	DEPARTMENT OF HEAL FOOD AND DRUG				
DISTRICT ADDRESS AND PHON			DATE(S) OF INSPECTION		
	vn Drive, Room 2032		2/6/2023-2/17/2023* FEI NUMBER		
Rockville, MI	20857		3008581988		
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED				
Mr. Ashish Zi	itshi, Vice President - Site	Head			
FIRM NAME		STREET ADDRESS	THE EFFECTS SECURITY STEEL SECURITY		
Cipla Limited	i		9 & 10, Pharma Zone H		
		AND SECTION ASSESSMENT OF THE PARTY OF THE P	ion Iiii, Indore Special Economic		
CITY, STATE, ZIP CODE, COUN	TDV	Zone Type establishme	NT INSPECTED		
	istrict Dhar, Madhya		& Non-sterile Drug Mar	nufacturer	
Pradesh, 454		Sterife	a Non-Stellie Diug Mai	lulacculel	
	, <u>, , , , , , , , , , , , , , , , , , </u>	ı			
This document lists of	observations made by the FDA representative(s)	during the inst	ection of your facility. They are ins	pectional	
observations, and do	not represent a final Agency determination rega	arding your con	pliance. If you have an objection re	garding an	
	implemented, or plan to implement, corrective				
	representative(s) during the inspection or submit tact FDA at the phone number and address above		on to FDA at the address above. If y	you have any	
questions, please con	tact FDA at the phone number and address above	ve.			
A MILES CONTRACTOR OF THE STATE	THE STREET STREET				
DURING AN INSPEC	TION OF YOUR FIRM WE OBSERVED:				
10					
PRODUCTION	N SYSTEM				
	trad a selection and contrades the commission of the first			-0	
OBSERVATIO	ON 1				
	e to thoroughly review any unexpla	ined discret	ancy and the failure of a h	atch or any of	
	to meet any of its specifications who	97			
ns components	to meet any of its specifications who	ether of hot	the batch has been already	distributed.	
O N 1	20 2021 1 1	1.	(b) (4)	C 11: T · (b)(4)	
On November	20, 2021, you conducted an ase	ptic proces		filling Line	
	e mL)); validation Batch No.		This media fill process v		
following the re	quirements of validation protocol F	/VP/APVS	M/01 entitled "Aseptic Pro	cess Validation	
Suspension Man	nufacturing"; approved on September	er 14, 2021.			
to stone and the second of the			· Version	N/40	
On the fourteen	th (14th) day of incubation, you obse	erved turbid	lity in (b) (4)	D)(4)	
of (b) (4)	. The microorganism				
stutzeri-Gram r	positive soil bacterium. The inve	etigation D			
cause to a (b)(4)	in the	that ma	y have occurred after (b)(4)	inspection	
Company of the second	The state of the s	The state of the s		inspection	
	or movement of the filled samples,				
	t was reported in the line during th				
mishandling of		ed in the b	atch manufacturing record	d or any other	
laboratory form	-				
	19 10 10 9		-		
	EMPLOYEE(S) SIGNATURE			DATE ISSUED	
SEE REVERSE	Saleem A Akhtar, Investigato		054 W 15 24	2/17/2023	
OF THIS PAGE	Jose E Melendez, Investigato	or - Dedic	saleem A Akhtar Investigator Signed By 2001638440 Date Signed 02-17-2023		
	Drug Cadre		X Date Signed 02-17-2023		
	L			1.	

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 1 of 23 PAGES

	DEPARTMENT OF HEA FOOD AND DR	ALTH AND HUMAN RUG ADMINISTRATIO			
DISTRICT ADDRESS AND PHOP	NE NUMBER Wn Drive, Room 2032		DATE(S) OF INSPECTION 2/6/2023-2/17/2023*		
Rockville, M		1	FEI NUMBER		
1000			3008581988		
NAME AND TITLE OF INDIVIDUA		112			
Mr. Ashish Zi	itshi, Vice President - Site	STREET ADDRESS			
Cipla Limited	d	Plot No.	9 & 10, Pharma Zone	Phase Ii,	
· · · · · · · · · · · · · · · · · · ·		Section I	iii, Indore Special		
CITY, STATE, ZIP CODE, COUN	TRY:	Zone Type establishmen	BLISHMENT INSPECTED		
	istrict Dhar, Madhya		Non-sterile Drug Ma:	nufacturer	
Pradesh, 454		700,00790000000000000000000000000000000	(1876/8500001	199 (1994), de tradición de desta de servición de conserva de entre de conserva de entre de la conserva de entre de la conserva de la conserva de entre de la conserva dela conserva de la conserva de la conserva de la conserva dela conserva dela conserva de la conserva dela conserva de la conserva de la co	
1	1. 611	1.1.1	1 E/X ID / A DX ICA I / O.1	4)	
According to th	e media fill acceptance criteria in	validation pro	ocol F/VP/APVSIM/U1,		
(D) (4)					
(b) (d)		1976 H 1976	pproved the questionable	(b) (4)	
	espite the fact that no definitive roo	ot cause was ic	lentified. Approximately	,	
commercial lots	s of Suspen	sion mg (b) (4)	mL, were released from l	Line uring	
state of the control	nuary 2022 to December 2022.	10010	I S S S A H S S A H S A		
The Assessment Assessment	Manual Communication of the Co				
OBSERVATIO		00 a r 153 a			
	gned to prevent microbiological co	ontamination of	of drug products purporting	ng to be sterile	
are not establish	ned, written and followed.				
C:Gaally n			1 to provent		
	nanufacturing process simulation			and the same of th	
	for the drug products purporting	70	e are deficient to ensur	re sterile drugs	
manufactured in	are safe and effective. For	example:			
1 The firm	n manufactures sterile solutions a	nd suspension	g for the US market in	filling lines by	
. (D)(4)	I Illanuraciures sierne sorunons ar	na saspension	machine	(b) (4)	
using (b) (4)	(b) (4)	is maintaine	l as a Grade A area that is	(b) (4)	
	Carea During filling operations	Is manualled	of the (ab	(b) (4)	
a Grade	C area. During filling operations	some portion	of the tau	out mm) are	
(b) (4)	to the Grade C area when the		Cinas Tanuary 2021	duning batab	
	4 ' 4 9 instances wil	1 Fai	Since January 2021		
	cturing there were 8 instances wh	hen power lai	dure occurred in the Gra	ade C area mai	
surround	ds the Grade A area as follows:				
1					
1					
	EMPLOYEE(S) SIGNATURE			DATE ISSUED	
SEE REVERSE	Saleem A Akhtar, Investigat			2/17/2023	
OF THIS PAGE	Jose E Melendez, Investigat	tor - Dedica	Signed By 2001638440		
	Drug Cadre		X Date Signed 02-17-2023 18 07 18		
				200	

