

File No: SEAC/GJ/IND3/469622/29906/2024

Government of India

Ministry of Environment, Forest and Climate Change (Issued by the State Environment Impact Assessment Authority(SEIAA), GUJARAT)



Date 09/08/2024



To,

Ukani Kiranben Lalitkumar

GREENSYN LIFE SCIENCE LLP

132, Vithhal Nagar Society, Hirabaug, Surat-395006, Gujarat, India., SURAT, GUJARAT, 395006 greensynlifescience@gmail.com

Subject:

Grant of prior Environmental Clearance (EC) to the proposed project under the provision of the EIA Notification 2006 -regarding.

Sir/Madam,

This is in reference to your application submitted to SEIAA vide proposal number SIA/GJ/IND3/469622/2024 dated 31/05/2024 for grant of prior Environmental Clearance (EC) to the proposed project under the provision of the EIA Notification 2006 and as amended thereof.

2. The particulars of the proposal are as below:

(i) EC Identification No. EC24B2403GJ5264431N

(ii) File No. SEAC/GJ/IND3/469622/29906/2024

(iii) Clearance Type Fresh EC

(iv) Category B1

(v) **Project/Activity Included Schedule No.** 5(f) Synthetic organic chemicals industry

No

(vii) Name of ProjectM/s. GreenSyn Life Science LLP(viii) Name of Company/OrganizationGREENSYN LIFE SCIENCE LLP(ix) Location of Project (District, State)GANDHINAGAR, GUJARAT

(x) Issuing Authority SEIAA

(xi) Applicability of General Conditions as per

EIA Notification, 2006

The proposal is for Environmental Clearance to M/s. GreenSyn Life Science LLP at Survey No. 1414 & 1417, Opp. Sheladia Industrial Park Gate, Village: Chhatral, Kadi- Chhatral Highway, Taluka: Kalol, District: Gandhinagar, Gujarat. It is a proposed an existing unit for manufacturing following products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

1. PP shall comply with all conditions of public hearing proceedings conducted on 13.03.2024

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- 2. PP shall carry out CER activity of their project cost, as per their submission vide OM of MoEF & CC dated 1.5.2018 and its amendment of Rs 7.8 Lakhs.
- 3. PP shall provide total Green area of 33% as per their submission.
- 4. Proponent shall provide all fire prevention and safety measures for fire control, even though fire NOC is not mandatory of labour and skilled department.
- 2.6 KLD industrial effluent from Boiler (0.5 KLD), Cooling (0.6 KLD), Washing (1.0 KLD) and Scrubber (0.5 KLD) alongwith domestic wastewater (0.7 KLD) shall be treated into ETP followed by RO and RO permeate (2.7 KLD) shall be reused in cooling purpose within premises and RO Reject (0.6 KLD) shall be mixed with concentrated stream High COD / TDS effluent for treatment and final disposal into Common Spray dryer

Annexure 1

Specific EC Conditions for (Synthetic Organic Chemicals Industry)

1. Specific Conditions:

S. No	EC Conditions					
1.1	1. Unit shall install CEMS [Continuous Emission Monitoring System] in line to CPCB directions to all SPCB vide letter no. B-29016/04/06PCI-1/5401 dated 05/02/2014 for effluent discharge and air emission as per pollutants discharge/emission from respective project and an arrangement shall also be done for reflecting the online monitoring results on the company's server, which can be assessable by the GPCB/CPCB on real time basis. [For Small/Large/Medium (Red Category) & Whichever (Air emission & Effluent discharge) is applicable]. 2. The National Ambient Air Quality Emission Standards issued by the Ministry vide G. S. R. No. 826 (E) dated 16th November, 2009 shall be complied with. 3. National Emission Standards for Bulk drug and formulation (Pharmaceuticals) Industry issued by the Ministry vide G. S. R. 541 (E) dated 06/08/2021 and amended from time to time shall be followed. 4. Unit shall have to adhere to the prevailing area specific policies of GPCB with respect to the discharge of pollutants, and shall carry out the project development in accordance & consistence with the same. 5. All measures shall be taken to avoid soil and ground water contamination within premises. 6. Safety & Health: a) PP shall obtain PESO permission for the storage and handling of hazardous chemicals. (If applicable). b) PP shall provide Occupational Health Centre (OHC) as per the provisions under the Gujarat Factories Rule 68-U. c) PP shall obtain fire safety certificate / Fire No-Objection certificate (NOC) from the concern authority as per the prevailing Rules / Gujarat Fire Prevention and Life Safety Measures Act, 2016. d) Unit shall adopt functional operations/process automation system including emergency response to eliminate risk associated with the hazardous processes. e) PP shall carry out mock drill within the premises as per the prevailing guidelines of safety and display proper evacuation plan in the manufacturing area in case of any emergency or accident. f) PP shall install adequate fire hydrant system with f					

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S. No	EC Conditions
	j) Unit shall never store drum/barrels/carboys of incompatible material/chemical together.k) Unit shall provide effective Isolation for Process area and storage of hazardous chemicals.
	l) The project management shall prepare a detailed Disaster Management Plan (DMP) for the project as per the guidelines from Directorate of Industrial Safety and Health.
	m) Unit shall obtain all required permissions from the Narcotics Control Bureau for manufacturing, storage and handling of Acetic Anhydride & any such chemicals.
	n) Provide double earthling to solvent storage tanks (1) Unit shall provide effective fire hydrants, water monitors & foam application system at solvent storage tank farm area. (2) Unit shall provide adequate safety system such as water sprinklers, water curtains, foam pouring system etc. to restrict cascade fire emergency in solvent tank farm.
	o) Unit shall never store drum/barrels/carboys of incompatible material/chemical together.
	p) Unit shall provide water sprinkler to the ammonia storage cylinder.
	q) Unit shall provide water sprinkler and bund/ dyke wall to ammonia storage tank.
	r) Unit shall Store Bromine Bottle in cool dry separate area, out of direct sunlight. s) Unit shall provide a spare tank with emergency transfer system and bund/ dyke wall to Br2
	storage tank.
	t) Unit shall provide safety valve & rupture disc to the Hydrogenation vessel.
	u) Unit shall provide chlorine leakage control emergency kit and FRP hood with scrubber system for chlorine safety.
	v) Unit shall provide safety valve and rapture disc, as well as auto dump or auto quench/, suppress
	system for exothermic reaction vessel safety.
	WATER 7. Total water requirement for the project shall not exceed 22.8 VID. Unit shall revee 2.7 VID of
	7. Total water requirement for the project shall not exceed 22.8 KLD. Unit shall reuse 2.7 KLD of treated effluent within premises. Hence, fresh water requirement shall not exceed 20.1 KLD and it shall be met through Borewell water supply only. Prior permission from concerned authority shall
	be obtained for procurement of water. 8. The industrial effluent generation from the project shall not exceed 9.5 KLD.
	9. Management of Industrial effluent shall be as under:
	• Concentrated Stream (6.9 KLD)
	• 6.9 KLD, High TDS & High COD stream generated from Process shall be treated into Primary Treatment and treated effluent shall be discharged into Common Spray dryer of M/s. Umiya Enviro Project LLP.
	• Dilute Stream (2.6 KLD):
	• 2.6 KLD industrial effluent from Boiler (0.5 KLD), Cooling (0.6 KLD), Washing (1.0 KLD) and
	Scrubber (0.5 KLD) alongwith domestic wastewater (0.7 KLD) shall be treated into ETP followed by RO and RO permeate (2.7 KLD) shall be reused in cooling purpose within premises
	and RO Reject (0.6 KLD) shall be mixed with concentrated stream - High COD / TDS effluent
	for treatment and final disposal into Common Spray dryer.
	10. Domestic wastewater generation shall not exceed 0.7 KL/Day for proposed project and it shall be treated in ETP. It shall not be disposed off through soak pit/ septic tank.
	11. Treated waste water shall be sent to common facilities (Spray dryer) only after complying with
	the inlet norms of common facilities prescribed by GPCB to ensure no adverse impact on Human
	Health and Environment.
	12. The PP shall ensure to dispose off Waste water to the Common Facilities having valid CTO of GPCB.
	13. Treated wastewater shall be subjected to Common spray dryer only after achieving inlet norms
	prescribed by GPCB ensuring content of effluent for COD so as not to get air borne during spray drying after APCM in order to achieve no adverse impacts on Environment and Human Health.

