DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION				
12420 Parklawn Drive, Room 2032		4/26/2022-5/9/2022*				
Rockville, MD 20857		FEI NUMBER 3002809586				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Mr. Pradipta Swain, Site Head & Vice Pres	• 1	erations				
FIRM NAME	STREET ADDRESS					
Sun Pharmaceutical Industries Ltd.	Halol – Baroda Highway					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Halol, Gujarat, 389350 India	Drug Manı	ufacturer				

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: **PRODUCTION SYSTEM**

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

A. None of the (b)(4)Aseptic Process Simulations (media fills) (Batch #s: (b) (4)

(b) (4)

) performed for

Injectable Suspension USP, $\binom{(b)}{(4)}$ mg/mL, $\binom{(b)}{(4)}$ mL from April 2020 thru March 2022 accurately represent the actual manufacturing process. This is a highrisk manually intensive dispensing and compounding process that uses sterile API that does not undergo^{(b) (4)} filtration after compounding or before filling. Some of the deficiencies include but were not limited to:

Commercial manufacturing process	Aseptic Process Simulation			
About ^{(b) (4)} g of sterile API is hand ^{(b) (4)}	About $\binom{(b)}{(4)}$ g of sterile $\binom{(b)}{(4)}$ is hand			
from ^{(b) (4)} sealed or previously opened	(b) (4) from (b) (4) sealed (b) (4)			
	container into ^{(b) (4)}			
(b) (4) canisters.	^{(b) (4)} canisters. The use of previously			

	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert Jose M Cayuela, Investigator - Dedicated Drug Cadre	Saleem A Akhtar investigator signeef by 2001638440 Date Signed 05-09-2022 18 43 07	date issued 5/9/2022
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVAT	IONS	PAGE 1 of 23 PAGES

DEPART	MENT OF HEALTH AND H FOOD AND DRUG ADMINIST					
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032		DATE(S) OF INSPECTION				
Rockville, MD 20857		4/26/2022-5/9/2022* FEI NUMBER 3002809586				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Mr. Pradipta Swain, Site Head &	Vice President,	-				
Sun Pharmaceutical Industries I	td. Halol	– Baroda Highway Ishment Inspected				
Halol, Gujarat, 389350 India		Ianufacturer				
 (b) (4) g of sterile API is hand (b) (4) unknown number of times (MBR states "slowly and gradually add") from canisters into the compounding tant time period varying from (b) (4) (including (b) (4) (including (b) (4) c times) for (4) batches mfd. from 5/2 was reported (not documented) the and tank remained opened during the and tank remained opened during the sterile API into compounding tank (b) (4) (b) (4) Change occurred during additional sterile API into compounding tank (b) (4) The same deficiencies apply to mg/mL (mL vials which share the total of (b) (4) and (b) batches of (b) (4) batches of (b) (b) (4) (b) (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c	an About Atates (b) (4) (composition (b) (4) (composition (b) (4) (composition (b) (4) (composition (b) (4) (composition (b) (4) (composition (b) (4) (composition (b) (4) (composition (composit	I bags of sterile API has not been ted. $\binom{(b)}{(4)}$ g of sterile $\binom{(b)}{(4)}$ is hand from $\binom{(b)}{(4)}$ canister into the unding tank for a period of $\binom{(b)}{(4)}$ for the first $\binom{(b)}{(4)}$ media fills. For last $\binom{(b)}{(4)}$ media fills was ed to $\binom{(b)}{(4)}$ and $\binom{(b)}{(4)}$ (actual ulated) $\binom{(b)}{(4)}$ for a total of about g were added to tank from $\binom{b}{b}$ hers, which is still less ulation and exposure time of the API than commercial batches Media Fill $\binom{(b)}{(4)}$ (11/19/21) mulated the addition of $\binom{(b)}{(4)}$ into npounding tank without actual n of the $\binom{(b)}{(4)}$ (PR No. 1056557). $\binom{(a)}{4}$ change has been simulated addition of sterile API.	A mL			
(4)			D			
SEE REVERSE Saleem A Akhtar, OF THIS PAGE Ileana Barreto-Pe	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert Jose M Cayuela, Investigator - Dedicated Drug Cadre					
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE	INSPECTION	AL OBSERVATIONS PAGE 2 of 23 PAGE	ES			

