DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032	08/26/2024-09/06/2024	
Rockville, MD 20857	FEI NUMBER 3004097901	
ORAPHARMInternationalresponses@fda.hl	hs.gov 5004097901	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Anil Arora, President - Global Manuf	acturing Operations	
FIRM NAME	STREET ADDRESS	
Granules India Limited	Survey No 160/A, 161E, 162 And 174/ Gagillapur Village, Dundigal- Gandimaisamma Mandal	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product 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:

FACILITY AND EQUIPMENT SYSTEM

OBSERVATION 1

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

Specifically,

А.	The	^{(b) (4)} non-dedicated	(b) (4) used in the manufacturing of drug	g products at your
	firm have	not been appropriately cl	eaned since their installation several years ago. For example	
			-	
			Table 1	(b) (4)
-		EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		A D. L MM	\$ y	09/06/2024
c	EE	Hellycon	Pratik S. Upadhyay, DDC	09/06/2024
		F	Investigator	
1 6273	HIS PAGE		how	
		genur	Joseph A. Piechocki, Investigator	
				k
FOR	M FDA 483 (09/08	PREVIOUS EDITION OBSOL	ETE INSPECTIONAL OBSERVATIONS	PAGE 1 OF 26 PAGES

	DEPARTMENT OF HEALTH AND FOOD AND DRUG ADMINI		
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, R Rockville, MD 20857	oom 2032	DATE(S) OF INSPECTION 08/26/2024-09/06/202 FEI NUMBER	24
ORAPHARMInternationalre NAME AND TITLE OF INDIVIDUAL TO WHOM REPORTISS	sponses@fda.hhs.gov	3004097901	
Anil Arora, President -	Global Manufacturing	Operations TADDRESS	
Granules India Limited	Sur Gag Gan	vey No 160/A, 161E, 162 illapur Village, Dundiga dimaisamma Mandal	
CITY, STATE ZIP CODE, COUNTRY Medchal-Malkhajgiri Di	.strict, Dru	stablishmentinspected g Product Manufacturer	
Telangana, 500043 Indi	.a		(b) (4)
EMPLOYEE(S) SIGNAT	URE EMPL	OYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	0	tik S. Upadhyay, DDC estigator	09/06/2024
//	Jos	eph A. Piechocki, Investigator	
FORM FDA 483 (09/08) PREVIOUS ED	ITION OBSOLETE INSPECTIO	ONAL OBSERVATIONS	PAGE 2 OF 26 PAGE

	DEPAR	TMENT OF HEAL	TH AND HUMA GADMINISTRATIC		
DISTRICT ADDRESS AND PHONE NU 12420 Parklawn Rockville, MD ORAPHARMInterna NAME AND TITLE OF INDIVIDUAL TO	Drive, Room 20 20857	32		DATE(S) OF INSPECTION 08/26/2024-09/06/20 FEI NUMBER 3004097901	024
Anil Arora, Pre				tions	
FIRM NAME Granules India			STREET ADDRESS Survey I Gagilla	No 160/A, 161E, 162 pur Village, Dundig isamma Mandal	
CITY STATE, ZIP CODE, COUNTRY Medchal-Malkha Telangana, 500		t,	TYPE ESTABLISHM	TA 영국은 국가장은 전시가 작가 ~~~) 15 강가지가 가지 않는 것 같아요.	
On 26-Aug-2024, we wet surfaces and bl	observed huild-up	o of white to off	-white color	powdery materials along v ative of potential bacteria HEPA filters of the	(b) (4) with water droplets,
growths inside Air P the chamber	urification Units (A	PUs) on and af	ter the (b) (4) (b) (4)	HEPA filters of the ^(b) of randomly selected Mo	(⁴⁴ Ducts along with dule (^{b) (4)} ID: (b) (4)
The (b) (4) and (b) (4)	equipment status fo	or Module	(b) (4) on 2	6-Aug-2024 was as follow:	s:
	paign ct Name B. No.	Current Campaign Start Date	No. of batch in the campaign	Previous Product Prior to Current campaign / Batch No.	Equipment status on 26- Aug-2024
SEE REVERSE OF THIS PAGE	PSV PSV		Pratik S. Investiga	ME AND TITLE (Print or Type) Upadhyay, DDC tor Piechocki, Investigator	DATE ISSUED 09/06/2024
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLE	te IN	SPECTIONAL O	DBSERVATIONS	PAGE 3 OF 26 PAGES

	DEPARTMENT OF HEALTH AND FOOD AND DRUG ADMINI		
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, R Rockville, MD 20857	oom 2032	DATE(S) OF INSPECTION 08/26/2024-09/06/202 FEI NUMBER	24
ORAPHARMInternationalre NAME AND TITLE OF INDIVIDUAL TO WHOM REPORTISS	sponses@fda.hhs.gov	3004097901	
Anil Arora, President -	Global Manufacturing	Operations TADDRESS	
Granules India Limited	Sur Gag Gan	vey No 160/A, 161E, 162 illapur Village, Dundiga dimaisamma Mandal	
CITY, STATE ZIP CODE, COUNTRY Medchal-Malkhajgiri Di	.strict, Dru	stablishmentinspected g Product Manufacturer	
Telangana, 500043 Indi	.a		(b) (4)
EMPLOYEE(S) SIGNAT	URE EMPL	OYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	0	tik S. Upadhyay, DDC estigator	09/06/2024
//	Jos	eph A. Piechocki, Investigator	
FORM FDA 483 (09/08) PREVIOUS ED	ITION OBSOLETE INSPECTIO	ONAL OBSERVATIONS	PAGE 2 OF 26 PAGE

	DEPAR	TMENT OF HEAL	TH AND HUMA GADMINISTRATIC		
DISTRICT ADDRESS AND PHONE NU 12420 Parklawn Rockville, MD ORAPHARMInterna NAME AND TITLE OF INDIVIDUAL TO	Drive, Room 20 20857	32		DATE(S) OF INSPECTION 08/26/2024-09/06/20 FEI NUMBER 3004097901	024
Anil Arora, Pre				tions	
FIRM NAME Granules India			STREET ADDRESS Survey I Gagilla	No 160/A, 161E, 162 pur Village, Dundig isamma Mandal	
CITY STATE, ZIP CODE, COUNTRY Medchal-Malkha Telangana, 500		t,	TYPE ESTABLISHM	TA 영국은 국가장은 전시가 작가 ~~~) 15 강가지가 가지 않는 것 같아요.	
On 26-Aug-2024, we wet surfaces and bl	observed huild-up	o of white to off	-white color	powdery materials along v ative of potential bacteria HEPA filters of the	(b) (4) with water droplets,
growths inside Air P the chamber	urification Units (A	PUs) on and af	ter the (b) (4) (b) (4)	HEPA filters of the ^(b) of randomly selected Mo	(⁴⁴ Ducts along with dule (^{b) (4)} ID: (b) (4)
The (b) (4) and (b) (4)	equipment status fo	or Module	(b) (4) on 2	6-Aug-2024 was as follow:	s:
	paign ct Name B. No.	Current Campaign Start Date	No. of batch in the campaign	Previous Product Prior to Current campaign / Batch No.	Equipment status on 26- Aug-2024
SEE REVERSE OF THIS PAGE	PSV PSV		Pratik S. Investiga	ME AND TITLE (Print or Type) Upadhyay, DDC tor Piechocki, Investigator	DATE ISSUED 09/06/2024
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLE	te IN	SPECTIONAL O	DBSERVATIONS	PAGE 3 OF 26 PAGES