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 2 of 23 PAGES

DISTRICT ADDRESS AND PHONE NUMBER	ID DRUG ADMINISTRATION DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	2/6/2023-2/17/2023*
Rockville, MD 20857	FEI NUMBER 3008581988
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	<u> </u>
	ite Head
Mr. Ashish Zitshi, Vice President - S	ite Head STREET ADDRESS
Mr. Ashish Zitshi, Vice President - S	National Conference of the Con
Mr. Ashish Zitshi, Vice President - S	Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic

Line Product	Batch #	Date	Market	Power Failure in Minutes
949				

SEE	REV	/ERSI	=
OF T	HIS	PAGE	Ξ

EMPLOYEE(S) SIGNATURE

Saleem A Akhtar, Investigator Jose E Melendez, Investigator - Dedicated Drug Cadre



DATE ISSUED 2/17/2023

	LTH AND HUMAN SERVICES UG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032	DATE(S) OF INSPECTION 2/6/2023-2/17/2023*	
Rockville, MD 20857	FEI NUMBER	
The second secon	3008581988	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Mr. Ashish Zitshi, Vice President - Site		
FIRM NAME Cipla Limited	Plot No. 9 & 10, Pharma Zone Ph	hago Ti
Cipia himited	Section Iiii, Indore Special Ed	
	Zone	
CITY, STATE, ZIP CODE, COUNTRY Dithompus District Dhom Madhara	TYPE ESTABLISHMENT INSPECTED	
Pithampur, District Dhar, Madhya Pradesh, 454775 India	Sterile & Non-sterile Drug Manu	uracturer
(0)(4)	1	
During power failure, the filling machin	e stops, however, the HVAC system i	n Grade Area
keep running as it	However, HV	AC system in
Grade C area does not work during power	AND THE PARTY OF T	the same of the sa
Protocols for Solutions and Suspension		
Version: 10 respectively) a power failure	경영하는 사이트 아이트 아이트 아이트 전환 전환 등 전에 아르아 전경이 되는 그 보고 한경이 아이트 아이트 이번 보고 있다. 그 보고 있다는 그 보고 있다.	and the second of the second o
during aseptic process simulation (media		
(D)(4)	g, which is considered the worst case into	
firm does not have scientific data esta	그들이 그렇게 되었다면 가게 하셨다면 하는데	
	~ ·	udies to fully
understand the effect that power failures h	ave on the manufactured batch.	
(b) (4)	(b) (4) /b)	(b) (4)
B. During the manufacturing of	Suspension mg and nL, batc	ch on
9/27/2021, cleaning was perf	ormed	lue to the fact
rformed at "" fa	ailed due to (()(4) The (()(4)	cleaning cycle
vas aborted at about (*) (4)	ALCOHOLD COMPANY OF THE PROPERTY OF THE PROPER	te documented
orming cleaning i.e., do	ne at The site	e did not raise
any deviation or investigate what caused the	that resulted in fail	ling
F 100 100 100 100	नीं	
EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE Saleem A Akhtar, Investiga: OF THIS PAGE Jose E Melendez, Investiga:		2/17/2023
Drug Cadre	LOF - Dedicated Saledi Annual Investigator Signed 92 201638440 Date Signed 92-17-2023	
	18 07 18	
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE II	NSPECTIONAL OBSERVATIONS	PAGE 4 of 23 PAGES

	DEPARTMENT OF HEAL FOOD AND DRUG		TION			
12420 Parkla	NE NUMBER Wn Drive, Room 2032		2/6/2023	TION -2/17/202	3*	
Rockville, M			FEI NUMBER 30085819	2000m		
			30003013	0.0		
NAME AND TITLE OF INDIVIDU	ALTO WHOM DEPORTISSIED					
5/5 / 75/5 40 VO 64/3 5/09	itshi, Vice President - Site	Head				
FIRM NAME		STREET ADDRES	S			
Cipla Limite	d				ne Phase I	
	Section Iiii, Indore Special Economic Zone				С	
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISH	MENT INSPECTED	95/20 5/4 V	Date - Call S	
Pithampur, D. Pradesh, 454	istrict Dhar, Madhya	Sterile	& Non-ste	rile Drug	Manufactu	rer
riadesii, 454	775 India					
			101	(b) (4))	
	the manufacturing of sterile drug	solutions				re is a
	wn such as the		or there is	a power fai	lure in the G	
	firm performs a clean	ing (exclu	des the clear	ning of the	tank)	in the
	A area. As of 1/1 e site	considere	(b)(4)	cleaning	as the wor	
interven	tion that occurs very rarely and it v	vas periori	ned		during me	
(b) (A)	In contrast, it was observed during			January 200	**************************************	
Clea	ning about times during the batc	n manurac	turing since	January 202	21 as fisted b	elow.
(b) (4)		1,) / 1 NT	25.1	Tour.	1
Produc	t Name	1	Batch No.	Market	Filling]
Line Produc	t Name	1	Batch No.	Market	Filling Start	
Line No.	t Name	1	Batch No.	Market		
Line Produc	t Name	1	Batch No.	Market		
Line No.	t Name]	Batch No.	Market		
Line No.	t Name]	Batch No.	Market		
Line No.	t Name]	Batch No.	Market		
Line No.	t Name]	Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name]	Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	t Name		Batch No.	Market		
Line No.	EMPLOYEE(S) SIGNATURE		Batch No.	Market	Start DATE ISSUED	
Line No.	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigate	or		Statem & Abblar	DATE ISSUED 2/17/2	
Line No.	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigato	or		Statem & Abblar	DATE ISSUED 2/17/2	
Line No.	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigato Jose E Melendez, Investigato	or			DATE ISSUED 2/17/2	
Line No.	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigato Jose E Melendez, Investigato	or		Statem & Abblar	DATE ISSUED 2/17/2	