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DISTRICT ADDRESS AND PHON 12420 Parklaw		DATE(S) OF	INSPECTION 2022-5/9/2022*	
Rockville, MI		FEI NUMBER		
Mr. Pradipta	stownow Report issued Swain, Site Head & Vice Pres	ident, Operatio	ns	
FIRM NAME	utical Industries Ltd.	street address Halol – Baroda	Highway	
CITY, STATE, ZIP CODE, COUNT	IRY	TYPE ESTABLISHMENT INSPECTE)	
Halol, Gujara	at, 389350 India	Drug Manufactu	rer	
hold pendin on 5/2/22, a (b) (4)		nvestigation PR No Agency committin $p_{(4)}^{(b)}$ mg/mL $^{(b) (4)}$	b. 1056557. During g to recall or rejec and v	g the inspection t all batches of
B. During the Suspension were observ	review of videos of media fills a USP, ^(b) ₍₄₎ mg/mL, ^(b) _b mL ^{(b) (4)} ed:	nd smoke studies , the follo	for ^{(D) (4)} wing inadequate a	septic practices
b. Smo a ^(b) (fillin	 ia Fill ^{(b) (4)} 4/14/20 video: The operator is observed hand container to the ^{(b) (4)} over the open original container The operator is observed c grabbing a large, ^{(b) (4)} down until seated. He was observed to hand ^{(b) (4)} down until seated. He was observed canister a few times to ^{(b) (4)} cand tall canister in order to traused had a short handle. At t container towards his body to ^(b) ke Study (8/3/21) of the ^{(b) (4)} tub containing open sterile ^{(b) (4)} air over the sterile ^{(b) (4)} 	canister with his arm. losing the canister stopper with erved un-stoppering the powder from inserting his glow ut the sterile powd nsfer it to the com imes, he leaned or ⁽⁴⁾ out the sterile powd filling station (opening fac and back of the with his left arm.	his gloved hands g and stoppering the ed hand inside the ler from the bottom pounding tank. The yer the open canist powder while block on showed the opera- ing up) from a ^{(b) (4}	aminar $\binom{(b)}{(4)}$ air rile powder by and pressing it the canister with e compounding (b) (4) n of the narrow he (^{b) (4)} er or tilted the ing $\binom{(b)}{(4)}$ air.
	Jose M Cayuela, Investigato Drug Cadre	r - Dearcarea	Investigator Signed By 2001638440 Calle Signed 05-09-2022 18 43 07	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL OBSERVA	TIONS	PAGE 3 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
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12420 Parklawn Drive, Room 2032	4/	/26/2022-5/9/2022*				
Rockville, MD 20857		NUMBER)02809586				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Mr. Pradipta Swain, Site Head & Vice Pres	ident, Opera	ations				
FIRM NAME	STREET ADDRESS					
Sun Pharmaceutical Industries Ltd.	Halol - Bar	roda Highway				
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INS	SHMENT INSPECTED				
Halol, Gujarat, 389350 India	Drug Manufa	acturer				

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your Quality Unit failed to identify the following manually intensive operations for environmental sampling as high-risk for microbial cross-contamination in SOP 027928 "Microbiological Monitoring of Parenteral Manufacturing Area" and Protocol SUN/S-EM/005 "Justification for Microbial Monitoring Sampling Site Selection for Aseptic Area (Filtration and Filling Room) of ^{(b) (4)} Parenteral Manufacturing Area (^{(b) (4)}) Block-^(b) ":

- A. Manual dispensing (^{(b) (4)} (^{b) (4)} perforated surface (^{b) (4)} (^b
- B. Manual transfer (^{(b) (4)}) of sterile API ^{(b) (4)}
 to the compounding tank through a funnel by ^(b)₍₄₎ operators. This transfer operation lasts approximately ^{(b) (4)}
 No environmental sampling has been performed close to this operation in the Grade-A ^{(b) (4)}
 filling room.
- C. Personnel monitoring of fingertips is not performed immediately after handling sterile (b) (4) API during dispensing and compounding. The product is not sterilized after this high-risk manually intensive operation.

	rile API is used for ^{(b) (4)}	Suspension USP, $\binom{(b)}{(4)}$	mg/mL , $(mL^{(b)})$
(b) (4)	and vials.		

	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert Jose M Cayuela, Investigator - Dedicated Drug Cadre	Saleem A Akhtar Investigator Signed By 2001638440 District Signed 05-09-2022 18 43 07	date issued 5/9/2022
EODM EDA 483 (00/08)	INSPECTIONAL OBSERVATION	ONS	PAGE 4 of 23 PAGES

DATE(S) OF INSPECTION		
4/26/2022-5/9/2022*		
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erations		
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FACILITIES & EQUIPMENT SYSTEM

OBSERVATION 3

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the production equipment used to manufacture ^{(b) (4)} dosage ^{(b) (4)} drug products is not adequately cleaned, maintained, and sanitized to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug products.

Significant deficiencies were observed during the inspection of various ${}^{(b)}(4)$ Equipment (equipment ID: ${}^{(b)}(4)$ 1, ${}^{(b)}(4)$ 4, ${}^{(b)}(4)$ 5, and ${}^{(b)}(4)$ 6) on 5/2/2022. All of this equipment is shared-use equipment and was tagged as "Clean" after completion of the product changeover "Type-B Cleaning". During the inspection of these ${}^{(b)}(4)$ we observed foreign matter, residue (that appeared white, ${}^{(b)}(4)$, and black colored), round pellets (that appeared as drug product), and small shiny fragments (that appeared as metal shavings) on product contact surfaces. There is no assurance that the products manufactured by this equipment are free from contaminants.

This equipment is used to manufacture the following products:

nt	Equipme Equipment nt Name Code			Product Name				No of Batche s	
(b) (4	(4)	(b) (4)	T239	(b) (4)	for ^{(b) (4)}	Tab	lets <mark>(</mark> mg	(b) (4)	
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FIRM NAME	Swain, S	ice nead	u a vice iles	STREET ADDRESS	eracions		
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naror, sajar	ac, 50550	- India		Drug nun	araooaror		
(b) (4)	1						
			(b) (4)	Pellet	(b) (4) (b) (4)	⁴⁾ % W/W	(b) (4)
			(b) (4)	Pellet	(b) (4) (b) (4	4) % W/W	() b
			(b) (4)			Pellets	(b
			^{(b) (4)} % W/W				5
			(b) (4)			Pellets	(b) (4)
			(b) (4) % W/W				(4)
			Total				(b) (4)
(b) (4)	(b) (4)	T358	(b) (4)	Pellet	(b) (4) (b) (4	4) % W/W	(b
	4					_	D.
			(b) (4)			Pellets	(b) (4)
			(b) (4) % W/W			_	(4)
			(b) (4)			Pellets	(b) (4)
			(b) (4) % W/W				(4)
			(b) (4)	Pellets (b)	%		(b) (4)
			(b) (4)	(+)	Pellets ^{(t}	o) (4) % W/W	(b
			Total				(b)
(b) (4)	(b) (4)	TC182	(b) (4)			tablets	(4) (4)
	2		(b) (4) mg				(4)
	<u> </u>		(b) (4)	for ^{(b) (4)}		Tablets	(b
			(mg				
			(b) (4) Pe	ellets ^{(b) (4)}	W/W Profe	essed Standard	(b
			(b) (4)		Tablets (ng	(b
			(b) (4)			blets (b) mg	(
			-			(4)	
SEE REVERSE	Saleem A		., Investigato	or	I		DATE ISSUED 5/9/2022
OF THIS PAGE	Ileana H	Barreto-	Pettit, Natio	onal Expe		Saleem A Akhtar Investigator Signed By 2001638440	
	Jose M (Drug Cad		Investigator	: - Dedica	ated -	X Date Signed 05-09-2022 18 43 07	
FORM FDA 483 (09/08)	FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS					PAGE 6 of 23 PAGES	