		H AND HUMAN SERVICES	
DISTRICT ADDRESS AND PHONE		DATE(S) OF INSPECTION 08/26/2024-09	/06/2024
Rockville, MD	20857	FEI NUMBER	, ,
ORAPHARMInter	nationalresponses@fda.hhs.go	v	
	resident - Global Manufactur		
FIRM NAME Granules India	a Limited	STREET ADDRESS Survey No 160/A, 161E	. 162 And 174/A.
1997 T.		Gagillapur Village, D	
CITY, STATE, ZIP CODE, COUNTR	RY	Gandimaisamma Mandal TYPE ESTABLISHMENT INSPECTED	
Medchal-Malkh Telangana, 50	najgiri District,)0043 India	Drug Product Manufactu	rer
The ^{(b) (4)} non-de	dicated		(b) (4
non de		^{(b) (4)} 1mor	ng the total (b) (4)
non-dedicated	^{(b) (4)} are used in the manufac	turing of ^{(b) (4)} drug products from Module	tts from Module (b) (4
	ducts from Module ^{(b) (4)} and rying strengths are sold into the USA		of which the following
U 1			
Module ^{(b) (4)} Bl	оск)		(b) (4)
Madula ^{(b) (4)}	ealt)		
Module Bl	ock)		(b) (4)
Module ^{(b) (4)} Bl	lock)		
			(b) (4)
	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	PSU	Pratik S. Upadhyay, DDC	09/06/2024
SEE REVERSE OF	00	Investigator	
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	* U	Joseph A. Piechocki, Invest	tigator
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	PECTIONAL OBSERVATIONS	PAGE 4 OF 26 PAGES

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12420 Parklaw Rockville, M	DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternationalresponses@fda.hhs.gov NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			-	DATE(5) OF INSPECTION 08/26/2024-09 FEI NUMBER 3004097901	/06/202	24	
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Anil Arora, P	President - G	lobal Manuf	acturi	street ADDRESS	ions			
Granules Indi	a Limited	2		Survey No 160/A, 161E, 162 And 174/A, Gagillapur Village, Dundigal- Gandimaisamma Mandal			'A,	
CITY STATE ZIP CODE COUNTRY Medchal-Malkhajgiri District, Telangana, 500043 India				TYPE ESTABLISHMEN Drug Proc	NT INSPECTED Suct Manufactu	rer		
On 27-Aug-2024, v								(b) (4
UV Spectroscopy products. Test dat indicating a potent substances) that we by HPLC, and UV	methods to iden ta revealed the tial risk for drug ere manufactured	ntify the prese presence of di products cross I using the	nce of fferent contam GGP/N	drug substa drug substa nination with MA/035. Sw	nces observed ab	ously ma ove the lets active	anufacture acceptance e materials	d drug e limit s (drug
	SWAB CHEM	ICAL ANAL	The second second second second	and the second se	IPLC by UV dete	ctor)		
Sr. No. P	Product Name	Location details	Peak I RT @	Detected at	Results in ppm		eptance iteria	(b) (4)
	EMPLOYEE(S) SIGNATURE			EMPLOYEE(S) NAM	E AND TITLE (Print or Type)		DATE ISSUED	
	OC 1						09/06/2	2024
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THIS PAGE	TP			Joseph A.	Piechocki, Invest	igator		2
FORM FDA 483 (09/08)	PREVIOUS EDITION	OBSOLETE	INSP	ECTIONAL O	BSERVATIONS		PAGE 5 O	F 26 PAGES

	D	EPARTMENT OF		I AND HUMAN	SERVICES		
Rockville,	awn Drive, Roo MD 20857	m 2032		-	DATE(S) OF INSPECTION 08/26/2024-09 FEI NUMBER 3004097901	9/06/202	4
ORAPHARMINT	cernationalresp	onses@fda.h	hhs.go	V			
	President - G	lobal Manut	factur		ions		
FIRM NAME Granules In	Granules India Limited				STREET ADDRESS Survey No 160/A, 161E, 162 And 174/A, Gagillapur Village, Dundigal- Gandimaisamma Mandal		
CITY, STATE, ZIP CODE, COUNTRYTYPE ESTABLISHMENT INSPECTEDMedchal-Malkhajgiri District,Drug Product ManufacturerTelangana, 500043 IndiaDrug Product Manufacturer							
			Tab				
	SWAB CHEM	ICAL ANALY	YSIS R	ESULTS (HI	PLC by PDA det	ector)	
Sr. No.	Product Name	Location details	Peak RT (Detected at	Results in ppm		ptance teria
SWAD	RESULTS GENE	RATED DED	and the second sec	ole 4	N METHOD (C	GPROAT	V[V428)
		Location		Detected at	Results in		ptance
Sr. No.	Product Name	details	RT	(ā) (b) (4)	nnm		teria (b) (4)
	EMPLOYEE(S) SIGNATURE			EMPLOYEE(S) NAME	AND TITLE (Print or Type)		DATE ISSUED
SEE REVERSE O THIS PAGE	PSU			Pratik S. Investigat	Upadhyay, DDC	tigator	09/06/2024
FORM FDA 483 (09/08)	PREVIOUS EDITIO	N OBSOLETE	INS	1	SERVATIONS		PAGE 6 OF 26 PAGES

