Rockville, MD 20857		8/16/2022-8/26/2022* FEINUMBER	
ROCKVIIIC, IID 20007	2.2	3004081307	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	To the second se		
Pankaj Vijay Shitole, Senior Director S.	ite Head		
Cipla Limited	A2117001108 00 A211	146, S-103 to S-105,	S-107 to S-
orpra Himroca		to L-147/1/2/3, L-14	
CITY, STATE, ZIP CODE, COUNTRY	L-150, S-1	116, Verna Industrial	Area
Verna, Salcette, Goa, 403722 India	Drug Manu		
(0) (4)			
• Batch	Suspens	ion (US Market), (1)	filling machine,
CFU/swab recovered from fill	ling	CFU/swab recovered	ed from filling
and CFU/swab reco	vered from filli	ng on Noveml	per 1, 2018.
(b) (4) (D) (4)			(b) (4)
Batch	Solution	on, filling machine	e, CFU/swab
from filling (b)(4) on Decem	ber 2, 2018.		
(b) (4)		(b) (4)	(0) (4)
Batch	Suspension		and the second s
	d (b)(4) CFU/swab	recovered from the filling	ng zone surface
on December 3, 2018.			
(D) (4)	27	(b) (4)	ENERGY ENERGY
• Batch			filling machine,
°°CFU/swab recov	OI	n December 4, 2018.	
(b)(4)	C	(b)(4)	211
• Batch	(b) (d) 1(4)		filling machine,
CFU/swab recovered from filling	g or	n December 4, 2018.	
D 4 1 (b) (4)	Comment	in (TIC Manian) (b) (4)	2111
Batch District District	b) (4		filling machine,
> CFU/swab recovered from f		" CFU/swab recover on December 6, 2018.	ed from filling
and (a) Cro/swab from	minig	on December 6, 2018.	
• Batch (b) (4)	Cuanana	ion (US Market), (0)(4)	Filling machine
CFU/swab recovered from filling	(8) (4)	nd (CFU/swab on filling	filling machine,
December 6, 2018.	ig a	ild M CTO/Swab on miling	on
December 0, 2010.			
• Batch (5)(4)	Suspens	ion (US Market), (b) (4)	filling machine,
Daten	Suspens	ion (OS Warket),	ming machine,
EMPLOYEE(S) SIGNATURE			DATE ISSUED
SEE REVERSE Justin A Boyd, Investigate			8/26/2022
OF THIS PAGE Teresa I Navas, Investigat Drug Cadre	or - Dedicat	Justin A Boyd Investigator Signed By 2000358686 Date Signed 08-26-2022	
Jonah S Ufferfilge, Invest	igator	X 12 02 35	
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FORM FDA 483 (00/08) DESUIGIS EDITION OBSOLETE	INSPECTIONAL OR	SERVATIONS	PAGE 2 of 11 PAGES

FORM FDA 483 (09/08)