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14. Unit shall provide ETP with adequate capacity.15. The unit shall provide metering facility at the inlet and outlet of ETP and maintain records for

S. No	EC Conditions					
	the same. 16. Proper logbooks of ETP; reuse/ recycle of treated/ untreated effluent; chemical consumption in effluent treatment; quantity & quality of treated effluent sent to common facilities; power consumption etc. shall be maintained and shall be furnished to the GPCB from time to time. AIR: 17. Unit shall not exceed fuel consumption for Boiler, Thermic Fluid Heater and D G Set as per the point no. 23 as mentioned above. 18. PP shall use approved fuels only as fuel in Boiler, Thermic Fluid Heater and D G Set. 19. Unit shall provide adequate APCM with flue gas generation sources to achieve the norms prescribed by GPCB.					
	20. Unit shall provide adequate APCM with process gas generation sources as the point no. 24 as mentioned above. 21. The fugitive emission in the work zone environment shall be monitored. The emission shall conform to the standards prescribed by the concerned authorities from time to time (e.g. Directors of Industrial Safety& Health). Following indicative guidelines shall also be followed to reduce the fugitive emission.					
	 Internal roads shall be either concreted or asphalted or paved properly to reduce the fugitive emission during vehicular movement. Air borne dust shall be controlled with water sprinklers at suitable locations in the plant. A green belt shall be developed all around the plant boundary and also along the roads to mitigate fugitive & transport dust emission. 					
	 22. Regular monitoring of Volatile Organic Compounds (VOCs) shall be carried out in the work zone area and ambient air. 23. For control of fugitive emission, VOCs, following steps shall be followed: a. Closed handling and charging system shall be provided for chemicals. b. Reflux condenser shall be provided over Reactors / Vessels. c. Pumps shall be provided with mechanical seals to prevent leakages. 					
	d. Air borne dust at all transfers operations/ points shall be controlled either by spraying water or providing enclosures.24. Solvent management shall be carried out as follows:					
	 Measures shall be taken to reduce the process vapors emissions as far as possible. Use of toxic solvents shall be minimum. All venting equipment shall have vapour recovery system Reactor shall be connected to adequate chilling system to condensate solvent vapors and reduce solvent losses. Reactor and solvent handling pump shall have mechanical seals to prevent leakages. The condensers shall be provided with sufficient HTA and residence time so as to achieve maximum solvent recovery. 					
	 Solvents shall be stored in a separate space specified with all safety measures. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done. Solvent storage and handling area shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses. 					
	25. Close loop solvent recovery system with adequate condenser system shall be provided to recover solvent vapours in such a manner that recovery shall be maximum and recovered solvent shall be reused in the process within premises. 26. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained. 27. Regular monitoring of ground level concentration of PM10, PM2.5, SO2, NOx, HCl, Cl2, Br2, HBr and VOCs shall be carried out in the impact zone and its records shall be maintained. Ambient					

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S. No	EC Conditions					
	air quality levels shall not exceed the standards stipulated by the GPCB. If at any stage these levels are found to exceed the prescribed limits, necessary additional control measures shall be taken immediately. The location of the stations and frequency of monitoring shall be decided in consultation with the GPCB.					
	HAZARDOUS / SOLID WASTES: 28. All the hazardous' solid waste management shall be taken care as per the point no. 31 and 32 as mentioned above. 29. Authorized end-users shall have permissions from the concerned authorities under the Rule 9 of the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016. 30. Unit shall explore the possibilities for environment friendly methods like co-processing of hazardous waste for disposal of Incinerable & land fillable wastes before sending to CHWIF & TSDF sites respectively. 31. The project proponent has to obtain membership of TSDF site & CHWIF before obtaining CTO of GPCB. 32. Management of fly ash shall be as per the Fly ash Notification 2009 & its amendment time to time and it shall be ensured that there is 100% utilization of fly ash to be generated from the unit. 33. The unit shall submit the list of authorized end users of hazardous wastes along with MoU signed with them at least two months in advance prior to the commencement of production. In the absence of potential buyers of these items, the unit shall restrict the production of the respective items. GREENBELTAREA 34. The PP shall develop green belt within premises (1125.39 Sq. m i.e. 33.03 % of the total plot area) as submitted before SEAC. Green belt shall be developed with native plant species that are significant and used for the pollution abatement as per the CPCB guidelines. It shall be implemented within 3 years of operation phase in consultation with GPCB. OTHERS: 35. The project proponent shall carry out the activities of amount of Rs. 7.80 Lakhs (Solar lights & Tree Plantation at common property of surrounding village at Chhatral, Ankhol and Dhanot.) proposed under CER and it shall be part of the Environment Management Plan (EMP) as per the MoEF&CC's OM no. F. No. 22-65/2017-IA.III dated 30.09.2020. This shall be monitoring report shall be submitted to the regional office of MoEF&CC as a part of half-yearly compliance report and to the District Collector. The monitoring re					

Additional EC Conditions

- $1.\ PP\ shall\ comply\ with\ all\ conditions\ of\ public\ hearing\ proceedings\ conducted\ on\ 13.03.2024$
- 2. PP shall carry out CER activity of their project cost, as per their submission vide OM of MoEF & CC dated 1.5.2018 and its amendment of Rs 7.8 Lakhs.
- 3. PP shall provide total Green area of 33% as per their submission.
- 4. Proponent shall provide all fire prevention and safety measures for fire control, even though fire NOC is not

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mandatory of labour and skilled department.

2.6 KLD industrial effluent from Boiler (0.5 KLD), Cooling (0.6 KLD), Washing (1.0 KLD) and Scrubber (0.5 KLD) alongwith domestic wastewater (0.7 KLD) shall be treated into ETP followed by RO and RO permeate (2.7 KLD) shall be reused in cooling purpose within premises and RO Reject (0.6 KLD) shall be mixed with concentrated stream - High COD / TDS effluent for treatment and final disposal into Common Spray drye

Annexure 2

Details of the Project

S. No.	Particulars	Details				
a.	Details of the Project	M/s. GreenSyn Life Science LLP				
b.	Latitude and Longitude of the project site	23.27875819064412,72.42099828519855 23.27918851815104,72.42175788287317				
	7	Nature of Land involved	Area in Ha			
	Land Requirement (in Ha) of the project or activity	Non-Forest Land (A)	0.3407			
c.		Forest Land (B)	0			
		Total Land (A+B)	0.3407			
d.	Date of Public Consultation	Public consultation for the project was held of	on			
e.	Rehabilitation and Resettlement (R&R) involvement	NO IS IT She IS				
f.	Project Cost (in lacs)	390				
g.	EMP Cost (in lacs)	97.8				
h.	Employment Details	Payments				

Details of Products & By-products

Name of the product /By-product	Product / By- product	Quantity		Mode of Transport / Transmission	Remarks (eg. CAS number)
Mefenamic acid	Product		Tons per Annum (TPA)		
Furosemide	Product	68.64	Tons per Annum (TPA)	Road	
Alpha Lipoic Acid (ALA)	Product	69.3	Tons per Annum	Road	

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Name of the product /By-product	Product / By- product	Quantity	Unit	Mode of Transport / Transmission	Remarks (eg. CAS number)
			(TPA)		
Letrozole	Product	3.24	(TPA)	Road	
Tamoxifen (TAM) Citrate	Product	5.952	Tons per Annum (TPA)	Road	
Proparacaine (Proxymetacaine) hydrochloride	Product	3.6	(TPA)	Road	
Oxybuprocaine hydrochloride	Product	3.84	Tons per Annum (TPA)	Road	
Mirogabalin besylate	Product	18.6	Tons per Annum (TPA)	Road	
Rivaroxaban	Product	21	Tons per Annum (TPA)	Road	
Tramadol hydrochloride	Product	25.92	(TPA)	Koad	
Apixaban	Product	11.76	Tons per Annum (TPA)		
Epinephrine or Adrenaline tartrate	Product	14.88	Tons per Annum (TPA)		
Nor-adrenalin tartrate	Product	14.208	Tons per Annum (TPA)		
Carbidopa	Product	13.2	Tons per Annum (TPA)		
Phenylephrine hydrochloride	Product	24	Tons per Annum (TPA)	Road	
Methoxyphenamine hydrochloride	Product	12.6	(1PA)	Road	
Ramipril	Product	15.192	Tons per Annum (TPA)		
Lisinopril	Product	15.744	Tons per Annum (TPA)	60.7	
Labetalol hydrochloride	Product	12.744	Tons per Annum (TPA)	X Y	
Nebivolol hydrochloride	Product	98.4	Tons per Annum (TPA)		
Duloxetine	Product	68.4	Tons per Annum (TPA)		
R-Lacosamide	Product	24.3	Tons per Annum (TPA)		
Ezetimibe	Product	14.04	Tons per Annum (TPA)		
Dapagliflozin	Product	21	Tons per Annum (TPA)		
Canagliflozin	Product	17.028	Tons per Annum (TPA)		
Empagliflozin	Product	19.776	Tons per Annum (TPA)	Road	

