	ALTH AND HUMAN SERVICES UG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	5/2/2022-5/10/2022*
Rockville, MD 20857	FEI NUMBER 3007373532
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mettu Madan Mohan Reddy, Director	
FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited	Unit Vii, Formulation Plant, Plot S-1, Survey 411, 425, 434-435, 458, Tsiic, Green Ind. Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Polepally, Mahaboob Nagar, Telangana, 509302 India	Drug Manufacturer
This document lists observations made by the FDA representative(observations, and do not represent a final Agency determination reobservation, or have implemented, or plan to implement, corrective action with the FDA representative(s) during the inspection or subquestions, please contact FDA at the phone number and address about	garding your compliance. If you have an objection regarding an e action in response to an observation, you may discuss the objection or mit this information to FDA at the address above. If you have any
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:  OBSERVATION 1  Investigations of an unexplained discrepancy and any of its specifications did not extend to other based on the specification of the sp	

products that may have been associated with the specific failure or discrepancy.

1.Investigations of out of specification (OOS) assay and dissolution results that led to the rejections of tablet batches identified a lack of control over compression machine settings including (b) (4)

and compaction force as a root cause. These investigations were not extended to all tablet products to ensure appropriate limits were set and that similar variations in machine settings had not resulted in the acceptance of tablets that did not meet specifications. For example:

A hypothesis study showed that increasing (b) (4) during compression to (b) (4) or higher could generate tablets meeting all in-process specifications. However, the portions of batches manufactured during the trial with (b) (4) that were increased to (b) (4) or

	EMPLOYEE(S) SIGNATURE  Justin A Boyd, Investigator  Darren S Brown, Investigator  Discrete S Brown, Investigator  Date Signed 05-10-2022  X 16 13 50	DATE ISSUED 5/10/2022
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DATE(S) OF INSPECTION 5/2/2022-5/10/2022* FEI NUMBER 3007373532			
FEI NUMBER			
3007373332			
, Formulation Plant, Plot S-1, 11, 425, 434-435, 458, Tsiic, d. Park			
TYPE ESTABLISHMENT INSPECTED  Drug Manufacturer			
uirements. The investigation included no mine if (b) (4) during manufacturing used the same variable assay results within			
USP. The investigation did not evaluate (b) (4) , including November 2020 that used			
limit was not extended to other tablet not have established (b) (4) limits. inpression data for any other tablet product ave caused variable assay values within a blets, or any other tablet produced for the			
ne 27, 2020, when batch (b) (4) of (g, (b)) mg did not meet the specification of (t) of (b) (b) (b) (c) (b) (d) on the compression			
roposed for (b) (4) and (b) (4) cospective review of compression machine			
Domen 5 Brown Investigation Signed By 2001647750 Date Signed 05-10-2022 X 16 13 50			

