	TH AND HUMAN SERVICES G ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032	2/19/2024-2/29/2024*	
Rockville, MD 20857	FEI NUMBER 3011905047	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	*	
Yugandhar Puvvala, CEO & Executive Direct	or	
FIRM NAME	STREET ADDRESS	
Eugia SEZ Private Limited	Plot No:S-5/B, S-6 & S-7, Survey 408-412, 418-435, 437-445, 452-459 Sez, Tsiic, Polepally (Village), Jadcherla Mandal	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Mahabubnagar District, Telangana, 509302 India	02 Sterile Drug Manufacturer	

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:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

- A. Your firm failed to follow EP4-PR-SOP-042, "Guidelines for Working in Aseptic Area" and EP4-MB-SOP-028, "Viable Monitoring Program". The following are examples but are not intended to be a list of all times the procedures were not followed.
 - Interventions into critical areas during aseptic manufacturing are not replicated during Aseptic Process Simulations, to assess risk and validate the performance of the interventions. For example:
- Removal of stuck vials through of the operator was observed reaching his whole arm, including the observed remove vials and stoppers. Aseptic Process Simulation Batch No. occurring between 3:33 PM and 3:35 PM, did not include the operator reaching to the same depth into the Grade A area, nor was the

EMPLOYEE(S)SIGNATURE Ashar P Parikh, Investigator Marcellinus D Dordunoo, Investigator	Mercelinus D Dordanoo Institution By Marcelinus D Dordanoo Institution By Marcelinus Dordanoo Signed By Marcelinus Dordanoo Cata Signed: 02-29-2004	DATE ISSUED 2/29/2024

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 9 PAGES

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intensity	of movement and duration of the in	ntervention accurate	ly replicated.	
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A 100 A	The written procedure, EP4-MB-S	A STATE OF THE PARTY OF THE PAR		
	nonitoring after interventions into c			
S	supply, prior to sanitization of hand		equate personnel monitori	ng, post
	interventions during fil	ling operations of	(h) (l) (h)	(0)(4)
I	injection USP (6)(4)g, Batch No.	on 02/19-2	0/2024, on (b) (4) Line-(b) in (c)	clude:
	AV (A)		A. (A.	
	of vials through (b)(4) No. (b)(4) at		on 02/19/2024. The	-
was obs	erved reaching his whole arm, inc	luding the (b)(4)	portion of his arm and th	e fabric
cleanroc	om gown, into the Grade A filling an	rea to remove vials a	and stoppers from the	(b) (4)
(b) (4) an	rea. No personnel monitoring was p	erformed.		
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- At	(b) (4) one operator passed a	spray bottle underr	neath the (b)(4) conveyer t	0
another	operator on the other side without e			
bottle. A	day (A)		AN (A)	and
returned	The state of the s		A 2 2 4 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
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	57PM - 3:07PM, one operator was p			
(b) (A)	his entire arm inside the Grade A ar	ea and did not clear	the vials located directly a	at the
	conveyer near Th	ie operator did not sa	anitize the area after perfo	rming
	1006 1 3/200		Transaction of the second	
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FORM FDA 483 (09/08)

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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 3 of 9 PAGES		Date Signed: 02-29-2004		
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 3 of 9 PAGES				
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	DEPARTMENT OF HEAL FOOD AND DRUG	G ADMINISTRATI	
DISTRICT ADDRESS AND PHOP	NE NUMBER Wn Drive, Room 2032		DATE(S) OF INSPECTION 2/19/2024-2/29/2024*
Rockville, MI			FEI NUMBER 3011905047
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l .			
NAME AND TITLE OF INDIVIDUA	ALTO WHOM REPORT ISSUED		
W. 10 1000 1000	vvala, CEO & Executive Direct	or	
FIRM NAME	en tratalouen der - Volumen - Sc. Frenziere eins bekonningen bir in die frenziere einer j Di G. Garden einst Na	STREET ADDRESS	Extension Control to the two cases with according according
	ivate Limited	418-435,	S-5/B, S-6 & S-7, Survey 408-412, 437-445, 452-459 Sez, Tsiic, Ly (Village), Jadcherla Mandal
Mahabubnagar India	District, Telangana, 509302	Sterile	Drug Manufacturer
docume	sample is 60 CFU. This plate had nted as "Nil" on the "Personal Mo Feb 13, 2024".		by both the analyst and a reviewer and ata Sheet For:
OBSERVATIO	ON 2		,
	are not always made of investigation	ons into une	explained discrepancies.
c :c 11			
Specifically,			
	vestigation initiated on September 2	26, 2023, de	injection USP (b)(4) g, batch OS results for bacterial endotoxin testing. etermined the source of the endotoxin was nese batches.
The investigation at the API manufacturer did not identify a definitive root cause but determine the probable cause of the OOS was "operating person might have missed to apply the to release the might have resulted in hold up of Considering the scope of proliferation on storage and stagnation of the development of endotoxins in the manufacturing process pertaining to subject batches." This probable cause was not confirmed to the source of endotoxin and this probable cause is also not limited specifically to the manufacture the OOS finisher product batches.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Ashar P Parikh, Investigator Marcellinus D Dordunoo, Inve		Marcellinus D Dordanoo Innes spater general Schreibung Dordanoo Spared S
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FORM FDA 483 (09/08)