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Name of the product /By-product	Product / By- product	Quantity	Unit	Mode of Transport / Transmission	Remarks (eg. CAS number)
Ertugliflozin	Product	20.7	(1PA)	Koad	
Bexagliflozin	Product	19.68	Tons per Annum (TPA)	Road	
Isoxsuprine	Product	19.2	(TPA)	Road	
Oxybutynin hydrochloride	Product	22.8	Tons per Annum (TPA)	Road	
Mirabegron	Product	22.8	(TPA)	Road	
Ponatinib hydrochloride (Cytotoxic)	Product	0.54	Tons per Annum (TPA)	Road	
Nilotinib hydrochloride mono- hydrate (Cytotoxic)	Product	0.696	Tons per Annum (TPA)	Road	
Telmisartan	Product	118.8	Tons per Annum (TPA)	Road	
Tranexamic acid	Product	100.8	Tons per Annum (TPA)	Road	
L-methylfo <mark>late</mark>	Product	13.824	Tons per Annum (TPA)	Road	
2,4-Dimethylthiophenol	Product	140.4	Tons per Annum (TPA)	Road	
Thiophenol	Product	113.4	Tons per Annum (TPA)		
Phenyl hydrazine	Product	93.6	Tons per Annum (TPA)		
5-Bromo-2-chlorobenzoic acid	Product	287.04	Tons per Annum (TPA)	Road	
2-amino-5-methylthiazole	Product	237.6	Tons per Annum (TPA)	Road	

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The proposal is for Environmental Clearance to M/s. GreenSyn Life Science LLP at Survey No. 1414 & 1417, Opp. Sheladia Industrial Park Gate, Village: Chhatral, Kadi- Chhatral Highway, Taluka: Kalol, District: Gandhinagar, Gujarat. It is a proposed an existing unit for manufacturing following products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

Furosemide 54-31-9 5.72 To treat high blood pressure. Variable Variable	Sr. No.	Name of Products	CAS No.	Quantity MT/Month	End Use of Product
Alpha Lipoic Acid (ALA) 1077-28-7 5.775 used to treat chronic diseases and as a antioxidant. 4 Letrozole 112809-51-5 7 Tamoxifen (TAM) Citrate 54965-24-1 0.496 Used to treat breast cancer. 12809-51-5 1290 Used to numb the surface of the ey temporarily before surgery, certain test or procedures. 1380-51-6-9 138245-21- 24 Local anaesthetic, used to numb to block the feeling of pain in your eye(suring short-term medical procedures.) 138245-21- 25 Used in the treatment of neuropathic pair during short-term medical procedures. 14 Mirogabalin besylate 1587-90-8 175 Used to treat and prevent blood clots. 1587-90-8 175 Used to treat and prevent blood clots. 1587-90-8 175 Used to treat and prevent blood clots. 1587-90-9 1690 Rivaroxaban 170 Tramadol hydrochloride 180-90-90-90-90-90-90-90-90-90-90-90-90-90	1	Mefenamic acid	61-68-7	14.85	· · ·
Alpha Lipote Acid (ALA) 1017-28-7 5.775 antioxidant. 4 Letrozole 112809-51-5 7 Tamoxifen (TAM) Citrate 54965-24-1 0.496 10.49	2	Furosemide	54-31-9	5.72	To treat high blood pressure.
Tamoxifen (TAM) Citrate 54965-24-1 0.496 Used to treat breast cancer. Proparacaine (Proxymetacaine) phydrochloride 5875-06-9 0.3 Used to numb the surface of the eyes temporarily before surgery, certain test or procedures. A local anaesthetic, used to numb of block the feeling of pain in your eye(suring short-term medical procedures.) Mirogabalin besylate 1138245-21- 2 Used in the treatment of neuropathic pain of pain in your eye(suring short-term medical procedures.) Mirogabalin besylate 1138245-21- 2 Used in the treatment of neuropathic pain of pain in your eye(suring short-term medical procedures.) Mirogabalin besylate 1138245-21- 2 Used in the treatment of neuropathic pain of pain in your eye(suring short-term medical procedures.) Mirogabalin besylate 1138245-21- 2 Used to treat and prevent blood clots. Tramadol hydrochloride 36282-47-0 2.16 Used to treat and prevent blood clots. Discarding the treatment of neuropathic pain of the extrement of neuropathic pain of pain in your eye(suring short-term medical procedures.) Used to treat and prevent blood clots. Used to treat and prevent blood clots. Discarding the treatment of neuropathic pain of the eye eye pain. Used to treat and prevent blood clots. Used to treat and prevent blood clots. Used to treat very low blood pressure. Used to treat Parkinson's disease of Carbidopa 1.184 Used to treat Parkinson's disease by colds, allergies, and hay fever. To treat asthma, chronic obstructive pulmonary disease (COPD) and postinfectious cough. Ramipril 87333-19-5 1.266 Used to treat high blood pressure. Used to treat high blood pressure (hypertension) and heart failure. Used to treat high blood pressure. Used to treat high blood pressure (hypertension) and heart failure.	3	Alpha Lipoic Acid (ALA)	1077-28-7	5.775	used to treat chronic diseases and as an antioxidant.
Proparacaine (Proxymetacaine) hydrochloride Oxybuprocaine hydrochloride Pisspannia Mirogabalin besylate Pisspannia Mirogabalin besylate Pisspannia Apixaban Tramadol hydrochloride Some Adrenaline tartrate To Carbidopa Nor-adrenalin tartrate Phenylephrine hydrochloride Methoxyphenamine hydrochloride Methoxyphenamine hydrochloride Pamipril Ramipril Lisinopril Labetalol hydrochloride Posspannia Posspannia Ramipril Labetalol hydrochloride Posspannia Some Adrenaline Some	4	Letrozole	112809-51-5	0.27	Used for treating breast cancer.
Proxymetacaine) hydrochloride 5875-06-9 0.3 temporarily before surgery, certain test or procedures.	5	Tamoxifen (TAM) Citrate	54965-24-1	0.496	Used to treat breast cancer.
Nytopholoride S987-82-6 0.32 block the feeling of pain in your eye(s during short-term medical procedures.	6	(Proxymetacaine)	5875-06-9	0.3	Used to numb the surface of the eye temporarily before surgery, certain tests, or procedures.
Rivaroxaban 366789-02-8 1.75 Used to treat and prevent blood clots. 10 Tramadol hydrochloride 36282-47-0 2.16 Used to treat and prevent blood clots. 11 Apixaban 503612-47-3 0.98 Used to treat and prevent blood clots 12 Epinephrine or Adrenaline tartrate 108341-18-0 1.184 Used in Asthma and Cardiac Failure. 13 Nor-adrenalin tartrate 108341-18-0 1.184 Used to treat very low blood pressure. 14 Carbidopa 28860-95-9 1.1 Used to treat Parkinson's disease 15 Phenylephrine hydrochloride 61-76-7 2 Used to relieve nasal discomfort cause by colds, allergies, and hay fever. 16 Methoxyphenamine hydrochloride 5588-10-3 1.05 To treat asthma, chronic obstructive pulmonary disease (COPD) and postinfectious cough. 17 Ramipril 87333-19-5 1.266 Used to treat high blood pressure (hypertension) and heart failure. 18 Lisinopril 83915-83-7 1.312 Used to treat high blood pressure (hypertension) and heart failure. 19 Labetalol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	7		5987-82-6	0.32	A local anaesthetic, used to numb or block the feeling of pain in your eye(s) during short-term medical procedures.
Tramadol hydrochloride 36282-47-0 2.16 Used to treat moderate to severe pain. 11 Apixaban 503612-47-3 0.98 Used to treat and prevent blood clots 12 Epinephrine or Adrenaline tartrate 51-42-3 1.24 Used in Asthma and Cardiac Failure. 13 Nor-adrenalin tartrate 108341-18-0 1.184 Used to treat very low blood pressure. 14 Carbidopa 28860-95-9 1.1 Used to treat Parkinson's disease 15 Phenylephrine hydrochloride 61-76-7 2 Used to relieve nasal discomfort cause by colds, allergies, and hay fever. 16 Methoxyphenamine hydrochloride 5588-10-3 1.05 Methoxyphenamine hydrochloride 5588-10-3 1.05 Used to treat high blood pressure (hypertension) and heart failure. 18 Lisinopril 83915-83-7 1.312 Used to treat high blood pressure (hypertension) and heart failure. 19 Labetalol hydrochloride 32780-64-6 1.062 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	8	Mirogabalin besylate		1.55	Used in the treatment of neuropathic pain
11 Apixaban 503612-47-3 0.98 Used to treat and prevent blood clots 12 Epinephrine or Adrenaline tartrate 51-42-3 1.24 Used in Asthma and Cardiac Failure. 13 Nor-adrenalin tartrate 108341-18-0 1.184 Used to treat very low blood pressure. 14 Carbidopa 28860-95-9 1.1 Used to treat Parkinson's disease 15 Phenylephrine hydrochloride 61-76-7 2 Used to relieve nasal discomfort cause by colds, allergies, and hay fever. 16 Methoxyphenamine hydrochloride 5588-10-3 1.05 Used to relieve nasal discomfort cause by colds, allergies, and hay fever. 17 Ramipril 87333-19-5 1.266 Used to relieve nasal discomfort cause by colds, allergies, and hay fever. 18 Lisinopril 87333-19-5 1.266 Used to treat high blood pressur (hypertension) and heart failure. 19 Labetalol hydrochloride 32780-64-6 1.062 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	9	Rivaroxaban	366789-02-8	1.75	Used to treat and prevent blood clots.
Epinephrine or Adrenaline tartrate	10	Tramadol hydrochloride	36282-47-0	2.16	Used to treat moderate to severe pain.
12 tartrate	11	Apixaban	503612-47-3	0.98	Used to treat and prevent blood clots
14 Carbidopa 28860-95-9 1.1 Used to treat Parkinson's disease 15 Phenylephrine hydrochloride 61-76-7 2 Used to relieve nasal discomfort cause by colds, allergies, and hay fever. 16 Methoxyphenamine hydrochloride 5588-10-3 1.05 To treat asthma, chronic obstructive pulmonary disease (COPD) and postinfectious cough. 17 Ramipril 87333-19-5 1.266 Used to treat high blood pressur (hypertension) and heart failure. 18 Lisinopril 83915-83-7 1.312 Used to treat high blood pressur (hypertension) and heart failure. 19 Labetalol hydrochloride 32780-64-6 1.062 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	12		51-42-3	1.24	Used in Asthma and Cardiac Failure.
Phenylephrine hydrochloride 61-76-7 2	13	Nor-adrenalin tartrate	108341-18-0	1.184	Used to treat very low blood pressure.
hydrochloride Methoxyphenamine hydrochloride S588-10-3 Ramipril By colds, allergies, and hay fever. To treat asthma, chronic obstructive pulmonary disease (COPD) and postinfectious cough. Ramipril By colds, allergies, and hay fever. To treat asthma, chronic obstructive pulmonary disease (COPD) and postinfectious cough. Used to treat high blood pressure (hypertension) and heart failure. Used to treat high blood pressure (hypertension) and heart failure. Used to treat high blood pressure (hypertension) and heart failure. Used to treat high blood pressure. Used to treat major depressive disorder and generalized anxiety disorder.	14	Carbidopa	28860-95-9	1.1	Used to treat Parkinson's disease
16 hydrochloride 5588-10-3 1.05 pulmonary disease (COPD) and postinfectious cough. 17 Ramipril 87333-19-5 1.266 Used to treat high blood pressur (hypertension) and heart failure. 18 Lisinopril 83915-83-7 1.312 Used to treat high blood pressur (hypertension) and heart failure. 19 Labetalol hydrochloride 32780-64-6 1.062 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	15		61-76-7	2	Used to relieve nasal discomfort caused by colds, allergies, and hay fever.
17 Ramipril 87333-19-5 1.266 (hypertension) and heart failure. 18 Lisinopril 83915-83-7 1.312 Used to treat high blood pressure (hypertension) and heart failure. 19 Labetalol hydrochloride 32780-64-6 1.062 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	16		5588-10-3	1.05	
18 Lisinoprii 83915-83-7 1.312 (hypertension) and heart failure. 19 Labetalol hydrochloride 32780-64-6 1.062 Used to treat high blood pressure. 20 Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. 21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	17	Ramipril	87333-19-5	1.266	· ·
Nebivolol hydrochloride 152520-56-4 8.2 Used to treat high blood pressure. Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	18	Lisinopril	83915-83-7	1.312	Used to treat high blood pressure (hypertension) and heart failure.
21 Duloxetine 136434-34-9 5.7 Used to treat major depressive disorder and generalized anxiety disorder.	19	Labetalol hydrochloride	32780-64-6	1.062	Used to treat high blood pressure.
21 Duloxetine 136434-34-9 5.7 and generalized anxiety disorder.	20	Nebivolol hydrochloride	152520-56-4	8.2	Used to treat high blood pressure.
R-Lacosamide 175481-36-4 2.025 Used to control partial onset seizures	21	Duloxetine	136434-34-9	5.7	Used to treat major depressive disorder and generalized anxiety disorder.
44	22	R-Lacosamide	175481-36-4	2.025	Used to control partial onset seizures