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	e, ZIP CODE, COUN L, Gujara	nry at, 38935	0 India		TYPE ESTABLISHME Drug Man		er	
		1		(b) (4)	$P_{\text{ollots}}(b) _{0/2}$	6 w/w		(b
				(b) (4)	Pellets (b) Pellets for (b)) (4)	Capsules ((
				mg (b) mg (b)	(b) mg		Capsules	b
				mg, (b) mg, (b) (b) (4) (b)	(4) mg	<u>a LISD</u> (b)	ma	(b)
					Capsule	$s USP_{(4)}^{(b)}$	mg	(4) (b)
	(b) (4)	(b) (4)	TC	Total (b) (4)		D	11 (b) (4)	(d) (b)
	(5) (4)		TC-			Pe	llets ^{(b) (4)}	(4)
		3	217	%W/W (b) (4)	<u> </u>	trap (b)		(b)
					Capsule	s USP (b) (4)	mg	(b) (4) (b)
				Total				(4)
	(b) (4)	(b) (4)	TC-	(b) (4)			tablets	(b
		5	352	(b) (4) (b) (4)				
				(b) (4)	for ^{(b) (4)}	Tab	lets (mg	(b) (4)
				(b) (4) Pe	ellets ^{(b) (4)}	w/w	-	(b
				(b) (4)	Pellet	$(b) (4)^{(b)}$)(4) % W/W	(b)
				(b) (4)	Pellets (b)	%		(4) (b) (4)
				(b) (4)	(4)		(b) (4) % W/W	(4 <u>)</u> (b
				Total				(b)
	(b) (4)	(b) (4)	TC353	(b) (4)			Pellets	(4) (b)
		6	20000	(b) (4) % W/W			1 cheas	(4)
				(b) (4)		Po	llets (b) (4)	(b) (4)
				%W/W		10		(4)
				(b) (4)		Dall	ets (b) % W/W	
					Pellets (b) 9/	rell	(4) 70 W/W	_b
				(b) (4)	Pellets for (b)	o W/W) (4)	Consula	-b
				I	reliets for		Capsules (b
		EMPLOYEE(S) SIG						DATE ISSUED
	EVERSE			, Investigato		~ +	Saleem A Akhtar	5/9/2022
OF THIS PAGE Ileana Barreto- Jose M Cavuela.				Investigato			Saleerin A Antical Investigator Signed By 2001638440 Date Signed 05-09-2022 18 43 07	
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12420 Parklaw	FOOD AND DRUG ADMINISTRA DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857			r
NAME AND TITLE OF INDIVIDUA Mr. Pradipta FIRM NAME	LTO WHOM REPORT ISSUED Swain, Site Head & Vic	ce President, Op		
	utical Industries Ltd.		Baroda Highway	
CITY, STATE, ZIP CODE, COUNT	I RY	TYPE ESTABLISHM	IENT INSPECTED	
Halol, Gujara	at, 389350 India	Drug Mar	nufacturer	
Grand T	Total	mg, (b) mg, (b) mg, (b) mg	9	(b) (4) (b) (4)
material, stains, nineteen (19) co OBSERVATIO Equipment used	020, the firm received about specks, and spots in the drumplaints were later confirm	ng products manufa ned during the com	sumer complaints pertain actured at the site. Eleven plaint investigation.	ing to foreign (11) out of
Specifically,	gn to facilitate operations f	or its intended use a	and cleaning and mannen	ance.
investigate abno filling machine of ^{(b) (4)} filling from the	injection ⁽⁰⁾ mg	ternal surface of va Block $\stackrel{(b)}{(4)}$), which g/mL $\stackrel{(b)}{(4)}$ mL vial bat		to ^{(b) (4)} in vial ted the filled vials generated during
the quality of	investigations attributed the these parts supplied by t rted: " <i>The supplied</i> ^{(b) (4)}	the equipment ma		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Inve Ileana Barreto-Pettit Jose M Cayuela, Inves Drug Cadre	, National Expe		DATE ISSUED 5/9/2022

INSPECTIONAL OBSERVATIONS

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 8 of 23 PAGES

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Mr. Pradipta Swain, Site Head & Vice President, Operations					
FIRM NAME STREET ADDRESS					
Sun Pharmaceutical Industries Ltd.	Halol - Baroda Highway				
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED				
Halol, Gujarat, 389350 India	Drug Manufacturer				

viscous...Due to such viscous liquid and close tolerance and during the production friction is generated between^{(b) (4)} and^{(b) (4)} which would be the cause of blackening." CAPA 700858 was approved on 9/26/20 to procure (b) (4) from a new manufacturer; however, the current MBR for injection USP, ^(b) (b) (4) mg/mL h mL vial approved on 4/5/22 still lists the following seven^{(b) (4)} that were previously identified in these investigations as damaged (scratches & dents) or discolored (abnormal appearance): H106, H102, H105, H156, H168, H169 & H170 as approved equipment. Your Quality Unit failed to establish adequate controls to prevent the usage of damaged equipment and has not conducted a thorough retrospective investigation of all distributed batches manufactured with damaged or poorly designed (b) (4) . Of the nine (9) impacted batches in these investigations, five (5) were released to the U.S. market.