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PAGE 4 of 9 PAGES

	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMA G ADMINISTRATI		
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FIRM NAME		STREET ADDRESS		
	ivate Limited	418-435,	:S-5/B, S-6 & S-7, Survey 408-412, 437-445, 452-459 Sez, Tsiic, ly (Village), Jadcherla Mandal	2,
CITY, STATE, ZIP CODE, COUN Mahabubnagar India	District, Telangana, 509302		Drug Manufacturer	
three basidentify specific specific confirm batches/ for prod Your fir were manufact B. While rev According the test of initial construction of the second continuation of the secon	a definitive root cause but identified to these three batches but were identified eaning procedure) after usage of sed OOS finished product and containers in stock for bacterial enduction. In utilized approximately this supplier becausing processes that resulted from the processes that resulted from the processes that resulted from the processes that the process of the process	a. The API ed additional entified as 'dedi dedi dedi As a API bat dotoxin. All are fore the stheir invest. As a sampling erved, which are fore this out of this out of the standard for this out of the standard for the standard f	I manufacturer investigation again did not all probable causes. These causes were not "no specific cleaning procedure dicated for (4)% (4)% (5)(4) solution a preventive action, your firm rejected that the state of the state of the state of the state of the supplier made any corrections to the state of t	not not to t
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Ashar P Parikh, Investigator Marcellinus D Dordunoo, Inve		DATE ISSUED 2/29/2024 Marcellinus D Dordunos Innes logical Dr. Marcellinus Dordunos Signato Dr. Marcellinus Dordunos Contr. ligores dec-29-2024	

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION		
12420 Parklawn Drive, Room 2032	2/19/2024-2/29/2024*		
Rockville, MD 20857	FEI NUMBER 3011905047		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	*		
Yugandhar Puvvala, CEO & Executive Direct	or		
FIRM NAME	STREET ADDRESS		
Eugia SEZ Private Limited	Plot No:S-5/B, S-6 & S-7, Survey 408-412,		
	418-435, 437-445, 452-459 Sez, Tsiic,		
	Polepally (Village), Jadcherla Mandal		
CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED			
Mahabubnagar District, Telangana, 509302 India	Sterile Drug Manufacturer		

Your firm's No. 04 Continuous Nonviable Particle Counter (NVPC), located near the of Line is not located in the position depicted in NVPC", Document No. APL-XVI-PR-EQP-002-02. It is actually located inside the Grade A area, near the accessible through of the ARABS, which is separated from the conveyor area by an located inside the Grade A area, near the located inside the Grade A area, near the located inside the Grade A area, near the located inside the Grade A area, near located in

OBSERVATION 4

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

Your firm has not validated your bit of the particulates, smaller than by Your firm was unable to provide any scientific justification or rationale for not including particulates on the lower end of the visual range (smaller than bit of the qualification of the stopper material bit of the particulates potentially generated from the bit of the stopper material bit of the particulates potentially generated from the the stopper material bit of the singular and primary mechanism for detection of objectionable foreign particulate matter within as visual inspection is limited to detection of surface level particulate contamination.

	EMPLOYEE(S)SIGNATURE Ashar P Parikh, Investigator Marcellinus D Dordunoo, Investigator	Macretinus D Dordunos Invest lights of Dordunos Invest lights of Dordunos Invest India (Naturellinus Dordunos Investigates (Naturellinus Dordunos India (Incidente Co.) 29-2024	DATE ISSUED 2/29/2024
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 6 of 9 PAGES

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Rockville, MD 20857	FEI NUMBER 3011905047		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	÷		
Yugandhar Puvvala, CEO & Executive Direct	or		
FIRM NAME	STREET ADDRESS		
Eugia SEZ Private Limited	Plot No:S-5/B, S-6 & S-7, Survey 408-412, 418-435, 437-445, 452-459 Sez, Tsiic,		
	Polepally (Village), Jadcherla Mandal		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Mahabubnagar District, Telangana, 509302 India	Sterile Drug Manufacturer		

OBSERVATION 5

Failure to maintain a backup file of data entered into the computer or related system.

