	DEPARTMENT OF HEALTH AND HUMAN SERV FOOD AND DRUG ADMINISTRATION	ICES
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION  3/28/2024 - 4/4/2024  FEI NUMBER  3002806710
Industry Information: www.fda.gov/oc/industry		3002800710
To: Vijayasarathi Ramaswami, Head - Glo	bal Quality	
FIRM NAME	STREET ADDRESS	
Cipla Limited	Patalganga Industr	ial Area, Plot No A-2, A-33, A-37/2/2, A-42
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHME	ENT INSPECTED
Raigad, Maharashtra, 410220, India	Human and animal	API and human drug product manufacturer
OBSERVATIONS; AND DO NOT REPRESENT A FINAL OBSERVATION, OR HAVE IMPLEMENTED, OR PLA	AGENCY DETERMINATION REGARDING YOUR COINTO IMPLEMENT CORRECTIVE ACTION IN RESP TATIVE(S) DURING THE INSPECTION OR SUBMIT TO AT THE PHONE NUMBER AND ADDRESS ABOVE.	ECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL MPLIANCE, IF YOU HAVE AN OBJECTION REGARDING AN ONSE TO AN OBSERVATION, YOU MAY DISCUSS THE HIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF
OBSERVATION 1		
Failure to clean and maintain equipm would alter the quality of the API be		
Specifically,		
Your firm does not properly clean an	d maintain 405 ceutical ingredient intended for the U	which is utilized in the manufacture of JS market as noted below:
• On 4/2/2024, we inspected what appeared to be two flying insections.		0-8). Upon opening the we noted ar the
during API manufacti	of the duct, multiple areas of external	The duct duct to the de of building and exposed to damage (dents) were observed and a
large gap in the duct seal was noted a were able to insert a folded 8 x 11 inc	pproximately 4 feet from the	p and confirmed that the duct seal was e, and the duration for which the breach
		Add Continuation Page
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND T	TLE (Print or Type)
SEE REVERSE For Newman	Lori M. Newman, Invest Sean R. Marcsisin, Invest	gator
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FORM FDA 483 (9/08) PREVIOUS EDITION OBSOL	INSPECTIONAL ORSER	VATIONS

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DISTRICT OFFICE ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/28/2024 - 4/ FEI NUMBER	
Industry Information: www.fda.gov/oc/industry	3002806710	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED		
To: Vijayasarathi Ramaswami, Head - Global Quality	STREET ADDRESS	
FIRM NAME	The state of the s	2 4 22 4 27/2/2 A 42
Cipla Limited CITY, STATE AND ZIP CODE	Patalganga Industrial Area, Plot No A	-2, A-33, A-31/2/2, A-42
Raigad, Maharashtra, 410220, India	Human and animal API and human dr	rug product manufacturer
Additionally, your firm lacks evidence that on maintenance was trained on the associated pro	en your firm documented that the gasket/sea le of the engineering technicians who perfor ocedure. Since 2/21/2024, your firm has man the manufacture of drug products for the U	Is were inspected. med the preventative nufactured aots of S market.