DISTRICT A		DEP	FOOD AND DRUG A			
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		wn Drive, Room MD 20857	2032	-	08/26/2024-09/06/20 FEINUMBER	24
ORAPH	Rockville, MD 20857 DRAPHARMInternationalresponses@fda.hhs.gov				3004097901	
NAME AND	TITLE OF INDIVIDU	JAL TO WHOM REPORT ISSUED				
Anil		President - Glo	bal Manufactur	ing Operat	cions	
		ia Limited			o 160/A, 161E, 162	And 174/A
024					ur Village, Dundiga	
				Gandimai	samma Mandal	
	E. ZIP CODE, COUR	khajgiri Distr	ict	Drug Prov	NTINSPECTED luct Manufacturer	
		500043 India	100,	Drug 1100		
2	territe (a real of Administra		Tab	le 5		
	*		(b) (d)	cule – UV Re	esults	
	Sr No	Sample Logation	Observed QC res	ulte (PPM)	Accontonce oritoria	(nnm)
i.	Sr. No.	Sample Location	Observeu QC res	uits (FFMI)	Acceptance criteria ((ppiii) (b)(4)
- 1						
			Mo	olecule – UV	Results	
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	(ppm)
						(b) (4)
- 1						
		·····	Molec	ule – UV Re	sults	
	A DEPART ADDRESS			results (PPM) Accentance criteria (nnm)		
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	(ppm)
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	(ppm) (b) (4)
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	
	Sr. No.	Sample Location	Observed QC res	ults (PPM)	Acceptance criteria	
Further			(b) (4)			(b) (4)
	rmore, swa	ab sample testing of	(refer to Tab	les 2 to 4) sh	Acceptance criteria owed unknown peaks, man domly eluting at different	ny of which had
area re nultip	rmore, swa sponse sev le swab sai	ab sample testing of veral times higher t mples tested by HPI	(refer to Tab) (refer to Tab) han the known acti- LC. These unknown	les 2 to 4) sh ve peak, ran peaks were	owed unknown peaks, mar domly eluting at different not identified and account	ny of which had retention time ed for in the ab
area re nultipl able. 7	rmore, swa sponse sev le swab sar Fhere is a j	ab sample testing of veral times higher t mples tested by HPJ potential that the up	(b)(4) (refer to Tab) han the known acti LC. These unknown known peaks could	les 2 to 4) sh ve peak, ran peaks were be due to act	owed unknown peaks, man domly eluting at different not identified and account ive and degradant materia	ny of which had retention time ed for in the ab ls of drug prod
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area re nultip able. T nanufa	rmore, swa sponse sev le swab sau Fhere is a j actured usi	ab sample testing of veral times higher t mples tested by HPI potential that the un ing these	(b)(4) (refer to Tab) han the known acti LC. These unknown known peaks could	les 2 to 4) sh ve peak, rand peaks were be due to act not identify a <i>EMPLOYEE(S) NAM</i> Pratik S.	owed unknown peaks, man domly eluting at different not identified and account ive and degradant materia ill the unknown peaks four <i>EAND TITLE (Print or Type)</i> Upadhyay, DDC	ny of which had retention time ed for in the ab ls of drug produ nd in swab sam
area re nultip able. 1 nanufa during SEE REVE	rmore, swa sponse sev le swab sau There is a j actured usi the inspec	ab sample testing of veral times higher t mples tested by HPI potential that the un ing these	(b)(4) (refer to Tab) han the known acti LC. These unknown known peaks could	les 2 to 4) sh ve peak, rand peaks were be due to act not identify a	owed unknown peaks, man domly eluting at different not identified and account ive and degradant materia ill the unknown peaks four <i>EAND TITLE (Print or Type)</i> Upadhyay, DDC	ny of which had retention time ed for in the ab ls of drug produ nd in swab sam
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Rockville, MI	420 Parklawn Drive, Room 2032 08/26/20 ockville, MD 20857 FE NUMBER RAPHARMInternationalresponses@fda.hhs.gov 30040979 THE AND TITLE OF INDIVIDUAL TO WHON REPORT ISSUED 30040979		DATE(S) OF INSPECTION 08/26/2024-09/06/20	2 4	
Anil Arora, P	resident - Global Mar	ufacturing Opera			
FIRM NAME Granules Indi	a Limited	Gagilla	No 160/A, 161E, 162 pur Village, Dundiga isamma Mandal		
CITY, STATE, ZIP CODE, COUNT Medchal-Malk Telangana, 5	hajgiri District,	0406679377680387769317	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer		
	2024, swab samples were co dedicated	ellected by your firm fi	rom the areas of APUs at the	(b) (4) (b) (4) (b) (4)	
Count (TVPC) cold of APUs and	to get carried with the product while is a potential for the several TNTC (Too I to get carried with the product while is the product while pr	Numerous To Count) or microorganisms, fur he high velocity air thr	ngal, yeast and mold grown ough the into	Viable Particulate inside these areas	
		Table 6		(b) (4)	
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE PSV M	Pratik S. Investiga	ME AND TITLE (Print or Type) Upadhyay, DDC tor Piechocki, Investigator	09/06/2024	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL C	DBSERVATIONS	PAGE 8 OF 26 PAGES	

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	DEPARTMENT OF HEALT FOOD AND DRUG			
Rockville, M	wn Drive, Room 2032 MD 20857 rnationalresponses@fda.hhs.gov		DATE(S) OF INSPECTION 08/26/2024-09/06/202 FEI NUMBER 3004097901	24
Anil Arora, P	a, President - Global Manufacturing Operation		tions	
FIRM NAME Granules Indi	Gagilla Gandima		ey No 160/A, 161E, 162 And 174/A, llapur Village, Dundigal- imaisamma Mandal	
Medchal-Malk Telangana, 5	hajgiri District,	1	oduct Manufacturer	
				(b) (4)
Alerts for some bu on 30-Aug-2024 f USP mg, mm were no FARs report results for fungal, Field Alert Report quality attributes p	b sample chemical test results for Mod t not all drug products that are manufactor or Tablets JISP (1)(4) g (mg ind orted for drug products manufactured u bacterial and TVPC. This was in devises if or filing field alerts. Additionally, pertaining to bacterial and fungal conta	ctured in mo ng, ^{(b) (4)} ng, using Modul iation of you you perform minations of	ID: GGP/MA/035), your find the control of the factor of t	Rs were reported (b)(4) Tablets (4) However, there a obtaining TNTC led: "Handling of sment to evaluate the USA market. (b)(4)
the following equi	pment:	(b) (4		01
UV Spectroscopy products. Test data	s were analyzed per protocol GGP/CV methods to identify the presence of a revealed the presence of different dru ucts cross-contamination with other d	f drug subs ig substance	tances of the previously m s above acceptance limit ind	anufactured drug icating a potential
	st			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE PSV M	Pratik S. Investiga	WE AND TITLE (Print or Type) Upadhyay, DDC ltor Piechocki, Investigator	DATE ISSUED
FORM FDA 483 (09/08) Pages	PREVIOUS EDITION OBSCLETE INS	PECTIONAL (DBSERVATIONS	PAGE 10 OF 26

	DEPARTMENT OF HEALT FOOD AND DRUG			
DISTRICT ADDRESS AND PHONE NUMBE 12420 Parklawn DJ			DATE(S) OF INSPECTION 08/26/2024-09/06/202	24
Rockville, MD 20			FEINUMBER	
ORAPHARMInternat:	nationalresponses@fda.hhs.gov		3004097901	
	ident - Global Manufactur		ations	
FIRM NAME		STREET ADDRESS		12 22 M
Granules India L	imited		No 160/A, 161E, 162 pur Village, Dundiga	
		Gandima	isamma Mandal	-
CITY, STATE, ZIP CODE, COUNTRY Medchal-Malkhajo	rivi Dictrict	TYPE ESTABLISHM	ent INSPECTED Dduct Manufacturer	
Telangana, 50004		Drug ric	duct Manufacturer	
manufactured using tabulated as follows.	^{(b) (4)} Swab samples test results fo		analysis by HPLC and UV	Spectroscopy are
	Tal	ble 7		(b) (4)
SEE REVERSE OF THIS PAGE	OVEE(S) SIGNATURE PSU M	Pratik S. Investiga	ME AND TITLE (Print or Typo) Upadhyay, DDC itor Piechocki, Investigator	DATE ISSUED 09/06/2024
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL C	DBSERVATIONS	PAGE 11 OF 26

		F OF HEALTH AND HUMA		
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Bockville, MD 20857 FEINUMBER		DATE(S) OF INSPECTION 08/26/2024-09/06/20	24	
	e and title of Individual to whom Report Issued All Arora, President - Global Manufacturing Operations			
FIRM NAME Granules Indi	STREET ADDRESS		No 160/A, 161E, 162 pur Village, Dundiga	
CITY, STATE ZIP CODE, COUN Medchal-Malk Telangana, 5	UNTRY TYPE ESTABLISHMENT INSPECTED .khajgiri District, Drug Product Manufacturer			
		Table 8		
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				ά.
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE PSV M	Pratik S Investiga	WE AND TITLE (Print or Typo) Upadhyay, DDC ator Piechocki, Investigator	DATE ISSUED 09/06/2024
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE	INSPECTIONAL (OBSERVATIONS	FAGE 12 OF 26