OBSERVATION 5

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

- A. The design of the Grade-A ^{(b) (4)} room where high-risk dispensing/weighing operations of sterile API ^{(b) (4)} and compounding process of ^{(b) (4)} $mL^{(b) (4)}$ and vials does not provide adequate protection (e.g., physical barrier) between the sterile API and the operators.
- B. Manual loading of tubs of sterile $^{(b)(4)}$ onto the filling $^{(b)(4)}$ does not provide adequate protection between the open $^{(b)(4)}$ and the operator.

	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert Jose M Cayuela, Investigator - Dedicated Drug Cadre	Sideem A AMMar Innestigator Supper By 2001638440 Date Stgned 05-09-2022 18 43 07	date issued 5/9/2022	
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Sun Pharmaceutical Industries Ltd. Halol - Baroda Highway				
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
lol, Gujarat, 389350 India Drug Manufacturer				

LABORATORY CONTROL SYSTEM

OBSERVATION 6

The written stability testing program is not followed.

Specifically, the QC Lab failed to test more than 200 stability samples within the time frame defined as per stability control procedure (SOP 027980, Version: 3.0). Many samples pertaining to the long term stability studies (for representative batches in the market) were not tested for more than six (6) months. Some examples include:

Produc	t Name	Batch No.	Stability Station	Condition	No. of Days Delaye d	Countr y	
(b) (4)	Injection, , ^(b) ml	(b) (4)	15M/LT108/ S19/04/3721	Long Term	221	US	
(b) (4)	$(\mathbf{b})(\mathbf{A})$					US	
						US	
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FORM FDA 483 (09/08)	FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS						23 PAGES

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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 12 of 23 PAGES	FORM FDA 483 (09/08) PREVIOUS EDITION OF	BSOLETE	INS	PECTIONA	L OBSERVATIONS		PAGE 12 of	23 PAGES	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION									
DISTRICT ADDRESS AND PHON 12420 Parklav	enumber vn Drive, Room 1	2032			DATE(S) OF INSPECTION 4/26/2022-5/9/2022*				
Rockville, MI				FEI NUMBER					
					000200				
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED								
Mr. Pradipta	Swain, Site He	ad & Vice	Pres	ident, (3			
Sun Pharmaceı	itical Industri	es Ltd.		Halol ·	- Baroda H	High	way		
CITY, STATE, ZIP CODE, COUN Halol, Gujara	rry at, 389350 India	a			HMENT INSPECTED	er			
		1							
Injectio		b	S19/	02/3368					
(b)	$y_{(4)}^{(b)}$ ml, $_{b}^{(m)}$ ml								
(4) (U)	3)								
The firm reported	ed confirmed out o	f specificat	ion re	sults for a	bout 147 sa	ampl	es (out of 2	215 st	tability
-	re not tested on tir				-			dout	of
specification res	sults were delayed	stability tes	sting f	or more t	han hundred	d (10	0) days.		
OBSERVATIO	DN 7								
	rols do not include				•				
	to assure that drug	products co	onforn	1 to appro	priate stand	lards	of identity	y, stre	ength,
quality and puri	ty.								
Specifically, vo	ur Quality Unit fa	iled to imp	lement	t adequate	e controls to	o pre	event cross	-cont	amination o
	samples prior to o	-		-		-			
_									
A.Failed	l sterility results ((investigation	on PR						, 22
	th CRT stability				-	· · · · ·			ated due to
	equate cleaning ar boratory personne		1011 01	laborato	ly surfaces	and	sample na	mann	ig deviation
by laboratory personner.									
B.Environmental monitoring (EM) excursion investigation (PR#1001344) was opened on									
9/25/21 to investigate settle plate counts that exceeded the action limit in three (3) separate									
locations within the Grade A $^{(b)(4)}$ vial filling line $^{(b)(4)}$ (Block $^{(b)}_{(4)}$) during filling operations of $^{(b)(4)}$ Injection, $^{(b)}_{(4)}$ mg/mL, $^{(b)}_{b}$ mL vials, batch $^{(b)(4)}$.									
Each sample site had a count of 1 CFU/mL of <i>Chaetonium globosum</i> (fungus). The									
Lach sample she had a count of a croning of chaetonium globosum (lungus). The									
	[
SEE REVERSE	EMPLOYEE(S)SIGNATURE Saleem A Akhta	r, Invest	igato	or		I			ATE ISSUED
OF THIS PAGE	Ileana Barreto	-Pettit,	Natio	onal Exp		1 1	Saleem A Akhtar Investigator Signed By 2001638440		, _ ,
	Jose M Cayuela Drug Cadre	, Investi	lgatoi	r - Dedi	cated		Date Signed 05-09-2022 18 43 07		
	Sing outro								
FORM FDA 483 (09/08)	BREVIOUS EDITION OBS	OLETE	INS	PECTIONA	OBSERVATI	ONS		P	AGE 13 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
12420 Parklawn Drive, Room 2032	4/26/2022-5/9/2022*			
Rockville, MD 20857	FEI NUMBER 3002809586			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
Mr. Pradipta Swain, Site Head & Vice President, Operations				
FIRM NAME STREET ADDRESS				
Sun Pharmaceutical Industries Ltd.	Halol - Baroda Highway			
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Halol, Gujarat, 389350 India	Drug Manufacturer			

environmental excursions were attributed to "un-noticed moisture at edges of exposed media plates and lapse in aseptic practices (i.e., touching of the media plate after contacting with less sanitized surface at the time of operation of the ${}^{(b)}(4)$ system) during handling of the media plate by the EM operator at the time of exposure or collection of media plate." This batch was released by your Quality Unit.