FORM FDA 483 (09/08)

DATE(S) OF INSPECTION 2/6/2023-2/17/2023* FEI NUMBER 3008581988	
FEI NUMBER	
Head STREET ADDRESS	
Plot No. 9 & 10, Pharma Zone Phase Ii,	
Section Iiii, Indore Special Economic	
Zone	
TYPE ESTABLISHMENT INSPECTED	
Sterile & Non-sterile Drug Manufacturer	

SEE REVERS	F
OF THIS PAG	Е

EMPLOYEE(S) SIGNATURE

Saleem A Akhtar, Investigator
Jose E Melendez, Investigator - Dedicated
Drug Cadre

Saleem A Akhtar Investigator Signed By 2001638440 Date Signed 02-17-2023 18 07 18 DATE ISSUED 2/17/2023

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

PAGE 6 of 23 PAGES

	DEPARTMENT OF HEA	ALTH AND HUM. RUG ADMINISTRAT		ES		
	ADDRESS AND PHONE NUMBER		DATE(S) OF INS			
Rockville, M	wn Drive, Room 2032		2/6/2023-2/17/2023* FEI NUMBER			
ROCKVIIIE, M	7 20837		300858	1988		
NAME AND TITLE OF INDIVIDUA						
Mr. Asnish Zi	itshi, Vice President - Site	T STREET ADDRESS				
Cipla Limited	4	5.50 MM 60 100-500	9 & 10	Pharma Zone F	Phase Ti	
oipia mimice	A.	The second secon	Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic			
		Zone	\$1000000005 \$100			
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHM			12/8111/03/15/03	
	istrict Dhar, Madhya	Sterile	& Non-s	terile Drug Mar	nufacturer	
Pradesh, 454	//S India	_3				
1						
1						
Cinas Isansams	2021, the site shipped about (1)	hatabaa af at	anila dana		(b) (4)	
and the second s	(D) (4)	let				
		265 725	ng routin	e batch manufact	uring, the firm	
failed to demon	astrate that its decision to perfor	m a	clean	ing intervention ")(-)	
(b)(4) during pro	ocess simulation is representative	of normal op	erations.	200		
O1		1				
l						
l						
OBSERVATION	ON 3					
Aseptic process	ing areas are deficient regarding t	he system for	monitori	ing environmental	conditions.	
A . The (0)(4)	are located in the	(Grade	A zone	of the filling lin	ne The	
(b) (4)						
				Sign AS		
Although the sp	noke studies do not evaluate/demo	onstrate the la	minar flo	w from the	area to prevent	
microbial conta	mination, your Report SR/AFP	SDC/01 ent	itled "Air	flow Pattern of (b)	in	
	amic condition"; approved on Oc					
the solution ma	nufacturing area for filling line	Woro 06		The report did r		
air flore pottom	by	that appears				
air flow pattern	(4)			v turbulence and v	where the other	
surfaces of the	is in direct contact with th	is Grade C Z	one.			
.	attraction of the contract of	C'11.	(b)(4)	11.1		
	mental monitoring of the aseptic				that microbial	
contaminants the	hat could impact critical areas v	were identifie	ed and in	ivestigated for		
l						
l						
	- 197 - 111 - 111 - 211			- i	Transaction of the same	
SEE DEVEDOS	EMPLOYEE(S) SIGNATURE	ton		ı	2 / 1 7 / 2 0 2 2	
SEE REVERSE OF THIS PAGE	Saleem A Akhtar, Investiga Jose E Melendez, Investiga		rated	Saleem A Akhfar	2/17/2023	
OF THIS PAGE	Drug Cadre	Deul	Jaceu	Investigator Signed By 2001638440 Date Signed 02-17-2023		
l				X 18 07 18		

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 7 of 23 PAGES

	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMA G ADMINISTRATI		ES		
DISTRICT ADDRESS AND PHOP	wn Drive, Room 2032		2 / 6 / 2 0	PECTION 23-2/17/2023*		
Rockville, M			FEI NUMBER			
			3008581988			
Mr Ashish 7:	itshi, Vice President - Site	Head				
FIRM NAME	resili, vice l'estache site	STREET ADDRESS				
Cipla Limited	d		t No. 9 & 10, Pharma Zone Phase Ii,			
		Section Iiii, I Zone			Indore Special Economic	
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHME		SATE SATER CASE II INDIAN	8W21172	
Pithampur, D: Pradesh, 454	istrict Dhar, Madhya	Sterile	& Non-s	terile Drug Man	ufacturer	
riadesii, 454	773 Iliula					
products distrib	uted to the US market.					
34	(0) (4)					
The filling Line	es.			suspension/liquid		
(b) (4)	are located in a room the	at is classif	ned as	area Withi	n the	
(a) (a)	These activities a	re in an env	rironment	classified as (b)(4)	as well. The	
(b) (4)	used for the drug produc	t are located	d in the	of the f	illing lines that	
is classified as	ar					
	y 6, 2020, and August 30, 2022, yo	ur environn	nental mo	nitoring program	did not require	
collecting surfa	ce swab samples from			even though du	ring filling, the	
(b) (4)			(b) (4)			
				ommercial lots of	drug products	
(i.e., suspension	/solutions) were manufactured/rele	ase/distribu	ted in the	USA market.		
OBSERVATIO	ON 4					
Appropriate con	ntrols are not exercised over compu	ters or relate	ed system	s to assure that ch	anges in	
master producti	on and control records or other reco	ords are inst	ituted onl	y by authorized pe	ersonnel.	
Cassifically an	manuista controla are not avencias	d arran tha a		and solated arreta	ma mad in the	
	propriate controls are not exercised			No. 2000 Contract of the Contr		
The second secon	of commercial drugs to assure or				erifical process	
parameters and	alarms is backed up, archived, and	retained. Fo	or exampl	e:		
A. During	the inspection of Sterile Filling Li	ne (equi	pment ID	; used	to manufacture	
sterile d	rugs for the US market) on 2/6/2023	3, it was obs	served tha	at the historical da	ta pertaining to	
	EMPLOYEE(S) SIGNATURE			Î	DATE ISSUED	
SEE REVERSE	Saleem A Akhtar, Investigat				2/17/2023	
OF THIS PAGE	Jose E Melendez, Investigat Drug Cadre	or - Dedic	cated	Saleem A Akhfar Investigator Signed By 2001638440 Date Stoned 02-17-2023		
	Drug Caure			Date Signed 02-17-2023		