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Sr. No.	Name of Products	CAS No.	Quantity MT/Month	End Use of Product
23	Ezetimibe	163222-33-1	1.17	Used to treat high blood cholesterol.
24	Dapagliflozin	461432-26-8	1.75	Used to treat type 2 diabetes.
25	Canagliflozin	842133-18-0	1.419	Used to treat type 2 diabetes.
26	Empagliflozin	864070-44-0	1.648	Used to treat type 2 diabetes.
27	Ertugliflozin	1210344-57- 2	1.725	Used to treat type 2 diabetes.
28	Bexagliflozin	1118567-05- 7	1.64	Used to treat high blood sugar levels caused by type 2 diabetes.
29	Isoxsuprine	395-28-8	1.6	Used to treat vascular diseases such as arteriosclerosis, Buerger's disease, and Raynaud's disease.
30	Oxybutynin hydrochloride	1508-65-2	1.9	Used to treat symptoms of an overactive bladder.
31	Mirabegron	223673-61-8	1.9	Used in the symptoms of overactive bladder.
32	Ponatinib hydrochloride (Cytotoxic)	1114544-31-	0.045	Used to treat chronic myelogenous leukaemia or Philadelphia chromosome-positive acute lymphoblastic leukaemia.
33	Nilotinib hydrochloride mono-hydrate (Cytotoxic)	9 <mark>23288-</mark> 90-8	0.058	Used to treat certain types of chronic myelogenous leukaemia.
34	Telmisartan	144701-48-4	9.9	Used to treat high blood pressure.
35	Tranexamic acid	1197-18-8	8.4	Used to treat heavy bleeding during your menstrual period.
36	L-methylfolate	31690-09-2	1.152	Used to treat or prevent low levels of folate in the body.
37	2,4-Dimethylthiophenol	13616-82-5	11.7	Used to make anti depression medicine.
38	Thiophenol	108-98-5	9.45	Used in the production of pharmaceuticals including of sulfonamides.
39	Phenyl hydrazine	100-63-0	7.8	Used as antipyretics.
40	5-Bromo-2-chlorobenzoic acid	21739-92-4	23.92	Intermediate of Dapagliflozin & used to treat patients with type 2 diabetes.
41	2-amino-5-methylthiazole	7305-71-7	19.8	Used in the preparation of pharmaceuticals chemical and used in characterization and DNA-interaction studies.
	Total		167.287	

Brief Note of Product Profile:

- No of Manufacturing Plants: 1
- Brief Note regarding number of Products to be manufactured considering plant capacity: Unit will
 manufacture at a time 2 to 3 products considering plant capacity.

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The project activity is covered in 5(f) and is of 'B' Category. Public Hearing was Carried out by Gujarat Pollution Control Board dated 13.03.2024.

The SEAC, Gujarat vide their letter dated 15/07/2024 had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project based on its meeting held on 19/06/2024. The proposal was considered by SEIAA, Gujarat in its meeting held on 03/08/2024 at Gandhinagar. After careful consideration, the SEIAA hereby accords Environmental Clearance to above project under the provisions of EIA Notification dated 14th September, 2006 subject to the compliance of the following conditions.