		OF HEALTH AND HUMA		
Rockville, M	enummer n Drive, Room 2032	1	DATE(S) OF INSPECTION 08/26/2024-09/06/202 FEI NUMBER 3004097901	24
	President - Global Mar		tions	
FIRM NAME Granules Indi	Gagillapur Villa Gandimaisamma Ma		No 160/A, 161E, 162 pur Village, Dundiga isamma Mandal	
	IP CODE, COUNTRY Al-Malkhajgiri District, Drug Product Manufacturer gana, 500043 India			
		Table 9		(b) (4)
		Table 10		(b) (4)
	EMPLOYEE(\$) SIGNATURE	EMPLOYEE(S) NA	ME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	PSU	Investiga	Upadhyay, DDC tor Piechocki, Investigator	09/06/2024
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE	INSPECTIONAL (PAGE 13 OF 26

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12420 Parklaw Rockville, M ORAPHARMInter	r ADDRESS AND PHONE NUMBER 20 Parklawn Drive, Room 2032 kville, MD 20857 PHARMInternationalresponses@fda.hhs.gov No TITLE OF INDIVIDUAL TO WHOW REPORT ISSUED		DATE(S) OF INSPECTION 08/26/2024-09/06/20 FEI NUMBER 3004097901	24
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CITY, STATE, ZIP CODE, COUNT Medchal-Malk Telangana, 5	najgiri District, Drug Product Manufactu			
	Т	able 11		
 many of which had retention times in retention times in r for in the above ta of drug products n during the inspectiusing these C. Your Preventat 1. Your firm simp filters. For example Your procedure SC AND NON VIAB 	a samples testing of these an area response several times high nultiple swab samples tested by HPI ble. There is a potential that the un- hanufactured using these on Additionally, your firm reporte of your block. ive Maintenance (PM) of block. ive Maintenance (PM) of test ly focused on replacing HEPA e, DP No.: GGMN212, Titled: "PROCI LE PARTICLE COUNT TEST FO ficient. There is no mention of Qua block, block	her than the kn LC. These unk known peaks o ^{(b) (4)} Your firm to no Field Al eficient for the filters of AP EDURE TO P R PROCESS ality Unit resp rall conditions	anown peaks were not identify could be due to active and d did not attempt to identify a erts for drug products that v e following reasons: Us without understanding th ERFORM HEPA FILTER IN EQUIPMENTS", Version: consibilities on the physical s of APUs of	eluting at different fied and accounted egradant materials all unknown peaks were manufactured the purpose of these NTEGRITY TEST 06, Effective date: yerification of the during periodic
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE PSU AA	Pratik S Investig	AME AND TITLE (Print or Type) . Upadhyay, DDC ator . Piechocki, Investigator	DATE ISSUED 09/06/2024
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE	NSPECTIONAL	OBSERVATIONS	PAGE 14 OF 26

	DEPARTMENT OF HEALTI FOOD AND DRUG A			
Rockville, M	n Drive, Room 2032	v	DATE(S) OF INSPECTION 08/26/2024-09/06/202 FEI NUMBER 3004097901	24
	resident - Global Manufactur	ing Opera	tions	
FIRM NAME Granules Indi	Gagillap		No 160/A, 161E, 162 And 174/A, apur Village, Dundigal- aisamma Mandal	
city, state, zip code, count Medchal-Malk Telangana, 5	hajgiri District,	TYPE ESTABLISHM		
of HEPA filters. In I timelines for the re- block particles larg and the surroundin determine the impa On 26-Aug-2024, and ^{(b)(4)} HEPA fil filters and ^{(b)(4)} filter ID: GGP/MA/035	ng areas of ^{(b) (4)} HEPA filter inside A act and risk or potential products cross- we observed powdery materials and po- ters. Further, white powdery materials rs indicating the integrity of ^{(b) (4)} HEPA . Swab samples collected from thes viously manufactured drug substances	tegrity test a your Engine erstanding t be any powd APU. As a n contamination tential dust were also ob A filters may se areas on	and (b)(4) rep terring unit simply focused the purpose of these (b)(4) HE terry materials present inside result, there were no invest ion. particles encrusted in areas particles e	on following the EPA filters was to the ^{(b) (4)} Duct igation logged to of ^{(b) (4)} Duct, ent of ^{(b) (4)} HEPA or Module essence of active
	⁹⁽⁴⁾ HEPA filter integrity test and s no evaluation of the condition of	⁴⁾ HEPA filte	(b) (4) HEPA filter replace er and its assembly for clean	ement for big is liness.
D. Cleaning of processing equipment is not adequately performed or documented. For example: 1. As part of Type-B cleaning of				
2. As part of Type surface by during the Type-	A cleaning of compression equipment (^{(b)(4)} the ^{(b)(4)} and ^{(b)(4)} pur A cleaning of Compression equipm	nches are to nent	the material is to be remov be cleaned by (6) (4) prior to the manufactu	On 27-Aug-2024
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	Pratik S. Investiga	ME AND TITLE (Print or Type) Upadhyay, DDC tor Piechocki, Investigator	DATE ISSUED
FORM FDA 483 (09/05) PAGES	PREVIOUS EDITION OBSOLETE INSI	PECTIONAL C	DBSERVATIONS	PAGE 15 OF 26

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	08/26/2024-09/06/2024 FE NUMBER	
DRAPHARMInternationalresponses@fda.h	3004097901	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Anil Arora, President - Global Manuf TRM NAME	facturing Operations	
Granules India Limited	Survey No 160/A, 161E, 162 And 174/	7
ordinarco fildra praticad	Gagillapur Village, Dundigal-	A1
	Gandimaisamma Mandal	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product Manufacturer	
(b)(4) (b)(4) (b)(4)	oserved apparent visible powder on ^{(b) (4)} punches, on the	(t
nd within dies from the previous batch manufact	tured.	
urthermore upon returning to the compression of	rea on 27-Aug-2024, the compression equipment had been f	inthe
	onal cleaning conducted was not documented within your exe	
leaning record.	onal cleaning conducted was not documented within your exe	cute
iouning rootiu.		
UALITY SYSTEM		
DBSERVATION 2		
	explained discrepancy and the failure of a batch or any	of it
	explained discrepancy and the failure of a batch or any other or not the batch has been already distributed.	of it
components to meet any of its specifications when	ther or not the batch has been already distributed.	
components to meet any of its specifications when Specifically, your investigations pertaining to Ou	ther or not the batch has been already distributed. at of Specification (OOS) and Out of Trend (OOT) investig	ation
components to meet any of its specifications when Specifically, your investigations pertaining to Ou are not thoroughly investigated and the CAPA ta	ther or not the batch has been already distributed.	ation
components to meet any of its specifications when Specifically, your investigations pertaining to Ou	other or not the batch has been already distributed. at of Specification (OOS) and Out of Trend (OOT) investig aken is inadequate to determine the risk to the drug product	ation
components to meet any of its specifications when Specifically, your investigations pertaining to Ou are not thoroughly investigated and the CAPA ta nto the US market. For example,	ther or not the batch has been already distributed. at of Specification (OOS) and Out of Trend (OOT) investig aken is inadequate to determine the risk to the drug product	ation ts sol
Specifically, your investigations pertaining to Ou are not thoroughly investigated and the CAPA ta nto the US market. For example, A. Your OOS and OOT Investigations for Proc horoughly investigated for Product:	ther or not the batch has been already distributed. at of Specification (OOS) and Out of Trend (OOT) investig aken is inadequate to determine the risk to the drug product cess Validation (PV) batch # (b)(4) (b)(4) (3 rd batch of PV) a (b)(4) (3 rd batch of PV) a	ation ts sol
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	DEPARTMENT OF HEALT FOOD AND DRUG			
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	AME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Anil Arora, President - Global Manufacturing Operation		ations	
FIRM NAME Granules Indi	lia Limited Survey N Gagillap		No 160/A, 161E, 162 pur Village, Dundiga isamma Mandal	281 COM - CAUSED - COURSES - COURSES - COURSES
OITY, STATE, ZIP CODE, COUN Medchal-Malk Telangana, 5	hajgiri District,	TYPE ESTABLISHN Drug Pro	NENT INSPECTED Dduct Manufacturer	
4. OOT Inve 4. OOT Inve individual classificat For the failing bate and Assay by similar test failure failed the first set indicating a syste	results above ion: Valid OOT ch # (3 rd batch of PV) at in-pr b)(4) tests, your firm did not reject the ba Your batches # (1 st PV batch	of initiation: 6 for ng term sta rocess contro atch as you r n post rejecti y ^{(b) (4)} est	we (b) (4) %, Stage: (b) (4) Tab 08-Mar-2023 Issue: OOT r ability (25°C/60%KH) at b) tests relating to (b) (4) rs	lets at in-process esult reported for Trend limit: for
Tablets Effective date: 20 <i>exhibit and validat</i> <i>released for comp</i> provided for this p (b)(4) tablets tablets). As such, y – Valid OOS). Moreover, your fi batch) and more batches as	-Feb-2020 is inadequate. Per this spe tion batches. If 'est re- pression by proposing 'b'(4) samp provision to bypass failing test results (b)(4) in the manufacturing. Also, blets at post compression) would be re- your test results at compression stage f m dispatched the failing batch # (2 nd PV batch) into the US market	there was no (b) (4) (b) (meet to the specification lim pression stage". There was stage and continuing to use o justification provided for 1	he failing (b) (4) e the failing (b) (4) e the failing (b) (4) e the failing (b) (4) e st (OOS/052/21 # (b) (4) m added n report number:
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	Pratik S. Investiga	ME AND TITLE (Print or Type) Upadhyay, DDC ator Piechocki, Investigator	DATE ISSUED 09/06/2024
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL (DBSERVATIONS	PAGE 17 OF 26