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 8 of 23 PAGES

	TH AND HUMAN SERVICES G ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032	2 / 6 / 2 0 2 3	CTION 3-2/17/2023*
Rockville, MD 20857	FEI NUMBER	393502+
A CANADA CONTRACTOR CO	30085819	}88
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	**************************************	
Mr. Ashish Zitshi, Vice President - Site	Head I street address	
Cipla Limited	S200 98	Pharma Zone Phase Ii,
	AND THE RESERVE OF THE PARTY OF	dore Special Economic
CITY, STATE, ZIP CODE, COUNTRY	Zone Type establishment inspected	
Pithampur, District Dhar, Madhya		erile Drug Manufacturer
Pradesh, 454775 India		
(b) (4)		
critical process parameters such as		etc.
and alarms is not available for verification.		
connected to this machine overwrites the d		
the existing data. The operators use a	(0)(4)	photos of the alarms and these
alarms are then included with the batch rec		on the (a) (b) (d)
are subject to deletion. The Site Head state	ed all other sterile fill	ing lines such as Line
lack these controls. Filling Lines	are	currently used to manufacture
sterile drugs for the US market.		
(D) (4)	(b) (4)	
B. Similarly,	(IDs:	used to manufacture
non-sterile iquids & suspensions for the		(6)
allow printing and transfer of electronic d		(6)(4)
		Manufacturing Head for
stated that the alarms pertaining to c	•	(b) (d)
acknowledged by the operators and ca		
Manufacturing Head, the firm considers all		,
not documented on the batch records and/or	equipment use logboo	oks.
(b) (4)		(b) (4)
(ID:	is routinely use	ed to manufacture
Suspension, (b)(4) mg (d) nL for the US ms	arket. It takes about	
Suspension (batch size:) on this (0)(4)	Since January 2021, the site
		The alarms regarding critical
process parameters generated during the ma	nufacturing of these b	atches could not be verified.
EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE Saleem A Akhtar, Investigate		2/17/2023
OF THIS PAGE Jose E Melendez, Investigate	or - Dedicated	Saleem A Akhlar Investigator Signed By 2001638440
Drug Cadre	[,	X Date Signed 02-17-2023 18 07 18
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INS	PECTIONAL OBSERVATION	NS PAGE 9 of 23 PAGES

	ALTH AND HUMAN SERVICES RUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032	DATE(S) OF INSPECTION 2/6/2023-2/17/2023*
Rockville, MD 20857	FEI NUMBER 3008581988
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	ANDERS OF
Mr. Ashish Zitshi, Vice President - Site	e Head LSTREETADDRESS
Cipla Limited	Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic Zone
Pithampur, District Dhar, Madhya Pradesh, 454775 India	Sterile & Non-sterile Drug Manufacturer
The firm's SOP (1035-B0035, Version: 2.0, Effective Electronic Data" (1035-B0035)	ctive Date: 4/30/2021), "Retention and Destruction of
QUALITY SYSTEM	
OBSERVATION 5 Procedures describing the handling of written and deficiently written or followed.	l oral complaints related to drug products are
Specifically, procedures related to investigation mcg are deficiently written	
A. Since 2020 the site distributed batche the number of patient complaints received	
7 7	7574

Year	distributed	No. of US Complaints Received	Batch Size (b)(4) Units)
2020	(b) (4)	324	(b) (4)
2021	_	1065	-
2022	.1	1619	
Total		3008	

SEE REVERSE Saleem A Akhtar, Investigator Jose E Melendez, Investigator - Dedicated Drug Cadre Saleem A Annar Salee	2/17/2023
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 10 of 23 PAGES

		F HEALTH AND HUMAND DRUG ADMINISTRATI		
12/12/0 Darels and PHO	NE NUMBER Wn Drive, Room 2032		DATE(S) OF INSPECTION 2/6/2023-2/17/202	2*
Rockville, M			FEI NUMBER	J.
			3008581988	
	AL TO WHOM REPORT ISSUED	2000 0200 0		
Mr. Ashish Z.	itshi, Vice President - S	Site Head STREET ADDRESS		
Cipla Limite	d	5.00 MM - 001 100 MM	9 & 10, Pharma Zo	ne Phase Ii,
			Iiii, Indore Speci	
CITY, STATE, ZIP CODE, COUN	ПВУ	Zone TYPE ESTABLISHME	ENT INSPECTED	
	istrict Dhar, Madhya		& Non-sterile Drug	Manufacturer
Pradesh, 454		2000 000 000 000 000 000 000 000 000 00		\$100 C V (100 C V V V V V V V V V V V V V V V V V V
771 1	11 6 1 6	(D) (4)		
The brea	akdown of complaints specific	ally for		is as follow:
	Year	-		
	2020			
	2021			
	2022			
In addit	ion to 3006 complaints, as of	$\frac{2}{4}$ 2023 the fin	n received about 266	complaints in 2023
that are	under investigation. The site d	lid not perform a	ny Health Hazzard Ev	aluation about these
complai	nts to evaluate if any market a	ction is warrantee	1.	
	17. 11			
	21, the firm performed a risk		760.740	in year 2020 as the
	complained about many issu			
(b) (4)	and stopp	ed working, me	dication was not (10)(4)	
(b) (4)	is not working etc. On 1/18/20			asures are available
and then	e is no risk to the product qual	lity and patient sa	fety.	
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		1.5	(b) (4)
As per y	your Executive Summary (effe	ective date: 1/31/	2023) of complaints for	or
about 20	653 (out of 3008 complaints)	were related to	and about	94 complaints were
regardin	(b) (4) 1 <u>0</u>	Together, ov	er 91% (2747/3008) o	f the complaints are
	to the performance of the pr	The second second second	And the second of the second o	AT A MARKET STATE PROPERTY OF THE PARTY OF T
	l in subsequent years (2021 and			
		A STATE OF THE PARTY OF THE PAR		
nas adec	quate controls in place, there is	s no risk to produ	ict quanty & patient sa	nety, and the min s
				0 9 6
	EMPLOYEE(S) SIGNATURE			DATE ISSUED
SEE REVERSE	Saleem A Akhtar, Invest			2/17/2023
OF THIS PAGE	Jose E Melendez, Invest Drug Cadre	igator - Dedic	Saleem A Akhlar Investigator Signed By 200163844I Date Signed 02-17-202	3
	Drug Cadre		X 18 07 18	
				20.5
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL O	BSERVATIONS	PAGE 11 of 23 PAGES
			NAME OF TAXABLE PARTY OF TAXABLE PARTY.	