A.CONDITIONS:

A.1SPECIFIC CONDITION:

- 1. PP shall comply with all conditions of public hearing proceedings conducted on 13.03.2024
- 2. PP shall carry out CER activity of their project cost, as per their submission vide OM of MoEF & CC dated 1.5.2018 and its amendment of Rs 7.8 Lakhs.
- 3. PP shall provide total Green area of 33% as per their submission.
- 4. Proponent shall provide all fire prevention and safety measures for fire control, even though fire NOC is not mandatory of labour and skilled department.
- 5. 2.6 KLD industrial effluent from Boiler (0.5 KLD), Cooling (0.6 KLD), Washing (1.0 KLD) and Scrubber (0.5 KLD) alongwith domestic wastewater (0.7 KLD) shall be treated into ETP followed by RO and RO permeate (2.7 KLD) shall be reused in cooling purpose within premises and RO Reject (0.6 KLD) shall be mixed with concentrated stream High COD / TDS effluent for treatment and final disposal into Common Spray dryer.
- 6. Unit shall install CEMS [Continuous Emission Monitoring System] in line to CPCB directions to all SPCB vide letter no. B-29016/04/06PCI-1/5401 dated 05/02/2014 for effluent discharge and air emission as per pollutants discharge/emission from respective project and an arrangement shall also be done for reflecting the online monitoring results on the company's server, which can be assessable by the GPCB/CPCB on real time basis. [For Small/Large/Medium (Red Category) & Whichever (Air emission & Effluent discharge) is applicable].
- 7. The National Ambient Air Quality Emission Standards issued by the Ministry vide G. S. R. No. 826 (E) dated 16th November, 2009 shall be complied with.
- 8. National Emission Standards for Bulk drug and formulation (Pharmaceuticals) Industry issued by the Ministry vide G. S. R. 541 (E) dated 06/08/2021 and amended from time to time shall be followed.
- 9. Unit shall have to adhere to the prevailing area specific policies of GPCB with respect to the discharge of pollutants, and shall carry out the project development in accordance & consistence with the same.
- 10. All measures shall be taken to avoid soil and ground water contamination within premises.

11. Safety & Health:

- a. PP shall obtain PESO permission for the storage and handling of hazardous chemicals. (If applicable).
- b. PP shall provide Occupational Health Centre (OHC) as per the provisions under the Gujarat Factories Rule 68-U.
- c. PP shall obtain fire safety certificate / Fire No-Objection certificate (NOC) from the concern authority as per the prevailing Rules / Gujarat Fire Prevention and Life Safety Measures Act, 2016.
- d. Unit shall adopt functional operations/process automation system including emergency response to eliminate risk associated with the hazardous processes.
- e. PP shall carry out mock drill within the premises as per the prevailing guidelines of safety and display proper evacuation plan in the manufacturing area in case of any emergency or accident.
- f. PP shall install adequate fire hydrant system with foam trolley attachment within premises and separate storage of water for the same shall be ensured by PP.
- g. PP shall take all the necessary steps for control of storage hazards within premises ensuring incompatibility of storage raw material and ensure the storage keeping safe distance as per the prevailing guidelines of the concerned authority.
- h. PP shall take all the necessary steps for human safety within premises to ensure that no any harm is caused to any worker/employee or labour within premises.
- i. Flame proof electrical fittings shall be provided in the plant premises, wherever applicable.

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- j. Unit shall never store drum/barrels/carboys of incompatible material/chemical together.
- k. Unit shall provide effective Isolation for Process area and storage of hazardous chemicals.
- I. The project management shall prepare a detailed Disaster Management Plan (DMP) for the project as per the guidelines from Directorate of Industrial Safety and Health.
- m. Unit shall obtain all required permissions from the Narcotics Control Bureau for manufacturing, storage and handling of Acetic Anhydride & any such chemicals.
- n. Provide double earthling to solvent storage tanks (1) Unit shall provide effective fire hydrants, water monitors & foam application system at solvent storage tank farm area. (2) Unit shall provide adequate safety system such as water sprinklers, water curtains, foam pouring system etc. to restrict cascade fire emergency in solvent tank farm.
- o. Unit shall never store drum/barrels/carboys of incompatible material/chemical together.
- p. Unit shall provide water sprinkler to the ammonia storage cylinder.
- q. Unit shall provide water sprinkler and bund/ dyke wall to ammonia storage tank.
- r. Unit shall Store Bromine Bottle in cool dry separate area, out of direct sunlight.
- s. Unit shall provide a spare tank with emergency transfer system and bund/ dyke wall to Br2 storage tank.
- t. Unit shall provide safety valve & rupture disc to the Hydrogenation vessel.
- Unit shall provide chlorine leakage control emergency kit and FRP hood with scrubber system for chlorine safety.
- v. Unit shall provide safety valve and rapture disc, as well as auto dump or auto quench/, suppress system for exothermic reaction vessel safety.

A. 2 WATER:

- 12. Total water requirement for the project shall not exceed 22.8 KLD. Unit shall reuse 2.7 KLD of treated effluent within premises. Hence, fresh water requirement shall not exceed 20.1 KLD and it shall be met through Borewell water supply only. Prior permission from concerned authority shall be obtained for procurement of water.
- 13. The industrial effluent generation from the project shall not exceed 9.5 KLD.
- 14. Management of Industrial effluent shall be as under:
 - Concentrated Stream (6.9 KLD)
 - 6.9 KLD, High TDS & High COD stream generated from Process shall be treated into Primary Treatment and treated effluent shall be discharged into Common Spray dryer of M/s. Umiya Enviro Project LLP.
 - Dilute Stream (2.6 KLD):
 - 2.6 KLD industrial effluent from Boiler (0.5 KLD), Cooling (0.6 KLD), Washing (1.0 KLD) and Scrubber (0.5 KLD) alongwith domestic wastewater (0.7 KLD) shall be treated into ETP followed by RO and RO permeate (2.7 KLD) shall be reused in cooling purpose within premises and RO Reject (0.6 KLD) shall be mixed with concentrated stream High COD / TDS effluent for treatment and final disposal into Common Spray dryer.
- 15. Domestic wastewater generation shall not exceed 0.7 KL/Day for proposed project and it shall be treated in ETP. It shall not be disposed off through soak pit/ septic tank.
- 16. Treated waste water shall be sent to common facilities (Spray dryer) only after complying with the inlet norms of common facilities prescribed by GPCB to ensure no adverse impact on Human Health and Environment.
- 17. The PP shall ensure to dispose off Waste water to the Common Facilities having valid CTO of GPCB.
- 18. Treated wastewater shall be subjected to Common spray dryer only after achieving inlet norms prescribed by GPCB ensuring content of effluent for COD so as not to get air borne during spray drying after APCM in order to achieve no adverse impacts on Environment and Human Health.
- 19. Unit shall provide ETP with adequate capacity.
- 20. The unit shall provide metering facility at the inlet and outlet of ETP and maintain records for the same.
- 21. Proper logbooks of ETP; reuse/ recycle of treated/ untreated effluent; chemical consumption in effluent treatment; quantity & quality of treated effluent sent to common facilities; power consumption etc. shall be maintained and shall be furnished to the GPCB from time to time.

A.3AIR:

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22. Unit shall not exceed fuel consumption for Boiler, Thermic Fluid Heater and D G Set as mentioned below.

Sr. no.	Source of emission With Capacity	Stack Height (meter)	Type of Fuel	Quantity of Fuel	Type of emissions i.e. Air Pollutants	Air Pollution Control Measures (APCM)
1	Boiler (2.0 TPH)		Agro-			
2	Boiler (0.8 TPH)	33	briquettes Or	Or	PM < 150 mg/Nm ³	Multi Cyclone Separator + Bag Filter + Water
3	Thermic Fluid Heater (2 Lakh KCal/hr)	e.'	Natural Gas	1429 SCM/Day	SO _X < 100 ppm NO _X < 50 ppm	Scrubber
4	D.G <mark>. S</mark> et (125 KVA)	11	Diesel	50 Litr/hr.		Adequate Stack Height

- 23. PP shall use approved fuels only as fuel in Boiler, Thermic Fluid Heater and D G Set.
- 24. Unit shall provide adequate APCM with flue gas generation sources to achieve the norms prescribed by GPCB.
- 25. Unit shall provide adequate APCM with process gas generation sources as mentioned below.