	H AND HUMAN SERVICES ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternationalresponses@fda.hhs.go NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	DATE(S) OF INSPECTION 08/26/2024-09/06/2024 FEI NUMBER 30.04.097801				
Anil Arora, President - Global Manufactu					
FIRM NAME Granules India Limited	STREET ADDRESS Survey No 160/A, 161E, 162 And 174/A, Gagillapur Village, Dundigal- Gandimaisamma Mandal				
CITY.STATE.ZIP CODE.CCUNTRY Medchal-Malkhajgiri District, Telangana, 500043 India	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer				
manufacturing and testing outcome of OOT test results. You manufactured tota	which batch # ^{(b) (4)} (3 rd PV batch) confirmed OOS and tches and dispatched them into the US market between ^{(b) (4)} atches distributed in the US market are still				
Lastly, the evaluation of market complaint revealed lack batch) for which the complaint investigation was limited similar complaints and not to the entire shelf life of	of efficacy complaint received for batch # PV				
B. Your OOT Investigation relating to unknown/unspeci	fied impurities are deficient. For example,				
numbers (b) (4) Results:	Results: Specification: (b) (4) %, Trend limit: NMT (b) (4) % of the specification limit.				
Results: Specification: NMT ^{(b) (4)} %, Trend limit: NMT ^{(b) (7)} 3. OOT Investigation number: OOT/072/21, Pro Results ^{(b) (4)} %					
4. OOT Investigation number: OOT/077/21, Pro Results:	ducts: Tablets USP mg, Batch numbers:				
Results: % Specification: NMT ^{(b) (4)} %, Trend limit: NMT ^(b)					
Your firm concluded the above OOT investigations for batches tested at release based on identifying the unknown peak found in their finished product at about This unknown peak was present in API lots					
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) NAME AND TITLE (Print or Type) Pratik S. Upadhyay, DDC Investigator Joseph A. Piechocki, Investigator				
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INS PAGES	PECTIONAL OBSERVATIONS PAGE 18 OF 26				

	IEALTH AND HUMA				
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternationalresponses@fda.hh	awn Drive, Room 2032 MD 20857 ernationalresponses@fda.hhs.gov		24		
Anil Arora, President - Global Manufa	mil Arora, President - Global Manufacturing Operations				
FIRM NAME Granules India Limited	Gagillar		NO 160/A, 161E, 162 And 174/A, apur Village, Dundigal- maisamma Mandal		
CITY, STATE.ZIP CODE. COUNTRY Medchal-Malkhajgiri District, Telangana, 500043 India	DE COUNTRY TYPE ESTABLISHMENT Malkhajgiri District, Drug Prod				
that were used in manufacturing these batches from as "Related Compound ^(b) / ₍₄₎ by your API supplier of Plan" mentioning in your investigation that "Decision of ^{(b)(4)} Tablets USP (Product codes: product test method # ^{(b)(4)} levels below ^{(b)(4)} %". However, your firm did not for batches # investigations) into the US market.	for which your fi on taken to not to ^{(b)(4)} If new er communication	rm established "Control Str use **** source API lots in the eded, **** API lots to be the a and shall be used if the u of Strategy and Action Plan	ategy and Action the manufacturing ested against drug nknown impurity		
Further, you ^{(b) (4)} only ^{(b) (4)} patches does not ensure the product performance for the rem ^{(b) (4)} throughout the product shelf life unt may have increased over the period of shelf life.	naining ^{(b) (4)} ba		rm stability which (b) (4) ted Compound (b) (4)		
C. (This is a repeat observation from the Januar	y 2023 inspectio	n)			
Your Deviation investigation number: DEV-GGP reported for swab sample analysis for equipment nar GCW/PP/027, swab location: Product ^{(b)(4)} Clea result: ^{(b)(4)} PPM, Acceptance limit: NMT ⁽⁰⁾⁽⁴⁾ PPM.	-23-0224, date ir me: B aning Verification	itiated: 08-Sep-2023, Issue lister Packaging Machine, e for ^{(b) (4)} active	e: OOS value was quipment number: swab analyses test		
Upon observing the failing test result during equipment cleaning practices on the potential ris packaged using non-dedicated ^{(b) (4)} Blister packaging equipment was largely used for	^{9) (4)} cleaning verific k for cross-conta · Packaging Macl ^{(b) (4)} drug products	eation, your firm did not ex- mination to the previous p nine. Along with packaging.	tend the impact of roducts that were (^{b)(4)} this blister		
D. Your OOT Investigation number: OOT/124/22, Products (b)(4) Tablets USP (b)(4) mg (b)(4) mg (b)(4) mg (b)(4) mg (c)(4) mg					
SEE REVERSE OF THIS PAGE	Pratik S. Investiga	WEAND TITLE (Print or Type) Upadhyay, DDC tor Piechocki, Investigator	DATE ISSUED 09/06/2024		
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE PAGES	INSPECTIONAL C	DESERVATIONS	PAGE 19 CF 26		

	CALTH AND HUMAN SERVICES RUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	08/26/2024-09/06/2024
Rockville, MD 20857	FEINUMBER
ORAPHARMInternationalresponses@fda.hhs	3004097901
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	.900
Anil Arora, President - Global Manufac	turing Operations
FIRM NAME	
Granules India Limited	Survey No 160/A, 161E, 162 And 174/A,
	Gagillapur Village, Dundigal-
	Gandimaisamma Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal-Malkhajgiri District,	Drug Product Manufacturer
Telangana, 500043 India	
Results:	(b) (4)
Results:	70
(b)(4)	
Limit: NMT %	

OOT Status: Invalid

Your firm invalidated the OOT results based on assumption of the most probable root cause could be due to glassware contamination without proving through testing that how Related Compound Impurity (4) ould be present in the glassware to the significant level to reach to the level of OOT.