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		TH AND HUMAN ADMINISTRATIO		
DISTRICT ADDRESS AND PHON	wn Drive, Room 2032		DATE(S) OF INSPECTION 8/16/2022-8/26/2022*	
Rockville, MI		31	FEI NUMBER 3004081307	
		5	3004001307	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
5 mg - 1994 - 20 24 mg - 200	Shitole, Senior Director Sit	e Head		
FIRM NAME	68	STREET ADDRESS	NOTES TO SOLUTION TO APPEAL	Edit 20 (editor to te
Cipla Limited	d	112, L147	146, S-103 to S-105, to L-147/1/2/3, L-14 116, Verna Industrial	17/A, L-138,
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHMENT	INSPECTED	THOU
Verna, Salcet	tte, Goa, 403722 India	Drug Manu	facturer	
(5)	CFU/swab recovered from filling)(4) (*) (1) (4) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1	n December 8, 2018.	
1023 T	(b)(4)	C -1-4	(b) (4) C*11:	(0)(4)
	Batch bid	Soluti	on, filling machin	
	December 8, 2018.	e Cro/s	swao nom	on
·	Secender 6, 2016.			
• I	Batch (b) (4)	Suspens	ion (US Market), (19)(4)	filling machine,
(b)	CFU/swab recovered from filling	(b) (4) b) (4)	and CFU/swab recover	
(b)	on January 2, 2019.	10.		
		agrifiae straugustas — variot si a		an interespondent the applicable
100 March 200 Ma	estigations identified the likely roo			
	the batch out of caution. No action			e this trend or
Impleme	ent corrective and preventive actions	s related to re	epeated sampling errors.	
In Janu	ary 2019 change control 1003-D	-19-00006	was opened and propos	ed eliminating
In January 2019 change control 1003-D-19-00006 was opened and proposed eliminating monitoring of the fill and other Grade A surfaces. The change control did not discuss				
historical data that demonstrated numerous out of limit results for these points resulting in the				
rejection	of batches.			
52927 - 11247	respondently at them was as the	THE REPORT LEADING		
Since th	e change control approval on Janu			
filling whether	and filling zone for hat there were continued surface ex		ntinued. There is no data	
impacte	d the US market batches manuf	actured from	January 2020-July 2022.	lat could have
For (b) (4)	monitoring of the fill w	as discontinu	ed. Monitoring for the Gr	rade A fill zone
and fill	was continued, but only on a	basis	and not associated with	each of the
				Transaction and
SEE REVERSE	EMPLOYEE(S) SIGNATURE Justin A Boyd, Investigator		I	8/26/2022
OF THIS PAGE	Teresa I Navas, Investigator	c - Dedicat	Justin A Boyd Investigator	2, 2, 1, 1, 1, 1
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	Jonah S Ufferfilge, Investig	Jator .		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OF	SERVATIONS	PAGE 3 of 11 PAGES

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12420 Parklas	we number wn Drive, Room 2032		8/16/20	22-8/26/2022*	7
Rockville, MI			FEI NUMBER	one treate he is a	
			3004081	.307	
NAME AND TITLE OF INDIVIDUA		933305 18	*		
Pankaj Vijay	Shitole, Senior Director Sit	e Head			
Cipla Limited	1	0.51140001000 00	T.146. S-	103 to S-105,	S-107 to S-
	-			47/1/2/3, L-1	
CITY, STATE, ZIP CODE, COUN	TDV	L-150, S		rna Industria	l Area
STATE OF THE PROPERTY OF THE P	tte, Goa, 403722 India	Drug Man		er	
				3.23	
US mar	ket batches manufactured from Jan	nuary 2020	-July 202	2. Additionally,	the limits were
assigned	the Grade C limits of (CFU for	an alert and	d CFU	for action, rather	than the Grade
A limit	s of < CFU. This is inconsisten	t with		for (b) (4)	
Suspens	ion, which identifies the limit for su	ırfaces in G	rade A ar	eas is < CFU. Si	urface sampling
	lling zone has recovered microbial	~			was not further
investig	ated because it was below the Grade	C limits. F	For examp	le:	
in the second			(b) (4)		
	CFU was recovered from a filling	zone sampl	e of		, 2022, after the
	nanufacturing of batch	of (b) (4)		Suspension	released to the
Ţ	US market (expiration (a)).			
(b)	(4)		(b) (4)		
•	• CFUs were recovered from a filling zone sample of on February 26, 2020, after the manufacturing of batch of of Suspension released to				
				sion released to	
,	he US market (expired (a)				
(b) (4)	C 1 A '4 ' C4 CII'	(b) (4)	1 (*11)	4.000	(b) (4)
For Grade A monitoring of the filling and filling zone were discontinued.					
mon g of the filling was continued, but assigned the Grade C limits. Surface monitoring recovered growth from a sample at this location was below the Grade C limits, so not					
investig		at this loca	ation was	below the Grade	C minis, so not
investig	aleu.				
(0)	CFU was recovered from a filling	(b) (4)	ple of (0)(4)	on June 28	2021, after the
		of (b) (4)	ipic or	on state 20,	for
(D)	(4)	-			
2. Samplin	g locations for non-viable particle of	counts and	viable mo	nitoring in the	filling rooms
2. Sampling locations for non-viable particle counts and viable monitoring in the have not established any sampling points within the machines to ensure they					
	3 1 3 1				
	EMPLOYEE(S) SIGNATURE				DATE ISSUED
SEE REVERSE	Justin A Boyd, Investigator	40,700			8/26/2022
OF THIS PAGE	Teresa I Navas, Investigator	r - Dedica	ated	Justin A Boyd Investigator Signed By 2000358686 Date Storled 08-25-2022	
	Drug Cadre Jonah S Ufferfilge, Investig	gator		X 12 02 35	1
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FORM FDA 483 (09/08)