	DEPARTMENT OF HEAL FOOD AND DRU	G ADMINISTRATION			
DISTRICT ADDRESS AND PHO	NE NUMBER Wn Drive, Room 2032		DATE(S) OF INSPECTION 2/6/2023-2/17/2023*		
Rockville, M		1	FEI NUMBER		
			3008581988		
NAME AND TITLE OF INDIVIDUA		** 1			
Mr. Ashish Zi	itshi, Vice President - Site	Head STREET ADDRESS			
Cipla Limited	d	Plot No.	9 & 10, Pharma Zone	Phase Ii,	
Promise Programme Company		Section I	Iiii, Indore Special		
CITY, STATE, ZIP CODE, COUN	ПРУ	Zone Type establishmen	NT INSPECTED		
	istrict Dhar, Madhya	Sterile 8	& Non-sterile Drug Ma	anufacturer	
Pradesh, 454	775 India	3	CONTRACTOR	STORY FOR THE STORY OF THE STOR	
		11 11 171	C 2 0 12 II 4 C 1	1 /	
	essment performed on 1/2021 is sti				
	e corrective actions to reduce the nu	imber of coi	inplaints related to the per	riormance of the	
product.	(
B The fire	n received two confirmed compla	ints # CON	1-1035-2021-01785 (for	hatch (B)(4)	
	(3) (4)		0/2022) and COM-1035-		
batch			ration date: 9/30/2022) of	and the second s	
	21 respectively. In both complaint				
(b) (4)	27 respectively. In John complaint	is the patien	as reported that the med	areation was not	
	201		(b) (4)		
During	the investigation of both complain			16.7.4E	
	piece		ged somewhere within th	(D) (4)	
	(4)		The vendor that supplies		
examine	ed the impacted samples and confir	med that the	e observed particle repor		
	tentially generated by the damaged			The	
	reported maintenance work was dor	ne on	C	when	
1	patches (vendor lot # blot # lot #		were manufactur	26.3.221	
(b)(4)	100 May	were used in	n batch	ies	
annalia i		bate ntenance wo	000 8797	(b) (4)	
and/or			potentially compromised	batches of	
(b) (4)	vendor were used t	ng. These p	ire about patches of	(4)	
hatches	as below:	o manuracu	ne about satenes of		
batches	as ociow.				
1					
1					
1					
1					
	F 19 19 19 19 19			Tr	
SEE REVERSE	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigat	or	I	2 / 1 7 / 2 0 2 3	
OF THIS PAGE	Jose E Melendez, Investigat		ated Saleem A Akhhar	2/17/2023	
I ST THIS T AGE	Drug Cadre		Investigator Signed By 2001638440 Date Signed 02-17-2023 18 07 18		
				-1	
	L			7/10	

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 12 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 2/6/2023-2/17/2023* FEI NUMBER Rockville, MD 20857 3008581988 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Ashish Zitshi, Vice President - Site Head Cipla Limited Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic Zone CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Sterile & Non-sterile Drug Manufacturer Pithampur, District Dhar, Madhya Pradesh, 454775 India

endor Batch	Batch	Manufacturing		Shipping
o. for	No.	date*	date*	date*
4)				

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE

Saleem A Akhtar, Investigator
Jose E Melendez, Investigator - Dedicated
Drug Cadre

Saleem A Akhlar Investigator Signed By 2001638440 Date Signed 02-17-2023 18 07 18 DATE ISSUED 2/17/2023

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

PAGE 13 of 23 PAGES

	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMAN SERVI	CES	
DISTRICT ADDRESS AND PHON	NE NUMBER	DATE(S) OF I		
With the second	wn Drive, Room 2032		023-2/17/2023*	
Rockville, MI	20857	FEI NUMBER 30085		
		2022A24 Man 4253		
1				
1				
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED	<u>t</u>		
The state of the s	itshi, Vice President - Site			
FIRM NAME	21	STREET ADDRESS	: -	4 44
Cipla Limited	i		O, Pharma Zone F	
i		Zone	Indore Special E	conomic
CITY, STATE, ZIP CODE, COUN	TRY	TYPE ESTABLISHMENT INSPECTED).	
Pithampur, Di	istrict Dhar, Madhya	Sterile & Non-	sterile Drug Man	ufacturer
Pradesh, 454		1970 (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970) (1970)	Tillife Foreigit för til 1960 vilkeriking – straveren	
C. The firm requires the complain extended It was of were key	of complaint records indicated the ntioned batches comprising of omplaints were received for batch of all complaints be investigated, replaint SOP does not require any four investigation is overdue. Some of period of time such as 314 day, 2 beserved that about 94 complaints per open for an extended period of the sex as Examples of few complaints is as	manufactural, Version: 14), "It viewed, and closed formal request for ecomplaints pertaining to the perfetime including but it	For example, a gred on Handling of Production in Extension and appropriate to the example of the example of the example of the example, and the example of t	et Complaints" In addition, val in case the e kept open for en justification. drug
	S. # Complaint Bri	ief complaint sumi	nary	Days
		•	V.	
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigate Jose E Melendez, Investigate Drug Cadre		Saleem A AMhtar Investigator Speed by 2001638440 Digital Speed 02-17-2023 18 07 18	2/17/2023
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL OBSERVAT	TIONS	PAGE 14 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 2/6/2023-2/17/2023* FEI NUMBER Rockville, MD 20857 3008581988 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Ashish Zitshi, Vice President - Site Head Cipla Limited Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic TYPE ESTABLISHMENT INSPECTED CITY, STATE, ZIP CODE, COUNTRY Sterile & Non-sterile Drug Manufacturer Pithampur, District Dhar, Madhya Pradesh, 454775 India (b) (4) Number delayed COM-1035-314 2021-01785 COM-1035-278 2021-02088 COM-1035-210 2022-01569 COM-1035-189 2021-00177 COM-1035-183 2021-00195 COM-1035-183 2021-02380 COM-1035-183 2022-01674 COM-1035-170 2022-01187 155 COM-1035-2021-01453 COM-1035-154 2021-02693 COM-1035-149 EMPLOYEE(S) SIGNATURE DATE ISSUED