26

Sr No	Specific Source of emission (Name of the Product & Process)	Type of Emission	Stack/Vent Height (meter)	Air Pollution Control Measures (APCM)
	7.	HCl < 20 mg/Nm ³	3//3	Water Scrubber
1	Process Reactor	Cl ₂ < 9 mg/Nm ³	12	followed by Alkali Scrubber
1	9	HBr < 30 mg/Nm ³	5///	Water Scrubber
2	Process Reactor	Br ₂ < 20 mg/Nm ³	12	followed by Alkali Scrubber
3	Solvent Recovery System	VOC	12	VOC Scrubber

- 27. The fugitive emission in the work zone environment shall be monitored. The emission shall conform to the standards prescribed by the concerned authorities from time to time (e.g. Directors of Industrial Safety& Health). Following indicative guidelines shall also be followed to reduce the fugitive emission.
 - Internal roads shall be either concreted or asphalted or paved properly to reduce the fugitive emission during vehicular movement.
 - Air borne dust shall be controlled with water sprinklers at suitable locations in the plant.
 - A green belt shall be developed all around the plant boundary and also along the roads to mitigate fugitive & transport dust emission.
- 28. Regular monitoring of Volatile Organic Compounds (VOCs) shall be carried out in the work zone area and ambient air.
- 29. For control of fugitive emission, VOCs, following steps shall be followed:
 - a. Closed handling and charging system shall be provided for chemicals.
 - b. Reflux condenser shall be provided over Reactors / Vessels.
 - c. Pumps shall be provided with mechanical seals to prevent leakages.

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- d. Air borne dust at all transfers operations/ points shall be controlled either by spraying water or providing enclosures.
- 30. Solvent management shall be carried out as follows:
 - ✓ Measures shall be taken to reduce the process vapors emissions as far as possible. Use of toxic solvents shall be minimum. All venting equipment shall have vapour recovery system
 - Reactor shall be connected to adequate chilling system to condensate solvent vapors and reduce solvent losses.
 - ✓ Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - ✓ The condensers shall be provided with sufficient HTA and residence time so as to achieve maximum solvent recovery.
 - ✓ Solvents shall be stored in a separate space specified with all safety measures.
 - Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - ✓ Solvent storage and handling area shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- 31. Close loop solvent recovery system with adequate condenser system shall be provided to recover solvent vapours in such a manner that recovery shall be maximum and recovered solvent shall be reused in the process within premises.
- 32. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained.
- 33. Regular monitoring of ground level concentration of PM10, PM2.5, SO2, NOx, HCI, Cl2, Br2, HBr and VOCs shall be carried out in the impact zone and its records shall be maintained. Ambient air quality levels shall not exceed the standards stipulated by the GPCB. If at any stage these levels are found to exceed the prescribed limits, necessary additional control measures shall be taken immediately. The location of the stations and frequency of monitoring shall be decided in consultation with the GPCB.

A.4 SOLID / HAZARDOUS WASTE:

34. All the hazardous/ solid waste management shall be taken care as mentioned below.

Sr. no.	Type/Name of Hazardous waste	Specific Source of generation (Name of the Activity, Product etc.)	Category and Schedule as per HW Rules.	Quantity (MT/Annum)	Management of HW
1	Discarded barrels/ container/ bags/liners	Handling of raw materials, products, etc	33.1	16	Collection, Storage & Sell to Authorized Vender.
2	ETP Sludge	Effluent Treatment Plant	35.3	78	Collection, Storage, Transpiration and Disposal at Approved TSDF Site.
3	Used Oil	Various Machineries	5.1	0.25	Collection, Storage and Used Within Premises as A Lubricant / Sold to Registered Recycler.
4	Distillation Residue	Manufacturing Process	20.3	163	Collection, Storage, Transpiration and send to co-processing or send to approved CHWIF Site.
5	Spent Catalyst	Manufacturing Process	28.2	11	Collection, Storage, Transpiration and send to co-processing or send to approved CHWIF Site.

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6	Process Residue	Manufacturing Process	28.1	162.7	Collection, Storage, Transpiration and send to co-processing or send to approved CHWIF Site.
7	Inorganic Salts	Manufacturing Process	28.1	423	Collection, Storage, Transpiration and Disposal at Approved TSDF Site.
8	Off specification products	Manufacturing Process	28.4	0.1	Collection, Storage, Transpiration and send to co-processing or send to approved CHWIF Site.
9	Date-expired products	Manufacturing Process	28.5	0.1	Collection, Storage, Transpiration and send to co-processing or send to approved CHWIF Site.
10	Spent Solvent	Manufacturing Process	28.6	526	Collection, Storage, and reuse/recycle within premises &/or send to solvent recovery facility
11	Bleed Liquor	Scrubber System	35.1	180	Collection and conveyed to ETP for further treatment and disposal.

NON-HAZARDOUS WASTE MANAGEMENT MATRIX

Sr. no.	Type/Name of non-hazardous waste Specific Source of generation (Name of the Activity, Product etc.)		Quantity (MT/Annum)	Management of HW	
1	Fly Ash	Boiler & TFH	148	Will be handled over to brick manufacturing Industries.	

- 35. Authorized end-users shall have permissions from the concerned authorities under the Rule 9 of the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016.
- 36. Unit shall explore the possibilities for environment friendly methods like co-processing of hazardous waste for disposal of Incinerable & land fillable wastes before sending to CHWIF & TSDF sites respectively.
- 37. The project proponent has to obtain membership of TSDF site & CHWIF before obtaining CTO of GPCB.
- 38. Management of fly ash shall be as per the Fly ash Notification 2009 & its amendment time to time and it shall be ensured that there is 100% utilization of fly ash to be generated from the unit.
- 39. The unit shall submit the list of authorized end users of hazardous wastes along with MoU signed with them at least two months in advance prior to the commencement of production. In the absence of potential buyers of these items, the unit shall restrict the production of the respective items.

A. 5OTHER:

- 40. The project proponent shall carry out the activities of amount of Rs. 7.80 Lakhs (Solar lights & Tree Plantation at common property of surrounding village at Chhatral, Ankhol and Dhanot.) proposed under CER and it shall be part of the Environment Management Plan (EMP) as per the MoEF&CC's OM no. F. No. 22-65/2017-IA.III dated 30.09.2020. This shall be monitored and the monitoring report shall be submitted to the regional office of MoEF&CC as a part of half-yearly compliance report and to the District Collector. The monitoring report shall be posted on the website of the project proponent.
- 41. As proposed, at least Rs. 1.71 lakhs shall be allocated for the conservation plan Schedule- I species. (MoEF&CC) (In case of Sch-I species)
- 42. The activities and the action plan proposed by the project proponent to address the socio-economic and public hearing issues in the study area, shall be completed as per the schedule presented before the Committee and as described in the EMP report in letter and spirit.
- 43. All the recommendations, mitigation measures, environmental protection measures and safeguards proposed in the EIA report of the project prepared by M/s. Paramarsh (Servicing Environment & Development) and submitted by the project proponent and commitments made during presentation before SEAC and proposed In the EIA report shall be strictly adhered to in letter and spirit.

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B.GENERAL CONDITIONS:

B.1 CONSTRUCTION PHASE:

- 44. Water demand during construction shall be reduced by use of curing agents, super plasticizers and other best construction practices.
- 45. Project proponent shall ensure that surrounding environment shall not be affected due to construction activity. Construction materials shall be covered during transportation and regular water sprinkling shall be done in vulnerable areas for controlling fugitive emission.
- 46. All required sanitary and hygienic measures shall be provided before starting the construction activities and to be maintained throughout the construction phase.
- 47. First Aid Box shall be made readily available in adequate quantity at all the times.
- 48. The project proponent shall strictly comply with the Building and other Construction Workers' (Regulation of Employment & Conditions of Service) Act 1996 and Gujarat rules made there under and their subsequent amendments. Local bye-laws of concern authority shall be complied in letter and spirit.
- 49. Ambient noise levels shall conform to residential standards both during day and night. Incremental pollution load on the ambient air and noise quality shall be closely monitored during construction phase.
- 50. Use of Diesel Generator (DG) sets during construction phase shall be strictly equipped with acoustic enclosure and shall conform to the EPA Rules for air and noise emission standards.
- 51. Safe disposal of waste water and municipal solid wastes generated during the construction phase shall be ensured.
- 52. All topsoil excavated during construction activity shall be used in horticultural / landscape development within the project site.
- 53. Excavated earth to be generated during the construction phase shall be utilized within the premises to the maximum extent possible and balance quantity of excavated earth shall be disposed off with the approval of the competent authority after taking the necessary precautions for general safety and health aspects. Disposal of the excavated earth during construction phase shall not create adverse effect on neighbouring communities.
- 54. Project proponent shall ensure use of eco-friendly building materials including fly ash bricks, fly ash paver blocks, Ready Mix Concrete [RMC] and lead free paints in the project.
- 55. Fly ash shall be used in construction wherever applicable as per provisions of Fly Ash Notification under the E.P. Act, 1986 and its subsequent amendments from time to time.
- 56. "Wind breaker of appropriate height i.e. 1/3rd of the building height and maximum up to 10 meters shall be provided. Individual building within the project site shall also be provided with barricades.
- 57. "No uncovered vehicles carrying construction material and waste shall be permitted."
- 58. "No loose soil or sand or construction & demolition waste or any other construction material that cause dust shall be left uncovered. Uniform piling and proper storage of sand to avoid fugitive emissions shall be ensured."
- 59. Roads leading to or at construction site must be paved and blacktopped (i.e. metallic roads).
- 60. No excavation of soil shall be carried out without adequate dust mitigation measures in place.
- 61. Dust mitigation measure shall be displayed prominently at the construction site for easy public viewing.
- 62. Grinding and cutting of building materials in open area shall be prohibited.
- 63. Construction material and waste should be stored only within earmarked area and road side storage of construction material and waste shall be prohibited.
- 64. Construction and demolition waste processing and disposal site shall be identified and required dust mitigation measures be notified at the site. (If applicable).