OBSERVATION 3

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

Specifically,

Your Quality Unit lacks oversight on the control and management of GMP documents that are critical in ensuring drug products manufactured and tested at your site are safe and effective. For example, at the initiation of this inspection on 26-Aug-2024, we observed three (3) trucks full of scrap materials leaving from your facility at around 8:19 am. The inspection of scrap materials from these trucks revealed presence of large number of torn pieces of GMP documents such as analytical balance printouts, worksheets with handwritten documentation in "blue color indelible ball-point ink pen" which were signed and dated along with large number of uncontrolled papers torn into pieces and crumpled having manufacturing and testing information. Similarly, during the walkthrough inspection of your QC laboratory, we observed cleaning personnel removing a large black color scrap bag from the area. The evaluation of this scrap bag revealed a large number of torn and few intact pieces of analytical balance printouts, pH meter printouts, and some printouts similar to Karl Fisher to the indelible ball-point ink pen which were solve the of torn and few intact pieces of analytical balance printouts, pH meter printouts, and some printouts similar to Karl Fisher to the indelible ball-point ink pen pertaining to testing activities. Per your SOP No.: GIL-CQA-028, Titled: "Good Documentation Practices", Version: 03, Section: 5.37 "blue indelible ball-point ink pen" is used for recording of GMP documentation.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF	PSU	Pratik S. Upadhyay, DDC Investigator	09/06/2024
THIS PAGE	4	Joseph A. Piechocki, Investigator	
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 20 OF 26

FOOD ANI	HEALTH AND HUMAN SERVICES
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	08/26/2024-09/06/2024
Rockville, MD 20857	FEI NUMBER
ORAPHARMInternationalresponses@fda.hh	as.gov 3004097901
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Anil Arora, President - Global Manufa	acturing Operations
FIRM NAME	STREET ADDRESS
Granules India Limited	Survey No 160/A, 161E, 162 And 174/A, Gagillapur Village, Dundigal- Gandimaisamma Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product Manufacturer
TALE AT A DESCRIPTION OF THE DESCRIPTION OF	
uncontrolled papers torn into pieces and crumpled No.: GGQA 057, Titled: "Responsibilities of Qual shall use the green color indelible ball-point pen a	"green color indelible ball-point ink pen" on large number I having manufacturing and testing information. Per your SC ity Assurance", Version: 04, Section: 5.3.4 "The QA personn at applicable areas of work i.e. manual issuance of document labels, BPR entries, approval of COA, certificate of compliance lytical records".

Upon putting together some of the torn pieces of documents with the help of your employees, your Quality Unit management stated the torn pieces belonged to original record, raw data and metadata pertaining to QC and manufacturing units and these documents should not have been destroyed. For example, but not limited:

Bat	terial Name: tch Number: mber:	(b) (4) (b) (b) (4) (b) (b) (b) (b) (b) (b) (b) (b) (b) (b	Number:	^{(b) (4)} Tablets ^{(b) (4)} m _ξ ^{(b) (4)} Specification Number	(b) (4) (b) (4) STP
	orksheets were		tests were torr	taining to Description, Identi into pieces by the Analyst. T l trucks at the initiation of ins	hese torn Raw Data
Nu	oduct Name: mber: mber (Raw Da	^{(b) (4)} Specificat ata Sheet): GGRDS	tion Number: MSC001.	(^{b) (4)} Batch Numl (^{w) (4)} STP Number:	her: (b)(4) A.R. Worksheet
SEE		e(s) SIGNATURE PSU		s) NAME AND TITLE (Print or Type) S. Upadhyay, DDC igator	DATE ISSUED
REVERSI		YA	Joseph	A. Piechocki, Investigator	
FORM FDA 483 (0 PAGES	09/08) P	REVIOUS EDITION OBSOLETE	INSPECTIONA	AL OBSERVATIONS	PAGE 21 OF 26

	DEPARTMENT OF HEALTI FOOD AND DRUG A			
	enummer n Drive, Room 2032	Lona nor Kerrio	DATE(S) OF INSPECTION 08/26/2024-09/06/202 FEI NUMBER	2.4
Rockville, M ORAPHARMInter	nationalresponses@fda.hhs.go	v	3004097901	
	President - Global Manufactur	ing Opera	tions	
Granules Indi	a Limited	Survey N	No 160/A, 161E, 162 . Dur Village, Dundiga	
CITY, STATE ZIP CODE, COUNT	rev.	Gandima:	isamma Mandal	
i and an an and an and	hajgiri District,	2222	duct Manufacturer	
evaluation The weigh on the tor laboratory	weight printouts (2) for Sartorius Balai of some of the torn pieces revealed th ts on the torn printouts and those found n balance printouts. These torn balan that your cleaning personnel tried to on 26-Sep-2024.	he weighing affixed inside ce printouts	activities pertaining to de your worksheets depicted were collected from a scr	⁽⁴⁾ Analysis tests. different weights ap bag from QC
PRODUCTION S	SYSTEM			
OBSERVATION	4			
products for th	f ^{(b)(4)} mat manufacturing, including te US market, has not been adequately a quality prior to further processing. For		^{(b) (4)} ised in ^(b)	monly performed ontaining drug from this process
allowe	naterial adhered to the walls of the ed to be collected through rance, as outlined in procedure GGMF	هه 194, "Inspec	as applicable, and inspec	ted for physical ^{(b) (4)} material from
in-pro the mo or dur includ adhere	en no documented scientific evidence to cess check of other (b)(4) material prior ost recent process validation of ring routine production. In addition, ling related substances, that could neg ed to the chamber walls during the succ	there has be gatively imp	(^{b) (4)} and collected me bincluding during evaluation (^{b) (4)} completed in een no evaluation of other act the quality of the	eets the minimum of samples from n December 2023 quality attributes, "naterial that has
operat				
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		ME AND TITLE (Print or Type) Upadhyay, DDC tor	DATE ISSUED
THIS FAGE	70	Joseph A.	Piechocki, Investigator	
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	DEPARTMENT OF HEALTH FOOD AND DRUG A			
	SAND PHONE NUMBER Arklawn Drive, Room 2032		DATE(S) OF INSPECTION 08/26/2024-09/06/202	24
	Le, MD 20857		FEINUMBER	.4
ORAPHARM	IInternationalresponses@fda.hhs.go	V	3004097901	
6.1/2014/2014/2017/20	pra, President - Global Manufactur	ing Opera	tions	
10.040033.0000	India Limited	Corrections in order and the	IO 160/A, 161E, 162 /	And 174/A.
		Gagillag	our Village, Dundiga	
CITY, STATE, ZIP C	ODE, COUNTRY	Gandima:	Samma Mandal	
	-Malkhajgiri District, na, 500043 India	Drug Pro	duct Manufacturer	
2.	After the of the m	aterial has o	ccurred, a significant amoun	t of material may
	remain adhered to the walls within the cham 2024 during Type-B cleaning of the		This material may be then	rved on 26-Aug-
	the next campaign batch, where the	(b) ("and material is subjected	
	operations. The equipment is not Type-C cl			
	campaign length has been reached. There has		\sim . The second secon	
	determination studies of the quality impact the	is callyover	material has on subsequent c	ampaign batches.
Contraction of the second s	cumentation of	^{(b) (4)} n	naterial into the batch is det (b)(4) (b)	ficient including
during	the manufacture of		^{(b) (4)} Tablets USP	ng Batch
	for the following:			
1.	The ^{(b) (4)} process is documented as part	of the clean	ing record of the equipment	and requires that
	The ^{(b) (4)} process is documented as part the ^{(b) (4)} s ^{(b) (4)} and the ^(b)	is remove	ed prior to (b) (4) There i	s no documented
	evaluation of the surrounding area prior to			nation with other
	operations in the area, including other cleaning	ng or manui	acturing operations.	
2.		(b) (4) mate	rial is (b) (4) the	batch. However,
	there is no record of who performed and ver	rified the	and when, how,	and at what unit
	operation the collected material was	⁽⁴⁾ the batch.		
Furthermor	e. market complaint MC-GGP-23-0066 was	received or	03-Mar-2023 due to the p	presence of black
particles in	^{(b)(4)} Batches		^{(b) (4)} The	root cause of the
complaint v	was determined to be the active ingredient, (b) (4) in color and the inspe	ution of the	^{(b) (4)} which was adhered to the ^{(b) (4)} naterial missed obse	e wall of the
as described	d in procedure GGMF194. The investigation is	s inadequate	as it did not extend correctiv	e actions to other
product	d in procedure GGMF194. The investigation is ^{(b)(4)} where ^{(b)(4)} and the which quality attributes may be impacted by	(b) (4) nroce	is used it did not evaluate	or identify those
products in	which quality attributes may be impacted by	/ the	and the (b) (4) p	rocess, and it did
not evaluate root cause.	e the adequacy of the visual inspection process	s and propos	e corrective actions related t	to this attributable
Toot cause.				
	EMPLOYEE(S) SIGNATURE	EMPLOYEE/SLNA	ME AND TITLE (Print or Type)	DATE ISSUED
		LINE LO TELLOTIVA	ne rue (rue (rue o 196)	09/06/2024
SEE	I PAU	Pratik S. Investiga	Upadhyay, DDC	0010012023
REVERSE		Investiga		
THIS PAG	BE 4/1	Joseph A.	Piechocki, Investigator	
FORM FDA 483 (0 PAGES	9/08) PREVIOUS EDITION OBSOLETE INSI	PECTIONAL C	BSERVATIONS	FAGE 23 OF 26