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PREVIOUS EDITION OBSOLETE

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	DEPARTMENT OF HEAL FOOD AND DRUG	TH AND HUMA G ADMINISTRATI		is	
12420 Daniel at			DATE(S) OF INS	PECTION 22-5/10/2022*	
Rockville, M	wn Drive, Room 2032 D 20857	1	FEI NUMBER		
1.0011.12120, 111			3007373	3532	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED				
Mettu Madan N	Mohan Reddy, Director				
FIRM NAME	gava vara	STREET ADDRESS	50.5	de Composition Substitution and Alberta	MONTH FOR MAN
Aurobindo Pha	arma Limited			lation Plant, F	
		Green Inc		434-435, 458,	TS11C,
CITY, STATE, ZIP CODE, COUN	TRY	TYPE ESTABLISHME			
	ahaboob Nagar, Telangana,	Drug Man	ufacture	er	
509302 India					
PI C da	ta to determine if high (b) (4)	imne	acted oth	er batches of (b)	(4) and
(b) (4)	Tablets or any othe	150 (0.0)		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
	radicts of any other	i tablet proc	iuci mai	was within expiry.	•
c Investigat	ion APL Unit 07/INV/15/20 was o	nened Augu	st 8 202	0 when batch (b)	(4) of
(b) (4)	to be used in (b) (4)	pened riage	151 0, 202	Cansules m	g was out of
specific	ation for content uniformity during	in-process	testing of		The batch was
rejected	The investigation identified that	variation o	f the cor	npression machin	
caused s	segregation within the (b) (4), causin	of the OOS	result for	content uniformit	tv
Cuaseas	, eausi	is the cos.	resunt for	content uniformi	
The inve	estigation was not able to identify	the (b) (4)	1156	ed during the man	infacturing No
	investigation was conducted to de				ise segregation
within the	ne (b) (4)	crimine win		would cut	ise segregation
This inv	restigation was not extended to revi	ew of all otl	her tablet	products that had	no established
(b) (4)	to determine if similar variati			had caused portion	
to be ou	t of specification.	New York Control of the Control of t		1	
d.Investigat	ion APL Unit 07/INV/014/21 was	opened Ju	ne 2, 20	21, when batch	b) (4) of
(b) (4)	T	ablets USI	(b) mg	was out of sp	ecification for
dissoluti	ion. The batch was rejected alon	g with bat	ch (4) (4)		vas considered
	ne, but meeting dissolution specific				
	se to be low hardness due to low				
Limits f	or (b) (4) compa	ction force l	nad not be	een established.	111 55.77
P. C.					
During	manufacturing of the two rejected	batches, th	e PLC c	ompaction data sl	howed the (b)
(b) (4)	force was (b) kN for portion	ns of the r	nanufact	uring. The PLC	data was only
-					
·	ř.				•
	EMPLOYEE(S) SIGNATURE			ı	DATE ISSUED
SEE REVERSE OF THIS PAGE	Justin A Boyd, Investigator Darren S Brown, Investigator	r		Darren S Brown	5/10/2022
OF THIS PAGE	Darren 5 brown, investigato.	L×.		Investigator Signed By 2001647750 Date Signed 05-10-2022 V 18 13 50	
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FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

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	DEPARTMENT OF HEAL FOOD AND DRUG			S	
DISTRICT ADDRESS AND PHON	NE NUMBER Wn Drive, Room 2032		5/2/202	PECTION 22-5/10/2022*	
Rockville, MI		:	FEI NUMBER 3007373		
Mettu Madan M	ALTOWHOM REPORT ISSUED Mohan Reddy, Director				
FIRM NAME	Hohan Reddy, Director	STREET ADDRESS	200		
Aurobindo Pha	0 000000 0000 000 000 000 000 000 000	Survey 4 Green In	11, 425, d. Park	lation Plant, F 434-435, 458,	
Polepally, Ma 509302 India	ahaboob Nagar, Telangana,	Drug Man		er	
had port thorough have me	d for batches in the same campaign tions of the batch with a (b) kN (b) (d) hly evaluate whether the portions of et all dissolution specifications. Batch to the US market.	of these oth	force r er batche	esult. The investig	25 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
identifie of the (b) the (b) batches includin	tity qualification FU7-MISC-ACTF and the hardness range for the product in-process checks had hardness in-process checks had hardness had in-process hardness results belog:  (41.4%), (43.7%).	et should be values belovalues belovalues	(b) _(b) (4) (4) W (4) kp (b) kp (4) l for at lea	kp. During (b) (4) b. During (b) (4) cp. Additionally, ast 40% of the in-	, 29.3% , 38.5% of other released process checks
batches have be	vas no review of PLC data for all within expiry or for other tablet pr en impacted by low <sup>(b) (4)</sup> ation in the dissolution rate within a	oducts to d	ompaction	n forces, causing	(C) (E) (E) (E) (E) (E) (E) (E) (E) (E) (E
dissoluti low con specifica (b) (4)	ion APL Unit 07/INV/003/20 was of and (b) (4) ion specification. The batch was rempaction force during compression ations, but had lower hardness and in these tablets released the drug applicated a portion of the batch, table	jected. The n resulting l lower we faster, resu	Tab investiga in tablet ight than ilting in t	lets (b) (b) mg di tion identified the s that were meet the target. The l he dissolution fai	id not meet the e root cause as ting in-process less compacted
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Justin A Boyd, Investigator  Darren S Brown, Investigator	r		Darrien S Brown Investigator 2001647750 Dalle Started 05-10-2022 X 18 13 50	DATE ISSUED 5/10/2022
FORM FDA 483 (09/08)	DEBUTORS EDITION OBSOLETE INS	SPECTIONAL C	BSERVATIO	ONS	PAGE 4 of 13 PAGES