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PAGE 4 of 11 PAGES

	EALTH AND HUMAN SERVICES DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	8/16/2022-8/26/2022* FEI NUMBER			
noonville, in 2000,	3004081307			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
Pankaj Vijay Shitole, Senior Director S				
FIRM NAME Cipla Limited	STREET ADDRESS L139 to L146, S-103 to S-105, S-107 to S-			
Cipia himited	112, L147 to L-147/1/2/3, L-147/A, L-138,			
	L-150, S-116, Verna Industrial Area			
Verna, Salcette, Goa, 403722 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer			
Verna, Saicette, Goa, 403722 india	Drug Manuraccurer			
maintain a Grade C environment surrour	unding the filling zone during routine operations. Some			
operations in the Grade C areas include	16)			
to the filling zone.				
Failure to have data to support air classif	fication of areas surrounding aseptic filling operations is			
a repeat observation from the August 201	[1] : [1] [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [1] : [
3. Sampling plans do not describe specific le	locations for collecting surface samples to ensure			
reproducible results and that the highest r				
) sold — is the system that the treatment and situated but to a laboration of the couple to the more in				
OBSERVATION 2				
	contamination of drug products purporting to be sterile			
did not include adequate validation of the aseptic	did not include adequate validation of the aseptic process.			
(b) (4)				
1. Smoke studies to evaluate airflow have n	9			
are used in the aseptic filling of Suspension.				
(b) (4)	ies conducted in the suspension manufacturing area for			
	report did not identify and further evaluate the following			
areas:				
4 1 1	1 (0)(4)			
a. Areas that appeared to show turb				
is kept during asepti he For example,	(b) (4)			
he For example,				
b. Areas that appeared to show	the weighing balance. For example,			
b. Areas that appeared to show	the weighing balance. For example,			
EMPLOYEE(S) SIGNATURE	DATE ISSUED			
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OF THIS PAGE Teresa I Navas, Investigat Drug Cadre	Signed By 2000358686 Date Signed 06-26-2022			
Jonah S Ufferfilge, Invest	X 12 02 35			
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS PAGE 5 of 11 PAGES			