• On 4/3/2024, we inspected the interior of the body valve. We noted various debris in the (caulking) material and unknown residue.  OBSERVATION 2	e duct to include what appeared to fragments	ctly adjacent to the sof duct sealant
Equipment and utensils are not cleaned and m would alter the safety, identity, strength, quali	aintained at appropriate intervals to prevent ty or purity of the drug product.	contamination that
A. We inspected the to include to include the to include the tablets USP. The following tablets to the tablets use the tablets	uring area which is utilized in the manufactulowing deficiencies were noted:	are of US drug products
• On 3/28/2024, we noted unknown res  (b)(4) The was in the pro  (a)(4) The	ocess of being cleaned of the previous batch material is white in color.	f the (b) (4) (b) (4) mg
		Add Continuation Page
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE Scon Marishlu	Lori M. Newman, Investigator Sean R. Marcsisin, Investigator	04/04/2024
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL ORSEDVATIONS	

		HEALTH AND HUMAN SERVICES D DRUG ADMINISTRATION	
DISTRICT OFFI	CE ADDRESS AND PHONE NUMBER	DA	TE(S) OF INSPECTION
12420 Parkl Rockville, N	lawn Drive, Room 2032 MD 20857		28/2024 - 4/4/2024
		FEI	NUMBER
Industry Info	ormation: www.fda.gov/oc/industry	30	002806710
	LE OF INDIVIDUAL TO WHOM REPORT IS ISSUED		
To. Vijaya	sarathi Ramaswami, Head - Global Quality		
FIRM NAME	Mildelli Managrama, 1.200	STREET ADDRESS	
Cipla Limite	ad		a, Plot No A-2, A-33, A-37/2/2, A-42
CITY, STATE AN		TYPE OF ESTABLISHMENT INSP	
Man St. St. St. St.	harashtra, 410220, India		nd human drug product manufacturer
bearing ho bolt of the	024, we noted an unknown spot or using, and unknown white residue on the basembly is exp  The above equipment was documented a	shaft bolt of the bosed to the drug product disc	(b)(4)bolt and (b)(4)assembly. The shaft charge flow path during
cleaning. Nobserved, the log "Do" Sy powder was cleaning an	T-308 "Operation and Cleaning of vetem" is inadequate because it lacks a moderate of the cleaning procedure should be repeated etails of Numbering and Cleanliness Verification of After Dismantling sobserved in ducts 23015 (b)(4) (1) (a) (b)(4) (a) (b)(4) (a) (b)(4) (b)(4) (b)(4) (c) (c)(4) (c)(4	d until results are satisfactory ification of home many and 23015 (4)06 of	igation in the case of a failed a cleaned duct, if any residue is 7. On 04/01/2024, we observed on Duct After Cleaning by Using ring Area that on 10/16/2023,  (6)(4)500 (6)(4)-500) after
OBSERVA			
ranure to a	dequately investigate out-of-specification	n results	
Specifically	′,		
OOS-1030- USP lot irm has fail o ensure all		nains open as of the current in DOS results remain to be dete	nspection for mined. As of 4/3/2024, your ing process and PSD OOS results n and management of the state of th
Nevos	EMPLOYEE(S) SIGNATURE	T-ADI OVER-TO-VI	Add Continuation Page
SEE REVERSE OF THIS	Fori newman	EMPLOYEE(S) NAME AND TITLE (Print	or Type) DATE ISSUED
OF THIS PAGE	Sen Marchism	Lori M. Newman, Investigator Scan R. Marcsisin, Investigator	04/04/2024
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	FOOD AND DICCO / I	DATE(S) OF INSPECTION
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AND TITLE OF INDIVIDUAL TO VICTORIA	JED 1'e	
y: Vijayasarathi Ramaswami, Head - Global Qi	ianty	
M NAME	Patalganga Indus	strial Area, Plot No A-2, A-33, A-37/2/2, A-42
ipla Limited		
TY STATE AND ZIP CODE	Human and anim	nal API and human drug product manufacturer
aigad, Maharashtra, 410220, India		
BSERVATION 4		
	0.114	
equipment qualification procedures are r	not followed	
specifically,		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	- a and Amiliantian of For	ninment for the
Your firm did not follow procedure 103	5-(1-(1)(1)42 - Quantication of Eq. (b)(4) in 2	2023 for (b) (4) USP active
Vann firm acquired and began using the	(b) (4) ·	ring (b) (4) operations to address particle
pharmaceutical ingredient manufacture	to help	ing operations to a sequinment to
cize OOS events. Per procedure 1035-G	-0042, your firm is to perform	a risk assessment for new equipment to 4/3/2024, your firm has not conducted a new equipment to a new equipm
dentify equipment criticality and guide	qualification activities. As of 4	4/3/2024, your firm has not conducted a 1
assessment nor qualification activities for	or the	(6) (4)
assessment nor quantication acri		_
OBSERVATION 5		
	and avaluated	and that critical deviations are investiga
Failure to ensure all production deviation	ons are reported and evaluated,	and that critical deviations are investigated
and the conclusions are recorded.		