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	LTH AND HUMAN SERVICES JG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
12420 Parklawn Drive, Room 2032	5/2/2022-5/10/2022*			
Rockville, MD 20857	FEI NUMBER 3007373532			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
Mettu Madan Mohan Reddy, Director	4-10-10-10-10-10-10-10-10-10-10-10-10-10-			
FIRM NAME	STREET ADDRESS	I-+ C 1		
Aurobindo Pharma Limited	Unit Vii, Formulation Plant, Pl Survey 411, 425, 434-435, 458,			
	Green Ind. Park	15110,		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Polepally, Mahaboob Nagar, Telangana,	Drug Manufacturer			
509302 India				
22 20101 41 - (b) (4) f		1 41 4 . 1 . 1 . 4 .		
22, 2019, when the (b) (4) compression force				
met specifications, but had lower hardness	and weight results than the rest of the ba	itch.		
_0	(b) (A)	8		
There was no established limit for setting	ng the compaction force on the	compression		
machine. The preventive action was to es				
product, but this was not extended to all otl	her tablet products, which still do not ha	ve established		
compaction force limits.				
A hypothesis study during the investigation	confirmed low compaction force tablets	s led to tablets		
with a faster drug release and tablets with				
release. The investigation did not include	a review of PLC data for all batches of	of (b) (4)		
and (b) (4)	Tablets within expiry or any other			
determine if operator changes to compacti	on force set points during a batch could	d have caused		
the acceptance of tablets that would not me				
in a recinii an sanatas an				
f.Investigation APL Unit 07/INV/004/20 was	opened February 6, 2020, when batches	(b) (4)		
	Tablets USP (b) mg and (b) (4)	NE		
Tablets	Tablets USP (b) mg and (b) (4) USP (b) mg failed dissolution. The	batches were		
rejected. The investigation identified the re-	oot cause as a cumulative effect of mor	re (b) (4) in the		
(b) (4) along with less compaction force app	lied during compression	iii iii		
along with less compaction force app	oned during compression.			
The investigation was not extended to eva	Justa DI C compaction force data for al	1 (b) (4)		
	patches within expiry or any other tab			
	이번 (BBAN) (BBB) : : - ''(1) [1] (BBB) : [1] (BBB) : -			
determine if similar low compaction forces	impacted dissolution rates in a portion of	of the batch.		
2 I 1' 1' A DI II -' 1 07/DNV/020/20 02	1 D 1 22 2020	1 1 1 1		
2.Investigation APL Unit 07/INV/020/20-02	was opened December 22, 2020, V	when batches		
100000000000000000000000000000000000000	Т			
EMPLOYEE(S) SIGNATURE	_	DATE ISSUED		
SEE REVERSE   Justin A Boyd, Investigator OF THIS PAGE   Darren S Brown, Investigato		5/10/2022		
Darren S Brown, investigato	Investigator Signed By 2001647750 Date Signed 05-10-2022			
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATIONS	PAGE 5 of 13 PAGES		