B.2 OPERATION PHASE:

B.2.1 WATER:

- 65. The water meter shall be installed and records of daily and monthly water consumption shall be maintained.
- 66. All efforts shall be made to optimize water consumption by exploring Best Available Technology (BAT). The unit shall continuously strive to reduce, recycle and reuse the treated effluent.

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B.2.2 AIR:

- 67. In case of use of spray dryer, the unit shall provide the adequate & efficient APCMs with spray dryer so that there should not be any adverse impact on human health & environment. Unit shall carry out third party monitoring of the proposed Spray dryer & it's APCM through the credible institutes and study report for impacts on Environment and Human Health shall be submitted to GPCB every year along with half yearly compliance report.
- 68. Acoustic enclosure shall be provided to the DG sets (If applicable) to mitigate the noise pollution and shall conform to the EPA Rules for air and noise emission standards.
- 69. Stack/Vents (Whichever is applicable) of adequate height shall be provided as per the prevailing norms for flue gas emission/Process gas emission.
- 70. Flue gas emission & Process gas emission (If any) shall conform to the standards prescribed by the GPCB/CPCB/MoEF&CC. At no time, emission level should go beyond the stipulated standards.
- 71. All the reactors / vessels used in the manufacturing process shall be closed to reduce the fugitive emission.

B.2.3 HAZARDOUS/SOLID WASTE:

- 72. The company shall strictly comply with the rules and regulations with regards to handling and disposal of Hazardous waste in accordance with the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016, as may be amended from time to time. Authorization of the GPCB shall be obtained for collection / treatment / storage / disposal of hazardous wastes.
- 73. Hazardous wastes shall be dried, packed and stored in separate designated hazardous waste storage facility with pucca bottom and leachate collection facility, before its disposal.
- 74. The unit shall obtain necessary permission from the nearby TSDF site and CHWIF. (Whichever is applicable)
- 75. Trucks/Tankers used for transportation of hazardous waste shall be in accordance with the provisions under the Motor Vehicle Act, 1988, and rules made there under.
- 76. The design of the Trucks/tankers shall be such that there is no spillage during transportation
- 77. All possible efforts shall be made for Co-Processing of the Hazardous waste prior to disposal into TSDF/CHWIF.
- 78. Management of fly ash (If any) shall be as per the Fly ash Notification 2009 & its amendment time to time and it shall be ensured that there is 100% utilization of fly ash to be generated from the unit.

B.2.4 SAFETY:

- 79. The occupier/manager shall strictly comply the provisions under the Factories Act 1948 and the Gujarat Factories Rules 1963
- 80. The project authorities shall strictly comply with the provisions made in Manufacture, Storage and Import of Hazardous Chemicals Rules (MSIHC) 1989, as amended time to time and the Public Liability Insurance Act for handling of hazardous chemicals etc. Necessary approvals from the Chief Controller of Explosives and concerned Govt. Authorities shall be obtained before commissioning of the project. Requisite On-site and Off-site Disaster Management Plans have to be prepared and implemented.
- 81. Main entry and exit shall be separate and clearly marked in the facility.
- 82. Sufficient peripheral open passage shall be kept in the margin area for free movement of fire tender/ emergency vehicle around the premises.
- 83. Storage of flammable chemicals shall be sufficiently away from the production area.
- 84. Sufficient number of fire extinguishers shall be provided near the plant and storage area.
- 85. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of toxic / hazardous chemicals.
- 86. All the toxic/hazardous chemicals shall be stored in optimum quantity and all necessary permissions in this regard shall be obtained before commencing the expansion activities.
- 87. The project management shall ensure to comply with all the environment protection measures, risk mitigation measures and safeguards mentioned in the Risk Assessment report.
- 88. Only flame proof electrical fittings shall be provided in the plant premises.
- 89. Storage of hazardous chemicals shall be minimized and it shall be in multiple small capacity tanks / containers instead of one single large capacity tank / containers.

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- 90. All the storage tanks shall be fitted with appropriate controls to avoid any leakages. Bund/dyke walls shall be provided for storage tanks for Hazardous Chemicals.
- 91. Handling and charging of the chemicals shall be done in closed manner by pumping or by vacuum transfer so that minimal human exposure occurs.
- 92. Tie up shall be done with nearby health care unit / doctor for seeking immediate medical attention in the case of emergency.
- 93. Personal Protective Equipments (PPEs) shall be provided to workers and its usage shall be ensured and supervised.
- 94. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity.
- 95. Training shall be imparted to all the workers on safety and health aspects of chemicals handling.
- 96. Occupational health surveillance of the workers shall be done and its records shall be maintained. Preemployment and periodical medical examination for all the workers shall be undertaken as per the Factories Act & Rules.
- 97. Transportation of hazardous chemicals shall be done as per the provisions of the Motor Vehicle Act & Rules.
- 98. The company shall implement all preventive and mitigation measures suggested in the Risk Assessment Report.
- 99. Necessary permissions from various statutory authorities like PESO, Factory Inspectorate and others shall be obtained prior to commissioning of the project.

B.2.5 NOISE:

100.The overall noise level in and around the plant area shall be kept well within the standards by providing noise control measures including engineering controls like acoustic insulation hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise level shall confirm to the standards prescribed under The Environment (Protection) Act, 1986 & Rules.

B.2.6 CLEANER PRODUCTION AND WASTE MINIMISATION:

- 101.The unit shall undertake the Cleaner Production Assessment study through a reputed institute / organization and shall form a CP team in the company. The recommendations thereof along with the compliance shall be furnished to the GPCB.
- 102. The company shall undertake various waste minimization measures such as :
 - a. Metering and control of quantities of active ingredients to minimize waste.
 - b. Reuse of by-products from the process as raw materials or as raw materials substitutes.
 - c. Use of automated and close filling to minimize spillages.
 - d. Use of close feed system into batch reactors.
 - e. Venting equipment through vapour recovery system.
 - f. Use of high pressure hoses for cleaning to reduce wastewater generation.
 - g. Recycling of washes to subsequent batches.
 - h. Recycling of steam condensate.
 - i. Sweeping / mopping of floor instead of floor washing to avoid effluent generation.
 - j. Regular preventive maintenance for avoiding leakage, spillage etc.

B.2.7 GREEN BELT AND OTHER PLANTATION:

- 103. The unit shall develop green belt within premises as per the CPCB guidelines. However, if the adequate land is not available within the premises, the unit shall take up adequate plantation on road sides and suitable open areas in GIDC estate or any other open areas in consultation with the GIDC / GPCB and submit an action plan of plantation for next three years to the GPCB.
- 104.Drip irrigation / low-volume, low-angle sprinkler system shall be used for the green belt development within the premises.
- 105.The PP shall develop green belt within premises (1125.39 Sq. m i.e. 33.03 % of the total plot area) as submitted before SEAC. Green belt shall be developed with native plant species that are significant and used for the pollution abatement as per the CPCB guidelines. It shall be implemented within 3 years of operation phase in consultation with GPCB.