	DEPARTMENT OF HEA	LTH AND HUMA UG ADMINISTRATI		
DISTRICT ADDRESS AND PHO	NE NUMBER	307101111111111111111111111111111111111	DATE(S) OF INSPECTION	
Vi	wn Drive, Room 2032		8/16/2022-8/26/202 FEI NUMBER	2*
Rockville, M	D 20857		3004081307	
NAME AND TITLE OF INDIVIDU	AL TO WHOM REPORT ISSUED			
	Shitole, Senior Director Si	to Hood		
FIRM NAME	Shirtore, Senior Director Si	STREET ADDRESS		
Cipla Limite	d	L139 to	L146, S-103 to S-10	5, S-107 to S-
**************************************		112, L14	7 to L-147/1/2/3, L	-147/A, L-138,
ST			-116, Verna Industr	ial Area
CITY, STATE, ZIP CODE, COUN	tte, Goa, 403722 India	TYPE ESTABLISHME	ent inspected ufacturer	
verna, saice	cte, Goa, 403722 India	Drug Man	uracturer	
During a. The the to r not r clear	cleaning of the filling more operator was observed to place his inside of the Grade A s that had already be wipe any of these areas before fining prior to filling of the next batch.	for for shand on the filling zone wiped wishing the clerk.	e filling assembly and a e. Additionally, the open ithin the Grade A areas eaning of this area. The	atch of an inner surface of rator was observed at the operator did are is no additional
b. The	operator did not wipe all reachabl	e areas outsi		For example, the he machine.
surfaces		erator did no	ugust 18, 2022, after be of wipe all surfaces inco of the machine. The op- wipe those areas.	luding rior
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Justin A Boyd, Investigator Teresa I Navas, Investigator Drug Cadre Jonah S Ufferfilge, Investi	or - Dedica igator	Signed By 200335666 Dafe Signed 06-26-2022 X 12 02 35	8/26/2022
FORM FDA 483 (09/08)	DREVIOUS EDITION OBSOLETE IN	SPECTIONAL C	DRSERVATIONS	PAGE 6 of 11 PAGES

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMAN SERVE G ADMINISTRATION	CES	
DISTRICT ADDRESS AND PHO	NE NUMBER	DATE(S) OF	INSPECTION	,
Rockville, M	wn Drive, Room 2032 D 20857	8/16/ FEI NUMBER	2022-8/26/2022*	
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NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED	<u> </u>		
Contract and the contract of t	Shitole, Senior Director Sit			
Cipla Limited	4	STREET ADDRESS	S-103 to S-105,	C 107 +0 C
Cipia Dimite			-147/1/2/3, L-14	
		L-150, S-116,	Verna Industrial	
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHMENT INSPECTE		
verna, Salce	tte, Goa, 403722 India	Drug Manufactu	rer	
2 Classia	g procedure CT-413 "Cleaning of	(b) (4)	leale	s detail of the
10-12 Call Control of the Control of	트로 후에 없는 경기 이번 어린 경향이 가지하는 그런 경향이 그 그래의 학생인이 모든데 되었다.			
	e of cleaning activities, does no			
	ons, and does not identify those ar	eas mat me operat	or is permitted to o	mit wiping and
instead i	rely on			
- 00	1.30.0			
The state of the s	ent details in cleaning procedures	for the aseptic area	is a repeat observ	vation from the
August 2	2019 FDA 483.			
av.	_			
4.	with the scheduled disinfectant i	s intended to disi	nfect places the of	perators cannot
	he process has not been qu	alified to show it	s effective or estab	lish parameters
for its us	se.			
	m1/43			
Failure to qualify a process for disinfection of aseptic manufacturing areas is a repeat				
observation from the 2019 FDA 483.				
OBSERVATIO	ON 4			
Appropriate con	ntrols are not exercised over comput	ers or related syste	ms to assure that ch	anges in
master producti	on and control records or other reco	rds are instituted o	nly by authorized po	ersonnel.
\$2500		(b) (4)	x x	
1. The Hu	man Machine Interface (HMI) for	the	filling machine	es use a shared
passwor	d, do not have audit trails, and do n	ot allow for the pri	nting or transfer of	electronic data.
Controls	s have not been established to ensur	e there are no char	iges to parameters i	n the approved
	Critical machine parameters es			
docume	nted in the batch records or o	checked during p	roduction. For ex	ample. during
investig	ation OOS-1003-2022-00022 for de	liverable volume v	ariations in	
Suspens	ion batch the machine p	arameters that cou	d impact fill volun	ne could not be
	EMPLOYEE(S) SIGNATURE		*	DATE ISSUED
SEE REVERSE	Justin A Boyd, Investigator			8/26/2022
OF THIS PAGE	Teresa I Navas, Investigato	r - Dedicated	Justin A Boyd Investigation	
	Drug Cadre	e cost v ermente s	Signed By 2000358686 Date Signed 08-26-2022 X 12 02 35	
	Jonah S Ufferfilge, Investi	gator		
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FORM FDA 483 (00/08)	DEPETATOR S EDITION OPEN PTE TNS	PECTIONAL OBSERVA	LIONS	PAGE 7 of 11 PAGES