	DEPARTMENT OF HEAL FOOD AND DRUG	TH AND HUMA GADMINISTRATIO			
DISTRICT ADDRESS AND PHON	wn Drive, Room 2032		5/2/2022-	-5/10/2022*	
Rockville, MI		2	FEI NUMBER	ATRION AND	
		-	300737353	32	
NAME AND TITLE OF INDIVIDUA					
Mettu Madan N	Mohan Reddy, Director				
Aurobindo Pha	arma Limited	STREET ADDRESS	Formulat	tion Plant, P	1ot S-1
Autobilido Tile	ilma bimited	State of the second sec		134-435, 458,	AND AND ADDRESS OF THE PARTY OF
		Green Ind			Verticescould distribute in
Polepally Ma	ahaboob Nagar, Telangana,	Drug Manu			
509302 India	maboob Nagar, Terangana,	Drug Manufacturer			
7E\ 74\		7F3 743			
(b) (4)		of (b) (4)		Table	ts mg failed
dissolution.	The investigation identified a	coarser part	icle size	in supplier ba	tch (b) (4) of
(b) (4)	, which is used as a (b) (	+)	(b) (d)	. The investiga	ation identified
this coarser	particle size caused uneven distribu	ition in the		stage and	
	l other (b) (4) materials during	(6) (4)	, whic	h led to fast dr	ug release and
variability ii	n dissolution.				
The impacte	ad (b) (4)	notab (b) (4)	was used	to manufactura	(b) batabas of
(b) (4)	ed <sup>(b) (4)</sup> vendor b Tablets b mg. In	addition to	the three (	OS batabas tl	(4) Datches of
hatches tha	it had not yet been released and	d all were	rejected	(b) (4) batches	(b) (4) (4)
batches tha	t had not yet been released and	i all were	rejected.	batches	V
	had already been released. T	he investigat	tion conclu	des there was n	o impact to the
released bat	ches based on passing finished pro-				
that passed	at the L3 stage, (b) batches at	the L2 stag	e. and (b)	batch at the	L1 stage. The
investigation	n does not justify the conclusion that	at this raw m	naterial four	nd to cause fast	er drug release
2,70	ity in dissolution would not have im				C
				700	
3.Investigation	APL Unit 07/INV/013/20 was op	ened Augus	st 3, 2020,	when batch (b	of of
(D) (4)	and (b) (4) Cap	sules USP	$mg_{(4)}^{(D)} mg$	failed for unsp	ecified organic
impurities a	nd was rejected. The investigation				
				of the holes in	
	encapsulation. The investigation				ermining if the
previous pro	oduct would cause a chromatography	y peak consi	stent with t	the OOS result.	
- 1 1 1 · ·	1 (b) (4)		NUMBER DRAWN		
The holes in					
were not ree	evaluated after the findings of this in	ivestigation.	Additiona	ny, there was n	o evaluation to
	EMPLOYEE(S) SIGNATURE				DATE ISSUED
SEE REVERSE	Justin A Boyd, Investigator		1		5/10/2022
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FORM FD 4 483 (00/08)	DESTRUIS EDITION OBSOLETE INS	PECTIONAL OF	RSERVATIONS		PAGE 6 of 13 PAGES

FORM FDA 483 (09/08)

	DEPARTMENT OF HEAL FOOD AND DRUG	TH AND HUMA G ADMINISTRATI		ES	
12/120 Parklas	NE NUMBER Wn Drive, Room 2032		DATE(S) OF INS	PECTION 22-5/10/2022*	
Rockville, M			FEI NUMBER	- C. (1946-1970), 13	
			3007373	3532	
NAME AND TITLE OF INDIVIDUA					
Mettu Madan N	Mohan Reddy, Director	STREET ADDRESS			
Aurobindo Pha	arma Limited	200 0000 100000	. Formu	lation Plant, P	lot S-1.
SCHOOLSE SESSENCE CONTROL SECTIONS				434-435, 458,	
CITY, STATE, ZIP CODE, COUN	TDV	Green In			
	ahaboob Nagar, Telangana,	Drug Man		er	
509302 India	चित्र क्षणां क्षणां व च । च श्रवा <b>अ</b> वत्ता के चित्र च कि च च च च च च च च च च च च च च च च च			N75-1	
1.2	6411-4:1411-641		C 4	1 1	9 22 22
including (b)	f the analytical methods for other p  (4) Capsules, (b) (4)	roducts ma	Coper	les, (b) (4)	irea equipment
Capsules, (b		d (b) (4)	-	les would have d	etected similar
	nination if present.	u	Capsul	les would have d	etected similar
cross contai	minution if present.				
Investigatio	n APL Unit 07/INV/012/21 was o	pened Apr	il 26, 20	21. when batch (t	o) (4) of
(b) (4)	1 (b) (4)	1 TICH	D (b)	(b) c 1 1 c	. 0. 1
organic imp	curity at the same retention time as	(b) (4)	. The ba	tch was rejected.	The root cause
was again a	ttributed to (b) (4) cross	s contamina	ition relat	ed to the (b) (4)	used during
	on. The investigation did not analy				or ensure
	al methods for other products man		n the san	ne shared equipme	ent would have
detected sin	nilar cross contamination if present.				
22112				4 14 14 14 14 14	
	Conformance (PNC) investigation				
implemente	d preventive actions to prevent	events the	hat lead	/b\ /4\	
chromatogra	aphy data. For example, PNC trendi	ng for		S	shows:
a 85 DNCs	opened related to HPLC instrument	e including	20 inetru	ment failures 28	communication
	and 7 carousel malfunctions.	5 including	27 msuu	ment failures, 20 C	Johnnancation
ianures,	and / carouser manufactions.				
b 44 PNCs	opened related to (b) (4) s	tandard fai	ilures re	sulting in the d	isregarding of
THE RESIDENCE AND THE PROPERTY OF THE PARTY	ography data.	tillian in	inares, 10	stitling in the ti	ioreguraning or
Individual P	PNC records did not identify correct	ive or preve	entive acti	ions.	
		100			
	- 20 July - 100 July -				1000
SEE REVERSE	Justin A Boyd, Investigator			I	5/10/2022
OF THIS PAGE		r		Darren S Brown Investigator	3/10/2022
	]			Signed By 2001647750 Date Signed 05-10-2022 X 18 13 50	
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FORM FDA 483 (00/08)	INS	SPECTIONAL C	DRSERVATI	ONS	PAGE 7 of 13 PAGES