SE	EF	RE	/EI	RS	E
OF	TH	HIS	P	٩G	E

Saleem A Akhtar, Investigator Jose E Melendez, Investigator - Dedicated Drug Cadre



2/17/2023

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

PAGE 15 of 23 PAGES

	LTH AND HUMAN SERVICES IG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	2/6/2023-2/17/2023* FEI NUMBER
	3008581988
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	· · · · · · ·
Mr. Ashish Zitshi, Vice President - Site	STREET ADDRESS
Cipla Limited	Plot No. 9 & 10, Pharma Zone Phase Ii,
	Section Iiii, Indore Special Economic Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, District Dhar, Madhya	Sterile & Non-sterile Drug Manufacturer
Pradesh, 454775 India	
2022-02314	
COM-1035-	146
2022-00869	
COM-1035-	139
2021-02056	
COM-1035-	137
2021-01757	
COM-1035-	131
2022-00260	
COM-1035-	127
2022-00272	
COM-1035-	125
2021-02998	123
COM-1035-	124
2021-00813	124
COM-1035-	121
2022-02396	121
COM-1035-	120
2021-00735	120
COM-1035-	118
2021-03710	118
	110
COM-1035-	118
EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE Saleem A Akhtar, Investigat	or 2/17/2023
OF THIS PAGE Jose E Melendez, Investigat	or - Dedicated Saleem AAAMar Investigator Signed By 2001638440 V Date Signed D2-17-2023
Drug Cadre	Dalle Signed 02-17-2023
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATIONS PAGE 16 of 23 PAGES

	DE	EPARTMENT OF HE	ALTH AND HUM RUG ADMINISTRAT			
DISTRICT ADDRESS AND PHONE			ROG ADIMINISTRAT	DATE(S) OF INSPECTION		
	n Drive, Room	2032		2/6/2023-2/ FEI NUMBER	17/2023*	
Rockville, MD	20857			3008581988		
NAME AND TITLE OF INDIVIDUAL	. TO WHOM REPORT ISSUED			Į.		
Mr. Ashish Zi	tshi, Vice Pre	esident - Sit	e Head			
FIRM NAME	258-04-4-00-0-1	encanded by the section	STREET ADDRESS			
Cipla Limited			33.3	9 & 10, Pha		
			Service Control of the Control of th	Iiii, Indore	Special E	Conomic
CITY, STATE, ZIP CODE, COUNTR	RY		Zone TYPE ESTABLISHM	ENT INSPECTED		
	strict Dhar, M	ladhya	Sterile	& Non-steril	e Drug Man	ufacturer
Pradesh, 4547	75 India					
	_	(6)	(4)			-
	<u> </u>	021-00099				Total Control of the
	C	COM-1035-				115
	2	022-00417				
	ō	COM-1035-				115
	2	022-02801				
	_	COM-1035-				114
		022-00531				114
		022-00331				
concerning a fail for it in the appli Specifically, you (1035-G-0014,	ur Quality Unit Version: 7.0), "	re distributed ba	atches of a dra it a Field Ale eport" for co	ert Report (FA	R) as required to the requirement of the requiremen	s established
02088; Lot		06/29/2021 and				
) (4)	Ouring the inves			Z 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		(b) (d)
(4)	Juling the lilves		(b) (4)	within the	761 741	a
(4)		P16 (0)(4)	ece was	111		1. 64
(4)						supplier of the
In May	2022, your Qua	1111 (6)	11.55			
COM-1035-202	1-02088; and dis	positioned both	as "Confirm	ed". You used	these poten	tially defective
r	100 100 100 100					The second
SEE REVERSE	Saloom A Albh	ar Investis	tor	1		2 / 1 7 / 2 0 2 3
OF THIS PAGE	Saleem A Akht			cated s	eleem A Akhtar	2/17/2023
	Drug Cadre			V Di	vestigator gned By 2001638440 ate Signed 02-17-2023 07 18	
					and the second s	
			100 ALTERNA TANA		- 20	
FORM FDA 483 (09/08)	PREVIOUS EDITION OF	SOLETE	INSPECTIONAL (OBSERVATIONS		PAGE 17 of 23 PAGES