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

	ALTH AND HUMAN SERVICES RUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032	8/16/2022-8/26/2022*	
Rockville, MD 20857	FEI NUMBER 3004081307	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Pankaj Vijay Shitole, Senior Director S	ite Head	
FIRM NAME	STREET ADDRESS	
Cipla Limited	L139 to L146, S-103 to S-105, S-107 to S-112, L147 to L-147/1/2/3, L-147/A, L-138 L-150, S-116, Verna Industrial Area	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Verna, Salcette, Goa, 403722 India	Drug Manufacturer	

evaluated.

2. Electronic laboratory notebooks are used to document analysis in the chemistry and microbiology laboratories. Analysts can make changes to data entries without triggering an event in the audit trail until they manually click the save button. For example, routine review and approval of QC data by a second person would not be able to determine if the data was original or had been changed prior to the analyst manually saving the entries.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

- 1. Procedures for reviewing electronic data and audit trails for production equipment (1035-G-0213) and in the QC laboratory (1035-L-0058) are general to apply to software used for different equipment. They do not identify and describe the items specific to the software to ensure the reviewer will effectively recognize and evaluate the relevant entries in the electronic data and audit trail. For example:
 - a. The reviewer of the audit log for the enVigil non-viable particle count software uses a general procedure and was unable to explain what different entries in the audit trail meant and their impact including: "flow error", "process autolog parmas terminated", "bad response", or "no response". Additionally, the approved list of users did not match the enabled user list in the software.
 - b. The reviewer for the Lab Solutions UV software explained that although not described in the procedures, he reviews errors, warnings, or abnormal audit trail entries. However, the was unable to explain which errors, warnings, or audit trail entries would be relevant

SEE REVERSE	
OF THIS PAGE	

EMPLOYEE(S) SIGNATURE

Justin A Boyd, Investigator

Teresa I Navas, Investigator - Dedicated

Drug Cadre

Jonah S Ufferfilge, Investigator



8/26/2022

PAGE 8 of 11 PAGES

	TH AND HUMAN SERVICES GADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	8/16/2022-8/26/2022* FEI NUMBER
ROCKVIIIE, PD 2003/	3004081307
]
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Pankaj Vijay Shitole, Senior Director Sit	e Head
FIRM NAME	STREET ADDRESS
Cipla Limited L139 to L146, S-103 to S-105, S-107 to 112, L147 to L-147/1/2/3, L-147/A, L-L-150, S-116, Verna Industrial Area	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Verna, Salcette, Goa, 403722 India	Drug Manufacturer

- a. During review for unreported data/manipulation/data integrity in August-October of 2021 there were 9 sequences chosen to review, November 2021-January 2022 there were 12 sequences chosen for review, and February-April of 2022 there were 15 sequences chosen for review.
- b. During review of appropriate integration in August-October of 2021 there were 20 sequences chosen to review, November 2021-January 2022 there were 11 sequences chosen for review, and February-April of 2022 there were 10 sequences chosen for review.

OBSERVATION 6

Procedures for the cleaning and maintenance of equipment are deficient regarding maintenance and cleaning schedules, including, where appropriate, sanitizing schedules.