FORM FDA 483 (09/08)

		LTH AND HUMAN SERVICE ADMINISTRATION	ES		
DISTRICT ADDRESS AND PHO	NE NUMBER	DATE(S) OF IN			
Rockville, M	wn Drive, Room 2032 D 20857	5/2/20 FEI NUMBER	22-5/10/2022*		
ROCKVIIIe, II	20037	300737	3532		
NAME AND TITLE OF INDIVIDU	AL TO WHOM REPORT ISSUED				
Mettu Madan I	Mohan Reddy, Director				
FIRM NAME	929(1 N)(8) (Q.1	STREET ADDRESS			
Aurobindo Ph	arma Limited		lation Plant, Plot S-1, , 434-435, 458, Tsiic,		
		Green Ind. Park	[하는 경기가 1940년 경기가 하나 14명 :		
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHMENT INSPECTED			
Polepally, Ma 509302 India	ahaboob Nagar, Telangana,	Drug Manufacturer			
509302 Ilidia					
OBSERVATION	ON 2				
Section recommendation and accommon to	ritten procedures for production and	l process controls des	signed to assure that the drug		
	he identity, strength, quality, and pu	•			
Parameters incl	uding (b) (4)	aı	nd (b) (4) compaction force, whic		
	variability within a batch, have not	been established as	part of process validation studie		
for any tablet pr	roduct other than (b) (4) Table	ets USP.			
	765 / A)		AST (A)		
1. Values	The state of the s	and the second s	and (b) (4) compaction force ar		
	nted on the "Monitoring of Critical				
	ecord. This form in the batch record	이 경기가 하는데 아이들이 있다면 하게 그 아이들이 얼마나 되어 하나요?			
associat	ed process validation reports did	not address these co	ompression machine parameters		
(b) (4)	Tablets USP (b) mg; (b) (4)	Tablets USP (b) 1  Fablets USP (g; (b) 1	mg; (b) (4)		
Tablets (b) (4)	(mg; (b) (4)	Tablets USP [g; 1	177		
	(b) (4) Tablets (b) (4)	mg; (b) (4)	Tablet		
(b) (4)	mg; (b) (4) Tablets	USP (b) mg; (b) (4)	Tablets USP (b) mg		
	Tablets USP (b) mg; and (b) (4)		Tablets (4) mg.		
2 D	1:1-4: :-:4:-4-1 -A S41		111		
2. Process	validations initiated after Septemb , and <sup>(b) (4)</sup> countil historical data can be gathered	er of 2020 have the	t have only proposed "tentative		
limita?	, and Co	Other then (b) (4)	nave only proposed tentativ		
for any	tablet product. The process valid	ations studies do no	, no minis have been manze		
	al data to demonstrate uniform ta				
compres	ssion machine settings. Until being	finalized the range	es are only "tentative limits" an		
	rators can operate the compression				
	investigation. For example:	machines outside of	mese minis without initiating an		
type or	investigation. For example.				
*	EMPLOYEE(S) SIGNATURE		DATE ISSUED		
SEE REVERSE	Justin A Boyd, Investigator		5/10/2022		
OF THIS PAGE	Darren S Brown, Investigato	r	Darren S Brown Investigator Skoned By 2001647750		
			Signed By 2001647750 Date Signled 05-10-2022 X 18 13 50		
	200	OBECTION I OPERATOR	PAGE 8 of 13 PAGES		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATI	IUNS FAGE 6 01 13 FAGES		