		LTH AND HUMAN SERVIC IG ADMINISTRATION	CES	
DISTRICT ADDRESS AND PHO	NE NUMBER	DATE(S) OF IN		
Rockville, M	wn Drive, Room 2032 D 20857	Z/b/ZU FEI NUMBER)23-2/17/2023*	
NOCKVIIIE, III	ROOKVIIIC, IID 20007		31988	
NAME AND TITLE OF INDIVIDU	AL TO WHOM REPORT ISSUED	<u> </u>		
Mr. Ashish Z	itshi, Vice President - Site	Head		
FIRM NAME	48	STREET ADDRESS	8 4979 697 69	19 (619)
Cipla Limite	d	Plot No. 9 & 10		
		Section Iiii, I Zone	.ndore special i	ECOHOMIC
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHMENT INSPECTED	CO SOUTH PLAN THEM	6221176
	istrict Dhar, Madhya	Sterile & Non-s	sterile Drug Man	nufacturer
Pradesh, 454	//5 India			
(b)(4)	facture batches of	(about [®]	units).	
The site Qualit	y Head confirmed the firm receive	d similar complaints	for all batche	s. For example,
	ar nature complaints were received		manufactured on	
(b) (4)	220 to 2022, your firm received a		(b) (4)	
(b) (4)	200 Sept. 100 Se	••	complaints for	
	associated to the performance of	i me drug product.		
OBSERVATION	ON 7			
	ities and procedures applicable to the	he quality control un	it are not fully foll	owed.
Specifically, yo	our Quality Unit failed to retain	numerous original	GMP records inc	cluding records
pertaining to	$(\stackrel{\text{(b)}}{(4)} \text{ mg/} \text{ mL})$	Ampoules,	7b3 743	nd (b)(4)
(b) (4)		Spray, batch (b)(4)		or these batches
Word ongoing is	(b)(4)			
were ongoing in	tespectively at	the start of the inspe	ction on 2/0/2023.	
A. During	inspectional walkthrough of the	facility premises at	about 9:45 am	on 2/6/2023. I
The state of the s	(b) (4)	loaded with		PARTY AND DESCRIPTION OF THE PARTY AND DESCRI
	ng documents were observ		crap bags loaded	
	the bags stored at central scrapyard			on this truck us
well as	the bags stored at central scrapyard	intended for sineddi	ng.	4140
a]	Numerous torn pieces of printer	weigh slips pertain	ing to packaging	of (b)(a)
(5)	Ampoules, batch (a)	(intended for	market).	
b. 1	Micro lab sample label san	nple; originating fro	m dated:	2/5/2023) with
	344		1	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	EMPLOYEE(S) SIGNATURE			DATE ISSUED
SEE REVERSE	Saleem A Akhtar, Investigat	or	1	2/17/2023
OF THIS PAGE	Jose E Melendez, Investigat		Saleem A Akhtar Investigation	SOURCE STATE
	Drug Cadre		Signed By 2001638440 Date Signed 02-17-2023 18 07 18	
			<u> </u>	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVAT	IONS	PAGE 18 of 23 PAGES

		TH AND HUMAN SERVICE G ADMINISTRATION	ES	
12420 Darklas	wn Drive, Room 2032	DATE(S) OF INS	SPECTION 23-2/17/2023*	
Rockville, MI		FEI NUMBER	rick teachers	
			1988	
NAME AND TITLE OF INDIVIDUA		II J		
Mr. Asnish Zi	itshi, Vice President - Site	Head STREET ADDRESS		
Cipla Limited	d	Plot No. 9 & 10 Section Iiii, I Zone		
City.state.zipcobe.coun Pithampur, Di Pradesh, 454	istrict Dhar, Madhya	Sterile & Non-s	terile Drug Mar	nufacturer
	(b) (4)	•		
(0)(4)	QA wet signatures pertaining to		(b) (4)	
	batch This b	atch is intended for the	he marl	cet.
S/SS W			(b) (4)	(b)(4)
20	An uncontrolled page with handy	and the second of the second o		and Line
(b)		cific time period as fo	ollow:	
d.	***:			
e.				
mL in-print	working in the manufacturing areas firm's SOP (1035-G-004, Version: trol" defines control document tification number or footer numbibution of product". This SOP rened for product expiry	that appeared to have 10.0, Effective Date as, "a control doc er associated with	: 9/19/2022) for "sument is a reco	performed perfor
Tetai	ned for product expiry			
				_
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigat Jose E Melendez, Investigat Drug Cadre		Saleem A AMhtar Investigator 2001638440 Date Signed 02-17-2023 18 07 18	DATE ISSUED 2/17/2023
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATI	ONS	PAGE 19 of 23 PAGES