(finished product, stability, raw material, validation, etc.). For example:

SOP MT-654, "Hold Time for Clean and Unclean Area and Equipments" version for cleaning of processing equipment such as batches and for processing equipment such as es. However, your cleaning validation studies

SEE	RE	/ERSE
OF '	THIS	PAGE

EMPLOYEE(S) SIGNATURE

Justin A Boyd, Investigator

Teresa I Navas, Investigator - Dedicated

Drug Cadre

Jonah S Ufferfilge, Investigator



8/26/2022

PAGE 9 of 11 PAGES

	DEPARTMENT OF HEAL FOOD AND DRUG			
DISTRICT ADDRESS AND PHON			DATE(S) OF INSPECTION	
Rockville, MI	vn Drive, Room 2032		8/16/2022-8/26/2022* FEI NUMBER	§
ROCKVIIIE, III	20037		3004081307	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
Pankai Vijav	Shitole, Senior Director Sit	e Head		
FIRM NAME	7.55 (13.75) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56) (1.56)	STREET ADDRESS		
Cipla Limited	l		L146, S-103 to S-105,	
			7 to L-147/1/2/3, L-1	
CITY, STATE, ZIP CODE, COUN	TRY	L-150, S	-116, Verna Industria	II Area
	te, Goa, 403722 India	Drug Man	ufacturer	
Section Section 2014 and the section of the section of the section 2014 and the section of the section 2014 and th				
executed for pro	oducts support the established		The following is a non-	exhaustive list
of examples:				
Tree Charles				
Schedule	e for the year 2022 of	(b) (4)	located in manufac	chiring (b)(4)
	nat the initial cleaning	ase	product based on solubili	-
A STATE OF THE PARTY OF THE PAR	ed on three batches. During routine			
manufac	_	manaractar	ing consecutive outer	ies are
manarac				
• Sahadul	e for the year 2022 of		located in manufact	(b) (4)
	nat initial cleaning validation was co	mplated for		
	atch, three different times, in 2019,			(b) (4)
	tive batches are manufactured.	2020, and 2	2021. During fournie manu	nacturing
consecu	ive batches are manufactured.			
0 1 1 1	C 4 2022 C(b)(4)	1	(b)(4)	
Schedule for the year 2022 of located in manufacturing shows that initial cleaning validation for w sed on solubility was executed using one				
	eaning validation for w			
	2018, subsequent verification studi			ch. During
routine i	nanufacturing consecutive bate	hes are mai	nufactured.	
*DATES OF I				
8/16/2022(Tue)	, 8/17/2022(Wed), 8/18/2022(Thu),	8/19/2022(Fri), 8/22/2022(Mon), 8/2	3/2022(Tue),
8/24/2022(Wed), 8/25/2022(Thu), 8/26/2022(Fri)			
<u> </u>	EMPLOYEE(S) SIGNATURE			DATE ISSUED
SEE REVERSE	Justin A Boyd, Investigator			8/26/2022
OF THIS PAGE	Teresa I Navas, Investigator	r - Dedica	ated Justin A Boyd Investigator	
	Drug Cadre	e contrato de la compansión de la compan	Signed By 2000358686 Date Signed 08-26-2022 X 12 02 35	
	Jonah S Ufferfilge, Investi	gator		

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 10 of 11 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 8/16/2022-8/26/2022* 12420 Parklawn Drive, Room 2032 FEI NUMBER Rockville, MD 20857 3004081307 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Pankaj Vijay Shitole, Senior Director Site Head L139 to L146, S-103 to S-105, S-107 to S-Cipla Limited 112, L147 to L-147/1/2/3, L-147/A, L-138, L-150, S-116, Verna Industrial Area CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Verna, Salcette, Goa, 403722 India Drug Manufacturer Teresa I Navas Investigator - Dedicated Drug Cadre Signed By: Teresa I. Navas -S Date Signed: 08-26-2022 12:03:13 Jonah S Ufferfilge Investigator Signed By: Jonah Ufferfilge -S Date Signed: 08-28-2022 12-03:46

SEE REVERSE OF THIS PAGE EMPLOYEE(S)SIGNATURE

Justin A Boyd, Investigator

Teresa I Navas, Investigator - Dedicated

Drug Cadre
Jonah S Ufferfilge, Investigator

Justin A Boyd Investigator Signed By 2000358686 Date Signed 06-26-2022 X 12 02 35 8/26/2022