	DEPARTMENT OF HEAL FOOD AND DRIL	TH AND HUMAN SERVICE ADMINISTRATION	ES	
DISTRICT ADDRESS AND PHONE	NUMBER	DATE(S) OF IN		
12420 Parklawr Rockville, MD	n Drive, Room 2032	5/2/20 FEI NUMBER	22-5/10/2022*	
ROCKVIIIe, FID	20037	300737	3532	
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED			
Mettu Madan Mo	ohan Reddy, Director	STREET ADDRESS		
Aurobindo Phan	rma Limited	Unit Vii, Formu	lation Plant F	21ot S-1
Indiabilido indi	Ind Binitoda	Survey 411, 425		Charles and the Control of the Contr
67		Green Ind. Park		> V441.0ACC0203CPyp4# %
Polenally Mak	naboob Nagar, Telangana,	TYPE ESTABLISHMENT INSPECTED  Drug Manufactur	or	
509302 India	laboob Nagar, Terangana,	Drug Handraccur	CI	
		18 200 PM		gares (see
a. (b)	(4) Tablets USP (b) mg, bat pril 15, 2022, the (b) (4) was (b)	ch (b) (4)	At the 3:48 in-pro	
Aj	pril 15, 2022, the (b) (4) was (b)	(4) and (b)		pared to a limit
of	: the (b) (4)	ras (b) (4) compar	red to a limit of (b)	; and
the	e (u) (4) compression force was (u)	kN (b) (4) compare	d to a limit of $\binom{(b)}{(4)}$	4) kN.
b (b)	(4)	(b) (b) (4)	TAN INC.	2004127147
U.	Tablets	(b) (d) mg, batch (b) (4)	. At the .	3:20 in-process
ch	neck on March 26, 2022, the (b)	(b) (4) was	and (t	44.3
	ompared to a limit of (b) (4) (4) and (b) 1-N (b) (4) compared		compression forc	e was $\binom{(0)}{(4)}$ kN
(6)	(4) and (b) $kN^{(b)}$ (compared	I to a limit of $(4)$ $(4)$	kN.	1.00.00
(b)	(4)	(b) 1 (b) (4)	A1 (	o) ·
c. (b)	Tablets USP neck on April 4, 2022, the (b) (4)	(b) (4)	. At the (a) and (b) (4)	
cn to	a limit of (b) (4); the (b)	(4) Was (D) (4		compared to
	limit of $^{(b)}$ and the $^{(b)}$	compression forc	and (b) 1-N (b) (4	) and (b) kN
	(4) compared to a limit of $(a)$ $(b)$ $(b)$ $(b)$ $(d)$	kN.	e was (4) KIV	and (b) kN
_	compared to a mint of (4) (4)	KIV.		
3 The estal	blishment of limits for (b) (4)			, and (b) (4)
	on force were proposed to be add	ed to existing comp	nercialized batch r	
F. 26. 20. 20. 20. 20. 20. 20. 20. 20. 20. 20	additional validation studies a	the control of the co		
effective	November 6, 2020. The protocol j	proposed using histo	orical data from (b)	batches to set
limits, the	ough no limits have been established	ed as a result of the	protocol as of May	9, 2022.
TO THE PARTY OF				See Harris Harris
The proto	ocol does not require additional san	npling or analytical	data to show the h	istorical ranges
-	oduce tablets meeting all finished			
	sed ranges.			
			37	T
The second secon	EMPLOYEE(S) SIGNATURE			DATE ISSUED
	Justin A Boyd, Investigator Darren S Brown, Investigator	•	Darren S Brown	5/10/2022
OF THIS FAGE	Darren D Drown, investigator	- 8	Investigator Signed By 2001647750 Date Signed 05-10-2022 Y 18 13 50	
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OBSERVAT	IONS	PAGE 9 of 13 PAGES