C		
Specifically,	AVAN	
Your firm does not evaluate atypical ev	Secretary Control of the Control of	active pharmaceutical ingredient packing
The (b)(4) API is to be pack	ted into	nts). Your firm has documented API bate cannot account for. For example,
per procedure PROD-39 - P	acking with special protection.	
of the finished API and 60(4)QC sample	ing of the batch even	its). Your firm has documented API bate
	The state of the s	The state of the s
<sup>(b) (4)</sup> API lot	(b) (4) have (b) (4) events oc	
		(b) (4)
	Name of the State	
		Add Continuation F
EMPLOYEE/OLOGOMATURE	EMPLOYEE(S) NAME /	AND TITLE (Print or Type) DATE ISSUED
SEE LOUI NEWMAN		AND TITLE (FIRE OF Type) DATE ISSUED
SEE Loui newman	Lori M. Newman, I	Investigator
SEE Lou neuman	Lori M. Newman, I. Sean R. Marcsisin,	Investigator 04/04/2024

a 3/16/2024 at 16:50, there was an audiovisual alarm for system. While the alarm was acknowledged and the system and that exceeds specifications, you did not provide evidence that a value as required for rectification in Annexure MT291/A5.    Comparison of the			OD AND DRUG ADMINISTRATION	
Industry Information: www.fda.gov/ocindustry  WINDER AND THE OF INGORDIAL TO WHOM REPORT IS ISSUED  TO: Visyassarathi Ramaswami, Head - Global Quality  Patalganga Industrial Area, Plot No A-2, A-33, A-37/2/2, A-4  TYPE OF ESTABLISHMENT INSPECTED  Ratigad, Maharashtra, 410220, India  DBSERVATION 6  The responsibilities and procedures applicable to the quality control unit are not fully followed.  Specifically,  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wystem" are not adequately followed in case an alarm occurs for high solid his arious drug product formulations for the US market, including  D35-G-0196 "Categorization and Handling of Alarms" defines a critical alarm as an alarm that may have a direct on product quality. Annexure to MT291 (MT291/A5 "List of Alarms, Possible Causes, and Rectification as a noncritical alarm.  Date of the solid his part of the system stopping due to very high meter, and check the limit the sure functioning of the meter, and check the limit the limit has been to QC for verification of the system. While the alarm was acknowledge and the system supple should be sent to QC for checking of the limit (value:  DATE ISSUED  DATE ISSUED  DATE ISSUED  DATE ISSUED  LOG M. Novaman, Investigator  Sean, M. Marchama, Investigator  DATE ISSUED  Lori M. Novaman, Investigator  Sean, M. Marchama,	DISTRICT	OFFICE ADDRESS AND PHONE NUMBER	DA	TE(S) OF INSPECTION
Industry Information: www.fda.gov/oc/industry  Industry Information: www.fda.gov/oc/industry  Industry Information: www.fda.gov/oc/industry  Industry Information: www.fda.gov/oc/industry  Information: www.fda.gov/oc/indust			3	/28/2024 - 4/4/2024
Industry Information: www.fda.gov/oc/industry  WINE AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  TO: Visyasarathi Ramaswami, Head - Global Quality  Patalganga Industrial Area, Plot No A-2, A-33, A-37/2/2, A-4  TYPE OF ESTABLISHMENT MESPECTED  Raigad, Maharashtra, 410220, India  DESERVATION 6  The responsibilities and procedures applicable to the quality control unit are not fully followed.  Specifically,  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed in case an alarm occurs for high  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed in case an alarm occurs for high  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed in case an alarm occurs for high  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed in case an alarm occurs for high  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed.  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed.  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed.  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of wastern" are not adequately followed.  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of Wastern" are not adequately followed.  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handling of Alarms" and MT291 "Operation of Wastern" are not adequately followed.  DESERVATION 6  The procedures 1035-G-0196 "Categorization and Handlin	Kockvill	ie, MD 20857		
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