C.Environmental monitoring investigation (PR#571630) was opened on 4/22/20 to investigate multiple environmental monitoring excursions in Grade A/B locations in Room ^{(b) (4)} (Block ^(b)₍₄₎) during Media Fill batch ^{(b) (4)} of ^{(b) (4)}.

Excursions were attributed to inadequate handling of sampled media plates at the QC Microbiology lab and inadequate sanitization of trays used for sample incubation.

QUALITY SYSTEM

OBSERVATION 8

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

Specifically, your Quality Unit failed to fulfil its key responsibilities assigned as per SOP 030295, Version: 2.0, "Key Responsibilities of Quality Unit". For example:

A. The list of objectionable conditions document that personnel may not have the necessary skill sets/training, experience, and/or scientific knowledge with respect to investigations & deviations, training, environmental monitoring, aseptic processing, stability testing, visual inspection, equipment cleaning & maintenance, facility design, and related systems in order to adequately

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FORM FDA 483 (09/08)	PAGE 14 of 23 PAGES		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
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FIRM NAME STREET ADDRESS					
Sun Pharmaceutical Industries Ltd.	Halol - Baroda Highway				
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED				
Halol, Gujarat, 389350 India	Drug Manufacturer				

assess the cGMPs and the impact on the finished sterile and non-sterile products.

- B. Quality Unit failed to take market actions as listed in "Drug Product Recall SOP 030153" for non-conforming batches on long-term stability, or the market action was taken when the batches were about to expire. For example:
 - a. Out of specification investigation OOS 1048015 was initiated on 11/20/2021 when (b) (4) representative batch of (b) (4) Tablets, (b) (a) mg batch (b) (4) (Mfg. Date: 02/2020; Exp Date: (b) (4) ; long-term stability, 18-month interval) failed to meet dissolution specifications in Level 1, Level 2, and Level 3 stages and the OOS results were confirmed. A Field Alert Report (FAR) was submitted on 11/23/2021. Your quality unit failed to recall the non-confirming batch from the market. The impacted batch (b) (4) was the representative batch for about (b) (4) commercial batches of (b) (4) Tablets in the market and your Quality Unit did not fully evaluate all of these distributed batches to ensure conformance to specifications. Instead, the retain samples from only six (6) batches were tested.
 - b. Out of specification investigation OOS 715576 was initiated on 10/14/2020 when four validation batches (also ^{(b) (4)} representative batches, long-term stability, 12-month interval) of Pantoprazole Sodium Injections (batch # JKU3595A, JKU3596A, JKU3597A, and JKU3629A) failed to meet specifications for related compounds ^(b) and ^(b) when tested for impurities analysis. The original OOS results were confirmed. The firm submitted the field alert report on 10/16/2020. These four validation commercial batches were manufactured in September 2019 (expiration date: February 2021). The quality unit failed to recall these batches in a timely manner. Instead, the firm recalled the impacted batches four months later in February of 2020; the month when all four batches were expiring.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
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Sun Pharmaceutical Industries Ltd.	Halol - Baroda Highway					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Halol, Gujarat, 389350 India	Drug Manufacturer					

OBSERVATION 9

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

- A. Two (2) manufacturing Investigations PR 949445 & PR 949338 were opened on 7/27/21 to investigate OOT and OOS results for related substances for (b) (4) Injection USP $\binom{(b)}{(4)}$ mg/mL, $\binom{b}{b}$ mL vials, batches $\binom{(b)}{(4)}$ and $^{(b)}$ (4) respectively. The root cause for the increased unknown impurities was identified as "extraneous matter present" in $^{(b)}$ (4) , which increased product filtration time exceeding the NMT (b) (4) API, batch ^{(b) (4)} $\begin{array}{ccc} (^{(b)}(^{4}) & \text{for batch}^{(b)}(^{4}) \\ \text{the}_{(4)}^{(b)} & \mu m_{(4)}^{(b)} & \text{filter}^{(b)}(^{4}) \\ \end{array}$) specified in the master batch record and changed the color of from ^{(b) (4)} to ^{(b) (4)} ." The identity or source of the extraneous matter could not be identified by the API or product manufacturers, but it was noted that Loss on Drying (LOD) test result for this API batch was higher than historical API batches. & ^{(b) (4)} These two finished product batches (^{(b) (4)}) were rejected; however, another and ^(b) (4) two (2) finished product batches ((b) (4)) were also manufactured with partial API, batch ^{(b) (4)} additions of this ^{(b) (4)} , but were released based on passing finished product results and historical stability data for this drug product. Even though these batches were included in the investigation, your quality unit failed to thoroughly assess the impact to the purity, quality and safety of these batches manufactured with potentially contaminated API with an unknown extraneous matter before release.
- B. Two (2) manufacturing investigations were opened on 5/21/21 and 12/3/21 to investigate water leaks coming from the LAF ceiling of filling area ^{(b) (4)} (Block ^(b)₍₄₎) as follows:

a.	PR	890889:	On	5/20/21,	during	filling	machine	set-up	operations	of
	(b) (4)			1	injectable	suspension	USP, $\binom{(b)}{(4)}$	mg/mL,	operations (mL vial, b	oatch