DISTRICT ADDRESS AND PHONE NUMBER	OOD AND DRUG ADMINISTRATION DATE(S) OF INSPECTION	
12420 Parklawn Drive, Room 2032	08/26/2024-09	/06/2024
Rockville, MD 20857	FEI NUMBER 3004097901	
ORAPHARMInternationalresponses@f	da.hhs.gov 3004097901	
Anil Arora, President - Global M	anufacturing Operations	
FIRM NAME	STREET ADDRESS	
Granules India Limited	Survey No 160/A, 161E	, 162 And 174/A,
	Gagillapur Village, D	
	Gandimaisamma Mandal	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Medchal-Malkhajgiri District, Telangana, 500043 India	Drug Product Manufactu	IET
OBSERVATION 5 Written procedures are not followed that des of in-process materials of each batch.	scribe the in-process controls to be conduct	ed on appropriate sam
Specifically,		
A. During the in-process sampling and testin	ng for (b) (4) Tablets US	P ng Batch
the following discrepancies were observe	ed for the sample collected on 27Aug2024 a	
	NA ISAL ISA	(b) (4)
1. According to the batch production	on record, the operator is to inspect both fac	ces of tablets from
	^{(b) (4)} of the compression equip	
verification. We observed and ve	our operator verbally confirmed that they di	d not count the tablets
did they look at both sides befo	ore documenting the tablet verification resu	
	ore documenting the tablet verification resu	
did they look at both sides before (b)(4) in-process sample contained	ore documenting the tablet verification resu	ilts and transferring to
 did they look at both sides before in-process sample container The operator is to perform a weight 	ore documenting the tablet verification results.	e compression equipm
 did they look at both sides before in-process sample contained The operator is to perform a weile We observed and your operator is 	ore documenting the tablet verification resu or. (b) (4) tablets from (b) (4) tablets from (b) (4) tablets from (b) (4) tablets the weight check uti	e compression equipm
 did they look at both sides before (b) (d) in-process sample contained 2. The operator is to perform a weight We observed and your operator we collected and stored within the 	ore documenting the tablet verification resu er. (b) (4) tablets from (b) (4) tablets from (b) (4) the verbally confirmed that the weight check uti (b) (4) in-process sample container, and the s	e compression equipm
 did they look at both sides before (b) (d) in-process sample contained 2. The operator is to perform a weight We observed and your operator we collected and stored within the 	ore documenting the tablet verification resu or. (b) (4) tablets from (b) (4) tablets from (b) (4) tablets from (b) (4) tablets the weight check uti	e compression equipm
 did they look at both sides before in-process sample container The operator is to perform a weit We observed and your operator is collected and stored within the tested from (*)(*) 	ight check of ^(b) (4)(4)(4)(4)(4)(4)(4)(4)(4)(4)(4)(4)(4)(e compression equipm lized (b) (4) tab amples were not discre
 did they look at both sides before (b)(4) in-process sample container 2. The operator is to perform a weiter we observed and your operator is collected and stored within the tested from (b)(4) the community B. During the in-process testing for (b) (4) the community of the in-proces testing for (b) (4) the community of the in-process testing	ight check of ^(b) (4) werbally confirmed that the weight check uti ^{(b)(4)} in-process sample container, and the supression equipment. ^{(b)(4)} Tablets USP	e compression equipm lized (^{b)(4)} amples were not discre
 did they look at both sides before (b)(4) in-process sample contained 2. The operator is to perform a weil We observed and your operator vertices of the context of the distribution (b)(4) the context of the contex	by the tablet verification results of the tablet verification results of the tablets from the tablet of tablets from the tablet of the tablets from the tablet of tablets tablet of tablets used that the weight check uting the tablet of tablets tablet of tablets tablet of tablets used tablet of tablet of tablets used tablet of tablet	alts and transferring to e compression equipm lized (b)(4) tab amples were not discre (b)(4) ng Batch (b) did not pass the in-pro
 did they look at both sides before (b)(4) in-process sample containers 2. The operator is to perform a weile We observed and your operator of collected and stored within the tested from (b)(4) the common beta before (b)(4) the common beta before (b)(4) and (b)(4) and (c)(4) and	are documenting the tablet verification results and the check of ^(b) (4) tablets from ^{(b) (4)} the verbally confirmed that the weight check uti ^{(b) (4)} in-process sample container, and the supression equipment. ^{(b) (4)} Tablets USP btained a ^{(b) (4)} reading of ^{(b) (4)} which coording to procedure GFMF009, "In-proc	and transferring to e compression equipm lized ^{(b) (4)} tab amples were not discre ^{(b) (4)} ng Batch ^(b) did not pass the in-pro ess Checks and Log B
 did they look at both sides before (b) (d) in-process sample containers 2. The operator is to perform a weil We observed and your operator of collected and stored within the tested from (b) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	a deviation is to be opened in the event of a document of	e compression equipm lized ^{(b)(4)} tab amples were not discre ^{(b)(4)} ng Batch ^(b) did not pass the in-pro ess Checks and Log B parameter found out of
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 did they look at both sides before (b)(4) in-process sample containers 2. The operator is to perform a weit We observed and your operator of collected and stored within the tested from (b)(4) the composite of the composite of	a deviation is to be opened in the event of a deviation is to be opened in the sample container and the sample container and the sample container and the sample container are the sample container and the sample container are the sample container	and transferring to e compression equipm lized ^{(b) (4)} tak amples were not discre ^{(b) (4)} ng Batch ^(b) did not pass the in-pro ess Checks and Log E parameter found out o
 did they look at both sides before (b)(4) in-process sample containers. 2. The operator is to perform a weit We observed and your operator of collected and stored within the tested from (b)(4) the come. B. During the in-process testing for 27-Aug-2024, we observed one tablet of limit of (b)(4) of (b)(4) Added and a functional stores and a function of the stores and a function of t	are documenting the tablet verification results. aght check of ^(b) (4)tablets from ^{(b)(4)} Heverbally confirmed that the weight check uti ^{(b)(4)} in-process sample container, and the sample sample set of ^{(b)(4)} Tablets USP betained a ^{(b)(4)} reading of ^{(b)(4)} which ccording to procedure GFMF009, "In-proc a deviation is to be opened in the event of a le was added to the printout and the sample ducted.	e compression equipm lized (b)(4) amples were not discre (b)(4) mg Batch (b) did not pass the in-pro ess Checks and Log E parameter found out o e was reanalyzed with
 did they look at both sides before in-process sample containers. 2. The operator is to perform a weit We observed and your operator is collected and stored within the tested from ^{(b)(4)} the common beta the stored from ^{(b)(4)} the common beta the stored operator is the stored from ^{(b)(4)} the common beta the stored operator is the store	a deviation is to be opened in the event of a deviation is to be opened in the sample container and the sample container and the sample container and the sample container are the sample container and the sample container are the sample container	(b)(4) (b)(4) (c)(4) (b)(4) (c)(4)
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 did they look at both sides before (b)(4) in-process sample containers 2. The operator is to perform a weiter we observed and your operator of collected and stored within the tested from (b)(4) the comtract of the contract of th	are documenting the tablet verification results. aght check of ^(b) (4)tablets from ^{(b)(4)} Heverbally confirmed that the weight check uti ^{(b)(4)} in-process sample container, and the sample sample set of ^{(b)(4)} Tablets USP betained a ^{(b)(4)} reading of ^{(b)(4)} which ccording to procedure GFMF009, "In-proc a deviation is to be opened in the event of a le was added to the printout and the sample ducted.	(b)(4) (b)(4) (b)(4) (c)(4)
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	HEALTH AND HUMAN D DRUG ADMINISTRATIO	
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032		08/26/2024-09/06/2024
Rockville, MD 20857		FEI NUMBER
ORAPHARMInternationalresponses@fda.h	hs dov	3004097901
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Anil Arora, President - Global Manuf	acturing Opera	tions
FIRM NAME	STREET ADDRESS	9 - 5 11 1 - 5 - 5 - 5 - 5 - 5 - 5 - 5 -
Granules India Limited	Survey N	No 160/A, 161E, 162 And 174/A,
	이 이 것 같아요. 이 것 같아요. 이 것 같아. 이 가 있다. 이 것 같아. 이 있 ? ? ? ? ? ? ? ? ? ? ? ? ? ? ? ? ? ?	our Village, Dundigal-
		isamma Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHM	
Medchal-Malkhajgiri District,	Drug Pro	duct Manufacturer
Telangana, 500043 India	Drug 110	adec nandraceurer
Terangana, 500045 Indra	L	
FACILITY AND EQUIPMENT SYSTEM OBSERVATION 6		
Building and facilities are not maintained to	ensure that produ	icts manufactured meet the quality, purity
characteristics, identity and strength which they pu	irport.	
Specifically,		
A. On 26-Aug-2024, we observed filters of vou	ir randomly selecte	d Air Purification Units pertaining to Module
(b)(4) ID: (b)(4) and Module	4) randonny selecte	was pertaining to Would
ID: and Module	ĨD.	were severely damaged