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	5/2/2022-5/10/2022*
Rockville, MD 20857	FEI NUMBER 3007373532
Mettu Madan Mohan Reddy, Director	STREET ADDRESS
Mettu Madan Mohan Reddy, Director	Unit Vii, Formulation Plant, Plot S-1, Survey 411, 425, 434-435, 458, Tsiic, Green Ind. Park
Mettu Madan Mohan Reddy, Director	Unit Vii, Formulation Plant, Plot S-1, Survey 411, 425, 434-435, 458, Tsiic,

4. (b) (4) limits were established for (b) (4) Tablets of (b) (4) based on historical data, but no validation studies to show these ranges are appropriate were conducted.

## **OBSERVATION 3**

Batch production and control records do not include complete information relating to the production and control of each batch.

During tablet compression, the machines are set to reject tablets above or below a set percentage of the compression force setting. If the percentage limits are not properly set, the compression machine could accept tablets that may not meet all specifications. The limits are set by production supervisors during machine set-up and can be changed by the supervisor at any time during manufacturing.

The batch records and written procedures do not include any instructions for setting these rejection limits. For all tablet products distributed to the US, the rejection percentages are captured in the machine PLC data, but there is no documentation in the batch records of how the limits were set, who set them, whether they were changed during processing, or review by quality personnel to determine if the limits were established correctly in order to reject tablets with low or high compaction forces that would not meet all specifications.

## **OBSERVATION 4**

The written stability testing program is not followed.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF IN	DATE(S) OF INSPECTION			
12420 Parklawn Drive, Rockville, MD 20857	Room 2032	5/2/20 FEI NUMBER	5/2/2022-5/10/2022* FEI NUMBER			
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT	RT ISSUED					
Mettu Madan Mohan Red	ddy, Director					
FIRM NAME	5/760 eg ii	STREET ADDRESS	의 (20일) <u>전략및 1일 3일</u>	20도) 정 (EE) 정((		
Aurobindo Pharma Limi	ted	SOUTH A SECURITION OF THE PROPERTY OF THE PROP	lation Plant, P	Charles and Charle		
		Survey 411, 425, 434-435, 458, Tsiic, Green Ind. Park				
CITY, STATE, ZIP CODE, COUNTRY	estant, della company	TYPE ESTABLISHMENT INSPECTED				
Polepally, Mahaboob N	Nagar, Telangana,	Drug Manufacturer				
509302 India						
Ctability camples are not	tested and approved with	: (b) (4)	-f the stability wit	11 deary data for		
Stability samples are not t assay and impurity metho	tested and approved with		of the stability wit	AND RESIDENCE OF THE PROPERTY		
			er tests as required	F		
FU7-QC-GEN-032. For 6				the state of the s		
removed from the stability	y chambers at least 50 wo	orking days earner v	vnich nad not yet o	een completed.		
Examples include:						
1 (b) (4)	т.11	1 I I I I I I I I I I I I I I I I I I I	12	41025000 00000		
1.		ets USP batch (b) (4)	The second secon	onth time point		
	f March 3, 2022. None of					
	The dissolution failed the					
	, but an instrument failur		g to be invalidated.	. Re-testing for		
L2 had not been in	nitiated as of May 9, 2022	å.				
76.3 7A3	(b) (d)					
2. (b) (4)	and (b) (4)		20.00	Tablets		
	mg, batch (b) (4)		point with a pull da			
11, 2022. The diss	solution testing was not in		21, 2022, and did n	ot meet the L1		
criteria. The L2 tes	st had not been initiated a	s of May 9, 2022.				
7272-2447						
3. (b) (4) Tablets (b) mg, batch (b) (4) , 12-month time point with a pull date of March 6,						
2022. None of the	testing was approved and					
3.44.55 (A.44.55.76.5 (A.44.55.46.5 (A.54.56.46.5 (A.54.56.46.5 (A.54.56.46.5 (A.54.56.46.5 (A.54.56.46.5 (A.5	A College Manufacture (Alberton et al. 1990)		THE STATE OF THE S			
4. (b) (4)	Capsules, b	oatch (b) (4)	, 18-month time p	oint with a pull		
date of March 4, 2022. None of the testing was approved and the dissolution testing had not yet						
been initiated.						
5. (b) (4) Suspension (b) g, batch (b) (4) , 24-month time point, with						
a pull date of March 9, 2022. None of the testing was approved and the assay and total titratable						
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EMPLOYEE(S) SIG	CNATIRE			DATE ISSUED		
	A Boyd, Investigator		I	5/10/2022		
	S Brown, Investigator	r	Darren S Brown Investigator			
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032	DATE(S) OF INSPECTION  5/2/2022-5/10/2022*  FEI NUMBER					
Rockville, MD 20857	3007373532					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Mettu Madan Mohan Reddy, Director						
FIRM NAME	STREET ADDRESS					
Aurobindo Pharma Limited	Unit Vii, Formulation Plant, Plot S-1, Survey 411, 425, 434-435, 458, Tsiic, Green Ind. Park					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Polepally, Mahaboob Nagar, Telangana, 509302 India	Drug Manufacturer					
(b) (4) testing had not yet been initiated.						