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B.3 OTHER CONDITION:

- 106. The projects covered under category 5(f) shall undergo the safety and environment audit regularly as per the standards laid down by the GPCB and CPCB.
- 107.PP shall carry out the safety audit and Risk Assessment Report as per the prevailing guidelines of safety.
- 108.Management of Fly Ash shall be as per the Fly Ash Notification 2009 & its amendment from time to time and it shall be ensured that there is 100 % utilization of fly ash to be generated from the unit.
- 109.EMP should invariably include provisions for environmental Monitoring and measures for noise pollution control measures.
- 110.In EMP proponent should seperately indicate majors of occupational health, fire and safety measures.
- 111.Prior EC is granted is subject to the proponent receiving all statutory permission / clearances / certificates and membership of respective agencies / authorities which ever applicable. Proponent shall inform progress from time to time, in six monthly compliance report to MOEFCC / SEIAA / SEAC/ GPCBfailing to which this provisional EC will stand withdrawn.
- 112. Wherever waste water or chemical water to be collected by tankers and transported to CETP etc. any diversion and disposal in open drainage (nallah) etc. causing human and environmental damage or loss will make it liable for action under the law.
- 113.All transport movement by tankers etc has to be done with maintenance of gate pass and logbook it should be verified by the inspecting authorities.
- 114.Non-hazardous waste data shall be informed to GPCB time to time so as to make an assessment and tieup with industry for generating sustainable power from the waste.
- 115.All chemical pharma industry etc. should ensure predictive and preventive maintenance of factory / boiler and reactive show as to avoid incident of fire and safety hazards.
- 116.EMP should include STP and detail cost including maintenance, transportation of waste water to CETP / CMEE etc as well as transportation cost or transit cost.
- 117.In LDAR preventive and predictive maintenance plan.
- 118.In LDAR leakage component, source of equipment leak, detention method should be given in table form.
- 119.In storage component should be shown separately in terms whether inflammable, toxic, corrosive, reactive etc.
- 120.In case of Fly Ash generation its management and disposal should be as per Government of India Notification and 100 % utilization should be ensured.
- 121.Project proponent shall install all environment management systems as per the CPCB/GPCB directives regarding the effluent discharge and air emission in working condition.
- 122. Project proponent shall display the copy of Environment Clearance at the site prominently.
- 123. Project proponent shall prepare and follow regular and preventive maintenance plan. The copy of same shall be submitted to SEIAA.
- 124. Project Proponent will have to display the safety procedure in working area.
- 125. The project proponent shall obtain all required permissions for safety, health and fire from competent authorities like PESO/Fire Authority etc. and intimate SEIAA.
- 126.Project Proponent will intimate SEIAA/SEAC/GPCB after obtaining the membership of common facilities like CETP / TSDF / CHWIF / CMEE / Common Spray Dryer as the case may be.
- 127. Extra care will be taken by PP to avoid any accidental blast in boiler, reactor or any machinery in the plant.
- 128.Environment monitoring, training and disaster management plan should be undertaken and complied at regular interval.
- 129.Integrated Regional Office of MoEF&CC,Gandhinagar and GPCB will monitor all environment, safety & health norms as per the prevailing rules.
- 130.The PP has to maintain the logsheets / registers / manifest / gate pass for discharge through tankers and SCADA system for pipeline discharge for the waste water generation and its disposal data and submit to the GPCB every quarter. GPCB shall verify the same on regular basis and inform SEIAA and take leagal action in the cases of non compliance.
- 131.Unit shall comply all the applicable standard conditions prescribed in Office Memorandum (OM) published by MoEF&CC vide no. F. No. 22-34/2018-IA.III dated 09/08/2018 for Pharmaceutical and Chemical industries mentioned at (Sr. no. XX).

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- 132. The project proponent shall allocate the separate fund for Corporate Environment Responsibility (CER) in accordance to the MoEFCC's Office Memorandum No. F.No.22-65/2017-IA.III dated 01/05/2018 to carry out the activities under CER in affected area around the project. The entire activities proposed under CER shall be monitored and the monitoring report shall be submitted to the regional office of MoEFCC as a part of half-yearly compliance report and to district collector. The monitoring report shall be posted on the website of the project proponent.
- 133.Rain water harvesting of surface as well as rooftop runoff shall be undertaken and the same water shall be used for the various activities of the project to conserve fresh water as well as to recharge ground water. Before recharging the surface run off, pre-treatment must be done to remove suspended matter.
- 134. The unit shall join and participate financially and technically for any common environmental facility / infrastructure as and when the same is taken up either by the Industrial Association or GIDC or GPCB or any such authority created for this purpose by the Govt. / GIDC.
- 135.Application of solar energy shall be incorporated for illumination of common areas, lighting for gardens and street lighting in addition the provision for solar water heating system shall also be provided.
- 136. The area earmarked as green area shall be used only for plantation and shall not be altered for any other purpose.
- 137.All the commitments / undertakings given to the SEAC during the appraisal process for the purpose of environmental protection and management shall be strictly adhered to.
- 138.The project proponent shall also comply with any additional condition that may be imposed by the SEAC or the SEIAA or any other competent authority for the purpose for the environmental protection and management.
- 139.In the event of failure of any pollution control system adopted by the unit, the unit shall be safely closed down and shall not be restarted until the desired efficiency of the control equipment has been achieved.
- 140. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any statutory authority.
- 141.During material transfer there shall be no spillages and garland drain shall be constructed to avoid mixing of accidental spillages with domestic wastewater or storm water.
- 142.Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
- 143.Leakages from pipes, pumps shall be minimal and if occurs, shall be arrested promptly.
- 144.No further expansion or modifications in the plant likely to cause environmental impacts shall be carried out without obtaining prior Environment Clearance from the concerned authority.
- 145.The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
- 146.The project proponent shall comply all the conditions mentioned in "The Companies (Corporate Social Responsibility Policy) Rules, 2014" and its amendments from time to time in a letter and spirit.
- 147. The project management shall ensure that unit complies with all the environment protection measures, risk mitigation measures and safeguards recommended in the EMP report and Risk Assessment study report as well as proposed by project proponent.
- 148. The project authorities shall earmark adequate funds to implement the conditions stipulated by SEIAA as well as GPCB along with the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.
- 149. The applicant shall inform the public that the project has been accorded environmental clearance by the SEIAA and that the copies of the clearance letter are available with the GPCB and may also be seen at the Website of SEIAA/ SEAC/ GPCB. This shall be advertised within seven days from the date of the clearance letter, in at least two local newspapers that are widely circulated in the region, one of which shall be in the Gujarati language and the other in English. A copy each of the same shall be forwarded to the concerned Regional Office of the Ministry.
- 150.It shall be mandatory for the project management to submit half-yearly compliance report in respect of the stipulated prior environmental clearance terms and conditions in soft copies to the regulatory authority concerned, on 1st June and 1st December of each calendar year.

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- 151.Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.
- 152. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
- 153. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
- 154. The company in a time bound manner shall implement these conditions. The SEIAA reserves the right to stipulate additional conditions, if the same is found necessary.
- 155.The project authorities shall inform the GPCB, Regional Office of MoEF and SEIAA about the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
- 156. This environmental clearance is valid for Ten years from the date of issue.
- 157. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
- 158. Submission of any false or misleading information or data which is material to screening or scoping or appraisal or decision on the application makes this environment clearance cancelled.

B.4 COMPLIANCE OF ENVIRONMENT CLEARANCE/REPORTING/ADMINISTRATION/APPEAL:

- 159.Project proponent shall inform to all the concerned authorities including Municipal Corporation and District Collector and shall also give wide publicity through advertisement in minimum two local newspapers within seven days, about the Environment Clearance order accorded.
- 160.Project proponent shall appoint a key person in the organization who shall be responsible for compliance of above condition fully on behalf of the proponent. It will not mean that appointing a key person will exempt the project proponent from the responsibility of compliance. Any change in key person shall immediately be informed to SEIAA and all concerned authorities.
- 161.Designated key person shall submit six monthly compliance report to SEIAA/SEAC, MOEF&CC, GPCB and Nodal Department of the Government.
- 162.The Nodal Department or any authority or officer authorized by MOEF&CC/SEIAA can inspect the site of the project and all the facilities, for verification of compliances of environment clearance conditions.
- 163.In case of violation reported upon, the project proponent shall be responsible for all the legal actions as per Environment Protection Act, 1986 including SEIAA may cancel, withdraw or keep in abeyance, the Environment Clearance accorded.
- 164.Any person including the project proponent affected by this Environment Clearance order may file appeal to Honorable National Green Tribunal West Zone branch, Pune, preferably within a period of thirty days from the date of issue of Environment Clearance as prescribe under section 16 of National Green Tribunal Act 2010.
- 165.All complaints and public grievance or representations may be addressed to SEIAA/SEAC in the email addresses (a) msseiaagj@gmail.com& (b) seacgujarat@gmail.com

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