and torn in many sections indicating these filters may have lacked integrity to block particles larger than ^{(b)(4)} As a result, we observed the ^{(b)(4)} HEPA filters contained apparent dust, powdery materials, and wet surfaces. Further, we observed patches of white powdery materials extruding from the corners of ^{(b)(4)} HEPA filters indicating the integrity of these filters may have been compromised.

During the inspection, per our requests your firm collected and tested swab samples from the

^{(b) (4)}HEPA filters of Module ^{(b) (4)}ID: GGP/MA/035. The swab analyses test results revealed presence of drug substances of previously manufactured drug products (refer to **Tables 2 to 5 and 9**) and colonies of bacterial and yeast (refer to **Table 6**).

B. During the walkthrough inspection of your service floor on 26-Aug-2024, we observed your Air Purification Units (APUs), Air Handling Units (AHUs), (b) (4) water tank, Equipment Cleaning Skid, (b) (4)

Ducts, ^{(b) (4)}Ducts, along with the floors and surfaces of equipment and utilities were covered with apparent off-white to white powdery materials and dust. Additionally, we observed the following concerns relating to the condition of your facility and equipment:

- 1. Bird droppings and feathers on the APUs, the floors surrounding to Module (b)(4) D (b)(4) D (b)(4) D (b)(4) The walls surrounding equipment were not secured enough in sections to prevent birds from getting inside the facility and stop dust and other environmental elements from damaging your equipment and facility.
- 2. The ^{(b)(4)} water tank had apparent reddish brown color stains indicating the tank was apparently rusted in the sections that contained water. The ^{(b)(4)} water tank and areas surrounding had wet surfaces and pool of standing water indicating potential for microbial, yeast and mold growth in these areas. Per General

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF	PSU	Pratik S. Upadhyay, DDC Investigator	09/06/2024
THIS PAGE	40	Joseph A. Piechocki, Investigator	
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 25 OF 26

DEPARTMENT OF HEAL FOOD AND DRUG			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032	***	DATE(S) OF INSPECTION 08/26/2024-09/06/2	2024
Rockville, MD 20857		FEINUMBER	1024
ORAPHARMInternationalresponses@fda.hhs.g	ov	3004097901	
Anil Arora, President - Global Manufactu:	ring Opera	ations	
FIRM NAME	STREET ADDRESS		
Granules India Limited	Gagilla Gandima	No 160/A, 161E, 16 pur Village, Dundi isamma Mandal	
CITY STATE ZP CODE COUNTRY Medchal-Malkhajgiri District,	Drug Pro	NENT INSPECTED	
Telangana, 500043 India			
 water. The sections of this cleaning skid and wat of microbial, yeast and mold on many sections 4. The equipment, ^{(b)(4)} and many sections of multiple areas. 	along with li	ose that is used for cleaning	ng.
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SEE	08/29/2024(Т 09/06/2024(F <i>емрсочее(s)</i> ма	ME AND TITLE (Print or Type) Upadhyay, DDC	
08/26/2024(Mor.), 08/27/2024(Tue), 08/28/2024(Wed), 0 09/03/2024 (Tue), 09/04/2024(Wed), 09/05/2024(Thu), 0 EMPLOYEE(S) SISMATURE	08/29/2024(T 09/06/2024(F <i>EMPLOYEE(S)NA</i> Pratik S. Investiga	ME AND TITLE (Print or Type) Upadhyay, DDC	DATE ISSUED 09/06/202