Specifically,

Nonviable Particle Counters, Model Number, 3423, Equipment ID No. PR-NVPCP-001, PR-NVPCP-002, PR-NVPCP-004, lack the functionality to save data internally and/or via backup, by which to verify printed non-viable particle counts in the Grade B (ISO 7) aseptic processing areas during set-up of and during set-up and manufacture of drug product. Additionally, NVPCs used in support of production operations, lack audit trail functionality, for example: electronic records of configuration of user accounts, passwords, and system date/time. These records are managed using manual logs that could not be verified electronically during the inspection. Deficiencies regarding accuracy of data and subsequent particle count calculations were also noted during qualification of the NVPCs.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A.There is no disinfectant efficacy study performed for during vial filling on Line (b)(4) Line (c)(5)(4) The exterior of the tubing used for drug product transfer tubing is not sterilized prior to

SEE REVERSE OF THIS PAGE

Marcellinus D Dordunoo, Investigator

Marcellinus D Dordunoo, Investigator

X Date issued 2/29/2024

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 7 of 9 PAGES

	DEPARTMENT OF HEAL FOOD AND DRUG	TH AND HUMA G ADMINISTRATI		ES	
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Rockville, MI			FEI NUMBER	14 PACIFIC 28 CT	
	300		301190	0047	
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<i>a</i>		Polepall	y (Villa	age), Jadcherla	Mandal
Mahahuhnagar	District, Telangana, 509302	Sterile	Drug Mar	nufacturer	
India	District, relangana, 303302	Scerife .	Drug Hai	nuraccurer	
111	HE STATE OF THE ST				73.4B
	in the filling assembly, located in the	ne Grade A	filling are	ea, directly above	(6) (4)
and open vi	als during production operations.				
	2 32		a (b) (4)		(b) (4)
(L) (A)	s no written procedure detailing the	e cleaning o	of (b)	step ladders,	1.05-8025080
and (6)(4)	Laminar Airflow Cabinet)		the Grade A al	
	cessing areas of your			your	Drug Lines.
and (b) (4)	y, no routine monitoring is perform Laminar Airflow Cabinets, that			f the various	step ladders,
	operations. A plate sample		of the	essing areas, befo	
ladder in yo		02/23/24 85	ampled at		
The second secon	have microbial growth.	(b) (4) monitor	ring locat	tions do not include	de areas where
these	(b) (4) within the aseptic proc			arons do not mera	ac areas where
, 1220.000					
OBSERVATIO	ON 7				
Employees engaged in the manufacture and processing of a drug product lack the training required to					
perform their as	ssigned functions.				
G 'C 11					
Specifically,					
Th1:1:46		. 1.6.4. 1	URIZE UR	.1:	(b)(4) Postricted
Access Barrier	risual inspectors to identify integrity System (4) RABS) (b) (4) has not be	y defects du	iring visu	al inspection of	Resultited
(b) (4) defect ki	t and trained on the defects with	in the train	ing kit	Subsequently on	the (b)(4)
inspectors are a	ssessed on the ability to detect defe	cts using (b)	of the (b)	numbered (b)(4)	sourced from
				Personnel Qualific	cation Protocol
the same kit used for training. However, per FU16-MIS-VSP-0740, "Personnel Qualification Protocol for Inspection", step (b)(4) "The inspector shall inspect all the in the kit and record					
*					
	EMPLOYEE(S) SIGNATURE			2	DATE ISSUED
SEE REVERSE	E Ashar P Parikh, Investigator		2/29/2024		
OF THIS PAGE	signed by Marcelinus Doroundo				
		X Date Signed: 03-29-2004 12-47-58			
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FORM FDA 483 (09/08)

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PAGE 8 of 9 PAGES

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Rockville, MI	20857		301190	5047	
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2000 1000 COST	vala, CEO & Executive Direct	or			
FIRM NAME		STREET ADDRESS			
Eugia SEZ Pri	ivate Limited	Plot No:	S-5/B,	S-6 & S-7, Surv	rey 408-412,
				5, 452-459 Sez,	
CITY, STATE, ZIP CODE, COUN	TRY	Polepall	y (Villa	age), Jadcherla	Mandal
The state of the s	District, Telangana, 509302	Control of the Contro		nufacturer	
India					
(6) (4	prior to, and post completion, of ty testing, are only performed	production (b) (4) on a	activities	s. Mechanically as	and for (4) RABS sisted methods
), 2/20/2024(Tue), 2/21/2024(Wed), 2/28/2024(Wed), 2/29/2024(Thu)	, 2/22/2024	(Thu), 2/	23/2024(Fri), 2/26	5/2024(Mon),
	EMPLOYEE(S) SIGNATURE				DATE ISSUED
SEE REVERSE OF THIS PAGE	Ashar P Parikh, Investigator Marcellinus D Dordunoo, Inve			Marcellinus D Dordunoo Inves ligator Signed By: Marcellinus Dordunoo Quantum Co-29-2004	2/29/2024

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 9 of 9 PAGES