DISTRICT ADDRESS AND DUO	FOOD AN	D DRUG ADMINISTRATION						
	orkville, MD 20857		DATE(S) OF INSPECTION					
- Par			2/6/2023-2/17/2023* FEI NUMBER					
	iie, MD 20037		31988					
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED	<u> </u>						
Mr. Ashish Z	itshi, Vice President - S	ite Head						
FIRM NAME	ψ.	STREET ADDRESS	5 5 <u>55</u> 557 55					
Cipla Limited	1	Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic		Participation of the Control of the				
		Zone						
CITY, STATE, ZIP CODE, COUN			TYPE ESTABLISHMENT INSPECTED					
	istrict Dhar, Madhya	Sterile & Non-s	Sterile & Non-sterile Drug Manufacturer					
Pradesh, 454	775 India							
B. You fail	ed to take market action as per	your Product Recall Pro	ocedure (# 1035-G	-0013, Version:				
10.0) ag	ainst batches (#							
(b) (4)	(b) (4)	spension that failed to	meet stability sp	ecifications for				
viscosity	towards the end of the shelf		A STATE OF THE PROPERTY OF THE	(0) (4)				
batches	(b) (4)		in the m					
ATTLANTONIO-PEROST		9 %;	(b) (4)					
Your Si	te Head stated these batches	The second second	and the same of th					
(-) (-)		and were distribu	ited in the Non US	market.				
LABORATOR	Y CONTROL SYSTEM							
	T COLUMN STOLEM							
OBSERVATIO	ON 8							
Laboratory reco	ords do not include complete da	ata derived from all tests.	examinations and	assay				
				necessary to assure compliance with established specifications and standards.				
The same to the sa								
Specifically, determination of conformance to written specifications of Total Aerobic Microbial Count								
opening, as	termination of conformance to	written specifications	of Total Aerobic M	11.45				
. (b) (4) in	termination of conformance to	22	of Total Aerobic M	ficrobial Count				
in (b) (4)	termination of conformance to	22		ficrobial Count				
in dr	termination of conformance to	22		ficrobial Count				
in (b) (4)	termination of conformance to	22	facturing of sterile	ficrobial Count				
in (b)(4) dr (b)(4)	termination of conformance to tent # 1035-MM-005-INH, Ve	used in the manu	facturing of sterile Micro Lab,	ficrobial Count and non-sterile				
in dr dr method (docum	ent # 1035-MM-005-INH, Ve	are tested in the ersion: 8.0, Effective Da	facturing of sterile e Micro Lab, te: 10/7/2022),	ficrobial Count and non-sterile as per test				
in dr dr method (docum After incubatio	ent # 1035-MM-005-INH, Ve n, the media plates are insp	are tested in the ersion: 8.0, Effective Da	facturing of sterile e Micro Lab, te: 10/7/2022),	ficrobial Count and non-sterile as per test ts (CFUs), the				
in dr dr method (docum After incubatio	ent # 1035-MM-005-INH, Ve	are tested in the ersion: 8.0, Effective Da	facturing of sterile e Micro Lab, te: 10/7/2022),	ficrobial Count and non-sterile as per test				
in dr dr method (docum After incubatio	ent # 1035-MM-005-INH, Ve n, the media plates are insp	are tested in the ersion: 8.0, Effective Da	facturing of sterile e Micro Lab, te: 10/7/2022),	ficrobial Count and non-sterile as per test ts (CFUs), the				
in dr dr method (docum After incubatio	ent # 1035-MM-005-INH, Ve n, the media plates are insp	are tested in the ersion: 8.0, Effective Da	facturing of sterile e Micro Lab, te: 10/7/2022),	ficrobial Count and non-sterile as per test ts (CFUs), the				
in dr dr method (docum After incubatio	ent # 1035-MM-005-INH, Ve n, the media plates are insp	are tested in the ersion: 8.0, Effective Da	facturing of sterile e Micro Lab, te: 10/7/2022),	ficrobial Count and non-sterile as per test ts (CFUs), the				
in dr dr method (docum After incubatio photograph of the	ent # 1035-MM-005-INH, Ven, the media plates are inspected media plates are to	are tested in the ersion: 8.0, Effective Da ected for number of coaken using	facturing of sterile e Micro Lab, te: 10/7/2022),	as per test ts (CFUs), the oftware)				
in dr dr method (docum After incubatio photograph of the	ent # 1035-MM-005-INH, Ven, the media plates are inspected media plates are to the inspected media plates ar	are tested in the ersion: 8.0, Effective Da ected for number of coaken using	facturing of sterile Micro Lab, 10/7/2022), Polony forming uni	as per test ts (CFUs), the oftware)				
in dr dr method (docum After incubatio photograph of the	ent # 1035-MM-005-INH, Ven, the media plates are inspected media plates are to the inspected media plates are to the inspected media pla	are tested in the ersion: 8.0, Effective Da ected for number of coaken using	facturing of sterile Micro Lab, te: 10/7/2022), blony forming uni Saleem A Akhtar Investigator Saleem 2001638440 Support by 2001638440	as per test ts (CFUs), the oftware)				
in dr dr method (docum After incubatio photograph of the	ent # 1035-MM-005-INH, Ven, the media plates are inspected media plates are to the inspected media plates ar	are tested in the ersion: 8.0, Effective Da ected for number of coaken using	facturing of sterile Micro Lab, 10/7/2022), Polony forming uni	as per test ts (CFUs), the oftware)				

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 20 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032	DATE(S) OF INSPECTION 2/6/2023-2/17/2023*			
Rockville, MD 20857	FEI NUMBER			
	3008581988			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
Mr. Ashish Zitshi, Vice President - S				
FIRM NAME Cipla Timitod	STREET ADDRESS			
Cipla Limited	Plot No. 9 & 10, Pharma Zone Phase Ii, Section Iiii, Indore Special Economic			
	Zone			
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Pithampur, District Dhar, Madhya	Sterile & Non-sterile Drug Manufacturer			
Pradesh, 454775 India				
or and then transferred	d on the documentation server. Analysis results pertaining			
(b) (4)	ted in LIMS and analysis for is			
documented on paper worksheets.	ted in Envis and analysis for			
On 2/6/2022 morning, the micro lab inspected	amples/media plates for growth			
	The following significant deficiencies were observed for			
this analysis:	The following significant deficiencies			
this analysis.				
A. For samples, the results were n	ot entered contemporaneously in LIMS for plate after			
	ples under the colony counter (that includes verification of			
	nalysis, and reading the media plate for growth), wrote the			
number of colonies observed on each	plate, made an entry on equipment use logbook indicating			
start time: end time: and	then entered results for all samples in LIMS.			
The firm's SOP (# 1035-L-0083), "M	icrobiological Best Laboratory Practices) requires that the			
QA reviewer shall verify microbial co	ount on all the plates / test results against reported results.			
	e QA reviewer verified microbial count on all the plates.			
The only evidence of a QA review for the reported results against the actual test results was				
available in LIMS. LIMS date/time stamps indicated the review of all				
in about seconds as follows:	imps indicates the resize to the second			
in about seconds as follows.				
Sr. Sample ID Observed coun	nt Result entered in Reviewed in LIMS			
The second secon				
No. (CFU per mL)	LIMS at (HH:MM:SS) at (HH:MM:SS)			
FURLANTIAN SIGNATURE	DATE ISSUED			
SEE REVERSE Saleem A Akhtar, Invest:	igator DATE ISSUED 2/17/2023			
OF THIS PAGE Jose E Melendez, Investi	igator - Dedicated Saleem A Akhtar			
Drug Cadre	Signed 6y 2001638440 Date Signed 02-17-2023 1 07 18 19 19 19 19 19 19 19 19 19 19 19 19 19			
32.				

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 21 of 23 PAGES

	DEPARTMENT OF HEAD FOOD AND DRU	LTH AND HUM JG ADMINISTRAT		ES	
DISTRICT ADDRESS AND PHOP	wn Drive, Room 2032		2/6/20	PECTION 23-2/17/2023*	
Rockville, M			FEI NUMBER		
			300858	1988	
NAME AND TITLE OF INDIVIDUA		Hond			
MI. ASHISH Z.	itshi, Vice President - Site	STREET ADDRESS	:		
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FORM FDA 483 (09/08)

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PAGE 22 of 23 PAGES

	DEPARTMENT OF HEAD FOOD AND DRU	LTH AND HUMA JG ADMINISTRATI		ES	
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PAGE 23 of 23 PAGES