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert Jose M Cayuela, Investigator - Dedicated Drug Cadre	Saleem A Akhiar Investgato Signed By 2001633440 Date Signed 05-09-2022 18 43 07	date issued 5/9/2022
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIO	ONS	PAGE 16 of 23 PAGES

	TH AND HUMAN SERVICES G ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	4/26/2022-5/9/2022*
Rockville, MD 20857	FEI NUMBER 3002809586
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Pradipta Swain, Site Head & Vice Pres	ident, Operations
FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Industries Ltd.	Halol - Baroda Highway
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Halol, Gujarat, 389350 India	Drug Manufacturer
filling area close to the ${}^{(b)}(4)$ stop day (5/21/21) after re-cleaning and the filling room; however, the batch the hold time of ${}^{(b)}(4)$. The root c ${}^{(b)}(4)$ for the ${}^{(b)}(4)$ law was leaking and was replaced; how had been leaking. A visual check inspection revealed this equipment leak location in the filling room an utility room floor that spilled over the	pping from the LAF ceiling to the Grade A $^{(b)}(4)$ per station. Filling operations resumed the following sterilization of filling equipment and sanitization of h was rejected as the filtered bulk solution exceeded ause of the water leak was identified as an old $^{(b)}_{(4)}$ boated in the utility floor above the filling room that ever, it was not known for how long this equipment k of the replaced $^{(b)}(4)$ during the FDA was located approximately 23' away from the ceiling nd personnel stated there was a lot of water on the he area. A review of maintenance records for the $^{(b)}_{(4)}$

during the inspection revealed this equipment was last inspected on 3/22/21 (2 months earlier) but the investigation did not provide these details and the Quality Unit failed to extend this investigation to other batches that were manufactured in this filling line during this time frame and could have potentially been impacted.

b. PR 1059368: On 12/3/21, another water leak was observed in the same room from the ceiling in the Grade B area outside of ^{(b) (4)} vial filling line before resuming filling operations of ^{(b) (4)} injection USP ^(b) mg/mL ^(b) mL vials, batch ^{(b) (4)}
^{(b) (4)}, after ^{(b) (4)} change. The investigation reported this issue had not occurred within the last year in this room even though it had occurred at least once 7 months earlier (PR 890889). The root cause was identified as water dripping from an unused ^{(b) (4)} water pipe with damaged insulation that accumulated on the utility floor above the filling line and leaked thru the ceiling. Filling operations continued and the repair was performed in the utility room. This batch was released based on satisfactory environmental monitoring and finished product testing results. Your investigation did not include an inspection of the ^{(b) (4)} LAF ceiling for water damage and gaps/cracks that could allow dirty water ingress from the utility room and crawl space into the aseptic filling room and extend the

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	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert Jose M Cayuela, Investigator - Dedicated Drug Cadre	Saleem A Akhtar Investaato Signed by 2001638440 Date Stoned 05-09-2022 18 43 07	date issued 5/9/2022
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVA	TIONS	PAGE 17 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
12420 Parklawn Drive, Room 2032	4/26/2022-5/9/2022*					
Rockville, MD 20857	FEI NUMBER 3002809586					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Mr. Pradipta Swain, Site Head & Vice Pres	ident, Operations					
FIRM NAME	STREET ADDRESS					
Sun Pharmaceutical Industries Ltd.	Halol – Baroda Highway					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Halol, Gujarat, 389350 India	Drug Manufacturer					

investigation to other potentially impacted batches.

C. Environmental monitoring (EM) investigation PR 812342 was opened on 2/14/21 to investigate EM excursions during filling operations of (b)(4) (b)(b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4)

Location	Type of Count		Organism ID	
	Sample			
(b) (4) VTLP (viable tub loading	Active air	3 CFU/m3	Staphylococcus walneri	
point)			Micrococcus luteus	
(b) (4) B (under LAF near (b) (4)	Settle plate	1 CFU/plate	Bacillus circulans	
stoppering)				

The investigation concluded that location (AA $^{(b)}(4)$ VTLP) was "situated outside of filling under LAF where product is not directly exposed." It also stated that any lapse in aseptic practice (frequent men/material movement) during the tub loading & tub unloading time, led to the viable excursion. However, the impact assessment did not identify that the tub loading location is a high-risk manually intensive operation where the operator loads tubs of open sterile facing up ($^{(b)}(4)$ /tub) with his gloved hands and a total of $^{(b)}(4)$ tubs were loaded for filling during the active air plate exposure time that had the excursion. This batch was released by your Quality Unit without rejection of any filled $^{(b)}(4)$ due to EM excursions in Grade A.

D. Out of specification investigation OOS 993797 was initiated on 9/17/2021 when ^{(b) (4)} mg, (9months, long-term stability; manufacturing date: 11/2020, expiration date: ^{(b) (4)}) failed to meet the dissolution specifications. The dissolution test for this product is performed by using ^(b)

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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIO	ONS	PAGE 18 of 23 PAGES