product non-conformance (PNC) reports have been opened to document stability samples that were not tested within established time frames. For example, the number of overdue stability samples documented in previous PNC (b) (4) reports include January 2022 (496 late samples), December 2021 (270 late samples), and November 2021 (148 late samples). No preventive actions have been implemented as part of these previous PNC reports to ensure stability samples are tested according to the established procedure.

## **OBSERVATION 5**

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Analysts can delete results from the ABT software used to perform microbial identification. Additionally, the laboratory personnel did not know how to access the audit trail for the software. Form FU7-QC-FORM-0164 "Standalone Instruments Audit Trail Checklist" was completed March 25, 2022. The reviewer indicated the audit trail was enabled and there was no data deletion or modification. At that time, the reviewer did not know how to access the audit trail.

## **OBSERVATION 6**

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

1. The PLC for (b) (4) Machine #7 displayed "0" for the (b) (4) during batch (b) (4) of (b) (4) Tablets (a mg on May 2, 2022. For in-process checks, the operators record the

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	DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032			DATE(S) OF INSPECTION 5/2/2022-5/10/2022*				
	Rockville, MD 20857		FEI NUMBER 3007373532				
			3007373332				
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED						
Mettu Madan N	Mohan Reddy, Director						
FIRM NAME	2-741.74.81.91	STREET ADDRESS		E9 1 E 9			
Aurobindo Pha	arma Limited	Unit Vii, Formulation Plant, Plot S-1, Survey 411, 425, 434-435, 458, Tsiic, Green Ind. Park					
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Polepally. Ma	ahaboob Nagar, Telangana,	Drug Man	ent inspected ufacturer				
509302 India	anaboob Nagar, Terangana,	Drug Han	araccurci				
nes hat	h reading for array time - int (b) (4)	113	antified as a suiti1	as noremet f-			
this prod	h reading for every time point. (b) (4)	IS 10	entified as a critical proces	ss parameter for			
2.The (b) (4)	Machine #7 PLC displays data	in real tim	e but has been configured	to only record			
	monitoring data (b) (4)		2, 2022, the (b) (4)	, a critical			
process	parameter, was observed outside th	ne establish	ed limit of (b) (4)	with a value of			
(b) (4)	during the manufacturing of batch (b)	) (4)		blets mg. This			
	captured during manual operator	checks, the	data recorded by the PL	C at (b) (4)			
intervals	s, or an alarm.						
*DATES OF I	NSPECTION			)			
and the second s	), 5/03/2022(Tue), 5/04/2022(Wed)	. 5/05/2022	(Thu), 5/06/2022(Fri), 5/09	9/2022(Mon).			
5/10/2022(Tue)	profession to the profession of the profession to the profession t	,	(1110), 0, 00, 2022(111), 0, 0,	(1/1011),			
Justin A Boyd Investigator							
X Signed By: 2000358888 Date Signed: 05-10-202	2 18:14:37						
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OF THIS PAGE	Darren S Brown, Investigator	2	Darren S Brown Investigator Signed By 2001647750 Date Signed 5-10-2022				
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