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-	Swain, Site Head & Vice Pr	-	perations			
FIRM NAME Sun Pharmaceu	tical Industries Ltd.	STREET ADDRESS Halol -	Baroda Highway			
CITY, STATE, ZIP CODE, COUNT Halol, Gujara	rry 1t, 389350 India	TYPE ESTABLISHM Drug Man	ENT INSPECTED Iufacturer			
points. I specs of analysis (0.05M T each of t The QC analyst p no ^{(b) (4)} reported If the su claimed 1, 2, 3, increasin hour (^(b) (4)	ets and the dissolution samples During the test Unit 1 at 1 hour in (4) (4) (4) %. The Quality Head st comprised of (4) dissolution ve Phosphate Buffer, pH 6.8) were these (4) vessels. The remaining Lab concluded that the tubing o pulled the samples for Unit 1 fro tablet). The QC Lab invalid the conforming results. spected samples were pulled fro by the QC Lab; then no (b) (4) and 10 hour time points. Ho ing trend for all the samples i.e., %). The firm shipped this batch	terval yielder ated the diss essels. $^{(b)}(4)$ used for the $^{(b)}(4)$ vess f the auto sam m the vessel dated the orig m the vessel content sh wever, the $^{(b)}$ 1 hour $^{(b)}(4)$ to the U.S. or	d the value of $\binom{(b)}{(4)}$ % and solution apparatus that we vessels containing the of test by dropping $\binom{(b)}{(4)}$ sels were filled with $\binom{(b)}{(4)}$ appler was not connected containing the $\binom{(b)}{(4)}$ and the $\binom{(b)}{(4)}$ in all results, analyzed the containing only the $\binom{(b)}{(4)}$ mould be observed in the $\binom{(b)}{(4)}$ content was of $\binom{(b)}{(4)}$.	failed to meet the vas used for this dissolution media tablet in only. properly, and the only (with new samples and (no product) as samples pulled at observed with an ar $\binom{(b)}{(4)}$ %), and 10		
complain regarding thorough complain (b) (4) laborator in the tab	ovember 17, 2020, to January 6, nts for ^{(b) (4)} g ^{(b) (4)} , dirty, and/or black investigations of these compla- nt (PR# 741288) were sent to the inclusions. All the other ry identification and/or character blets. Instead, your Quality Unit ets from the other eight (8) complete the second se	ck specks in aints because e laboratory f r eight (8) c ization test re t assumed tha	Tablets, $\binom{(b)}{(4)}$ mg the tablets. The firm only the tablets receiv for identification or chara omplaint investigations sults for the inclusions of t the identification of the	batch ^{(b) (4)} failed to conduct ed from the first acterization of the failed to include r specks observed		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investiga Ileana Barreto-Pettit, Nat Jose M Cayuela, Investigat Drug Cadre	tional Expe		DATE ISSUED 5/9/2022		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL (OBSERVATIONS	PAGE 19 of 23 PAGES		

	NEDADTMENT OF III	TALTH AND HUM	AN SERVICES	
DISTRICT ADDRESS AND PHON		CALIH AND HUM DRUG ADMINISTRAT	ION	
	vn Drive, Room 2032		DATE(S) OF INSPECTION 4/26/2022-5/9/2022*	
Rockville, MI			FEI NUMBER 3002809586	
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NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED			
Mr. Pradipta	Swain, Site Head & Vice Pr	resident, Op	perations	
FIRM NAME		STREET ADDRESS		
Sun Pharmaceu	itical Industries Ltd.	Halol –	Baroda Highway	
	at, 389350 India	Drug Mar	nufacturer	
F. Complai mg, bate identific sample identific manufac Your Qu take corr G. From Ja crystalliz Inspectio stopperin	Additionally, as part of the ab (retain) samples; however, it fairy testing of the black specks int investigation PR# 468068 re ch ${}^{(b)(4)}$ having ${}^{(b)}_{(4)}$ spectation and/or characterization test and in the in-house control (relation of the specks found on the turing of the product without sci- nality Unit failed to conduct adece rective and preventive action to e an 2020 thru April 2022, you zation of ${}^{(b)(4)}$ on of the complaint samples to c ng, leaks and cracks) and re-disser ry of your sister company in NJ test	egarding ^{(b) (4)} Tables (b) (4) (b) (4) (c)	e the identify and/or char d in the control (retain) ts, ${}^{(b)}_{(4)}$ mg batch numb and ${}^{(b)(4)}$ Tab n the tablets, failed to in the ${}^{(b)}_{(4)}$ specks observed Your Quality Unit com the from the ${}^{(b)(4)}$ mature is analyses of these comp lity and purity of your dru received at total of 811 USP, ${}^{(b)}_{(4)}$ mg/mL, ${}^{(b)}_{b}$ & llization, check the vials fa als in warm water bath is p	acterization with samples for the pers (b) (4) lets USP (b) (b) clude laboratory in the complaint actuded that the erial used in the laints in order to g products. complaints for $\begin{pmatrix} (b)\\ (4) \end{pmatrix}$ mL vials. for integrity (i.e.,
lacked o addition discontin	locumentation of their training , as per Protocol No: SUN/S-I nued warming the complaint cry	g and qualific EMC/531/01 ystallized sam	cation to perform these approved on 7/16/19, yc ples to redissolve the cry	inspections. In our Quality Unit stals because all
(4) prev	EMPLOYEE(S) SIGNATURE Saleem A Akhtar, Investig Ileana Barreto-Pettit, Na Jose M Cayuela, Investiga	ator tional Expe	rt Saleem A Alitar Investigator	DATE ISSUED 5/9/2022
FORM FDA 483 (09/08)	Drug Cadre PREVIOUS EDITION OBSOLETE	INSPECTIONAL	OBSERVATIONS	PAGE 20 of 23 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
12420 Parklawn Drive, Room 2032	4/26/2022-5/9/2022*					
Rockville, MD 20857	FEI NUMBER 3002809586					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Mr. Pradipta Swain, Site Head & Vice Pres	· · · ·					
FIRM NAME	STREET ADDRESS					
Sun Pharmaceutical Industries Ltd.	Halol – Baroda Highway					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Halol, Gujarat, 389350 India	Drug Manufacturer					

and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended." However, you lacked raw data to confirm crystals in these complaint samples adequately re-dissolved in a timely manner. According to consumer complaints PR260646 & 238781 received in Feb/March 2019, complaint samples took over 5 hours in a water bath (35-40°C) to re-dissolve the crystals; however, your complaint investigations concluded that there were no issues with the batches and the product was acceptable.

OBSERVATION 10

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically, employees engaged in the manufacturing and processing of parenteral and ^{(b) (4)} dosage drugs lack adequate training to perform visual inspection of the drugs manufactured at the site. For example:

A. On 4/27/2021, a qualified operator ^(b)₍₆₎ was challenged to detect the known defects (critical and major) in ^(b)₍₄₎ vials (presented to her from vial kit ID: PMA/LYV/006/00) under real conditions. She failed to detect defects in all of the ^(b)₍₄₎ vials. The operator ^(b)₍₆₎ has been performing visual inspection of the filled vials since 2014. Discrepancies were also observed pertaining to the records of her routine eye exams (operator, ^(b)₍₆₎) that were conducted during the last two years.

During the	e last t	wo years,	operator	(b) (6)	performe	d 100%	visual	inspection	of	many
injectable/n	ion-inject	table sterile	drugs inc	ludın	g (b) (4)	1	njections.	(0) (4)		
injections,			injection				injectio	ons, ^{(b) (4)}		
injections,	(b) (4)	i	njections,	(b) (4)	i	injectior	ıs, ^{(b) (4)}			

FORM FDA 483 (09/08)	Jose M Cayuela, Investigator - Dedicated Drug Cadre PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVAT	X 164 Style 05-09-2022 16 43 07	PAGE 21 of 23 PAGES
	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator Ileana Barreto-Pettit, National Expert	DATE ISSUED 5/9/2022	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER			DATE(S) OF INSPECTION			
12420 Parklawn Drive, Room 2032 Rockville, MD 20857		FEINUMBER				
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Mr. Pradipta	Swain, Site Head & Vice Pres	ident. Operations				
FIRM NAME	Swain, Site near a vice field	STREET ADDRESS				
	tical Industries Ltd.	Halol - Baroda Highway				
CITY, STATE, ZIP CODE, COUNT Halol, Gujara	ry 1 t, 389350 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer	2			
laioi, sujuiu	ic, sossos mara	Drug Humaraooaror	-			
solution,	and ^{(b) (4)} . The firm 2020. Twenty-one (21) batches (shipped ^(b) batches	of these products	s into the U.S.		
since Jar	n 2020. Twenty-one (21) batches (out of these (b) batch	nes) were visually	y inspected by		
the operation	ator $\binom{(D)}{(6)}$. There is no assurance if th	ese distributed batche	s were effectively	y inspected for		
	nd major defects. Since January 20			S		
· · · ·	nts pertaining to foreign material	, stams, spots, and s	specks in the in	jectable drugs		
snipped	to the US from this site.					
B. There is	no assurance how the manufacturi	ng and QA visual insp	pectors are qualif	fied to identify		
	(i.e., critical, major, and minor)		-			
_	on kit, which should include physic	_	-			
	batches that the manufacturing and					
	e for training and qualification. Acc	ording to your manag	ement, the visual	inspection kit		
is destroyed after the qualification process.						
C. The visu	C. The visual inspection process of ^{(b) (4)} Tablets, ^(b)					
batches (black specks in th	-		
to release the products to the U.S. market. These black specks were detected during the						
complair	nt investigation (PR# 741288) and i	nspection of control (r	retain) samples.			
D. The visu	al inspection process of ^{(b) (4)}		Ta	ablets, (b) mg		
batches (batches ^{(b) (4)} and ^{(b) (4)} manufactured in July 2020 and October 2020 failed to detect					
black sp	black spots observed in complaints PR# 882709 and PR# 883690.					
*DATES OF IN	NSPECTION					
	, 4/27/2022(Wed), 4/28/2022(Thu),	4/29/2022(Fri), 5/02/2	2022(Mon), 5/03/	/2022(Tue),		
5/04/2022(Wed), 5/05/2022(Thu), 5/06/2022(Fri), 5/09/2022(Mon)						
	EMPLOYEE(S) SIGNATURE			DATE ISSUED		
SEE REVERSE	Saleem A Akhtar, Investigate			5/9/2022		
OF THIS PAGE	Ileana Barreto-Pettit, Natio		Saleem A Akhtar Investigator Signed By 2001638440 Date Signed 05-09-2022			
	Jose M Cayuela, Investigator Drug Cadre	- Dedicated	X 18 43 07			
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OBSERVATION	NS	PAGE 22 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 4/26/2022-5/9/2	2022*			
Rockville, MD 2			4/20/2022-3/3/2022* FEI NUMBER 3002809586				
NAME AND TITLE OF INDIVIDUAL TO V							
Mr. Pradipta Sw FIRM NAME	ain, Site Head & Vice Pres	street ADDRESS	erations				
	cal Industries Ltd.		Baroda Highway				
CITY.STATE.ZIP CODE.COUNTRY Halol, Gujarat,	389350 India	TYPE ESTABLISHME Drug Man	ufacturer				
lleana Barreto-Petiti National Expert Signed By: lleana Barreto-petiti Date Signed: 05-09-2022 18:44:	-S6 Jose M Cayuela Investigator - Dedicated Drug Cadre Signed By: 2000631739 Date Signed: 06-08-2022 18:46:44						
SEE REVERSE OF THIS PAGE	PLOYEE(S)SIGNATURE aleem A Akhtar, Investigat Leana Barreto-Pettit, Natio Dise M Cayuela, Investigato: rug Cadre	onal Exper		DATE ISSUED 5/9/2022			
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL O	BSERVATIONS	PAGE 23 of 23 PAGES			