

S. J. PANDIT, IFS (Retd.)
MEMBER SECRETARY
SEIAA (GUJARAT)



STATE LEVEL ENVIRONMENT
IMPACT ASSESSMENT
AUTHORITY
GUJARAT

Government of Gujarat

No. SEIAA/GUJ/EC/5(f)/1377 /2021

Date: 2 JUL 2021

By R P A D
Time Limit

Sub: Environment Clearance to M/s. Raks Pharma Private Limited for setting up manufacturing plant of 'Synthetic Organic Chemicals' [API & its Intermediates] at Plot. No. Z/111/A, Dahej-SEZ-II, Taluka. Vagra, Dist. Bharuch. In Category 5(f) of Schedule annexed with EIA Notification dated 14/09/2006.

Ref: Your Proposal No. SIA/GJ/IND2/174963/2020.

Dear Sir,

This has reference to your application along with Form-1 dated 18/02/2021 submitted to SEIAA, seeking Environmental Clearance under Environment Impact Assessment Notification, 2006.

The proposal is for Environmental Clearance to **M/s. Raks Pharma Private Limited for setting up manufacturing plant of 'Synthetic Organic Chemicals' [API & its Intermediates] at Plot. No. Z/111/A, Dahej-SEZ-II, Taluka. Vagra, Dist. Bharuch.** It is an existing unit for manufacturing following products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

Sr. No	Name of Products	API OR INTERMED AITE	CAS no. / CI No.	Quantity MT/Month			End use of the products *
				Existing	Proposed	Total	
1.	Tramadol HCl	API	27203-92-5	9.583	0.000	9.583	Relieve moderate to moderately severe pain
2.	Divalproex Sodium	API	76584-70-8	15.000	0.000	15.000	To treat certain types of seizures (epilepsy)
3.	Metaxalone	API	1665-48-1	18.333	0.000	18.333	Muscle relaxant used to relax muscles and relieve pain caused by strains, sprains
4.	Sildenafil Citrate	API	171599-83-0	12.500	0.000	12.500	To treat male sexual function problems, sildenafil works by increasing blood flow to the penis to help a man get and keep an erection.
5.	Linezolid	API	165800-03-3	6.667	0.000	6.667	Used to treat infections, including pneumonia, and infections of the skin. Linezolid is in a class of antibacterials called oxazolidinones.
6.	Citalopram	API	59729-33-8	10.000	0.000	10.000	To treat depression. Citalopram is in a class of antidepressants called selective serotonin reuptake inhibitors
7.	Darunavir	API	206361-99-1	0.250	0.000	0.250	HIV Protease Inhibitors
8.	Solifenacin Succinate	API	242478-38-2	0.292	0.000	0.292	Muscarinic antagonist & Treatment of urinary incontinence
9.	Vardenafil Hydrochloride Trihydrate	API	330808-88-3	0.025	0.000	0.025	An oral therapy of erectile dysfunction
10.	Eltrombopag Olamine	API	496775-62-3	0.042	0.000	0.042	Antithrombocytopenic.
11.	Bosentan	API	147536-97-8	0.017	0.000	0.017	Pulmonary artery hypertension
12.	Apremilast	API	608141-41-9	0.042	0.000	0.042	Psoriatic Arthritis
13.	Brexipiprazole	API	913611-97-9	0.008	0.000	0.008	As an adjunctive treatment of major depressive disorder (MDD)



							and for treatment of schizophrenia.
14.	Finafloxacin	API	209342-40-5	0.004	0.000	0.004	Is a fluoroquinolone antibiotic indicated in the treatment of acute otitis externa (swimmer's ear) caused by the bacteria <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i> .
15.	Netupitant	API	290297-26-6	0.021	0.000	0.021	The combination of netupitant and palonosetron is used to prevent nausea and vomiting caused by cancer chemotherapy
16.	Safinamide Mesylate	API	202825-46-5	0.025	0.000	0.025	Is indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.
17.	Atovaquane	API	95233-18-4	0.025	0.000	0.025	Used to treat <i>Pneumocystis jirovecii</i> [Pneumocystis carinii] pneumonia (PCP; type of pneumonia most likely to affect people with human immunodeficiency virus [HIV]) in teenagers and adults
18.	Obeticholic Acid	API	459789-99-2	0.003	0.000	0.003	Obeticholic acid is indicated for the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid, used as a monotherapy in adults
19.	Pirfenidone	API	53179-13-8	0.167	0.000	0.167	Antifibrotic and anti-inflammatory
20.	Ranolazine	API	95635-55-5	0.067	0.000	0.067	Chronic angina
21.	Rosuvastatin Calcium	API	147098-20-2	0.008	0.000	0.008	It works by reducing the amount of cholesterol made by the liver.
22.	Dapagliflozin	API	461432-26-8	0.008	0.000	0.008	Anti-diabetic
23.	Neostigmine Methyl Sulphate	API	51-60-5	0.002	0.000	0.002	Cholinesterase inhibitor
24.	Phenoxybenzamine HCl	API	63-92-3	0.003	0.000	0.003	Long-acting, adrenergic, alpha-receptor blocking agent
25.	Rolapitant	API	552292-08-7	0.010	0.000	0.010	is used along with other medications to prevent nausea and vomiting that may occur several days after receiving certain chemotherapy medications. Rolapitant is in a class of medications called antiemetics
26.	Cariprazine	API	839712-12-8	0.005	0.000	0.005	Is used to treat certain mental/mood disorders (such as bipolar disorder, bipolar depression, schizophrenia). Cariprazine belongs to a class of drugs known as atypical antipsychotics. It works by helping to restore the balance of certain natural substances in the brain.
27.	Ephedrine Sulphate	API	134-72-5	0.004	0.000	0.004	Allergic disorders, such as bronchial asthma
28.	Nebivolol	API	99200-09-6	0.004	0.000	0.004	Is used alone or in combination with other medications to treat high blood pressure. Nebivolol is in a class of medications called beta blockers. It works by relaxing blood vessels and slowing heart rate to improve

							blood flow and decrease blood pressure.
29.	Fluphenazine	API	69-23-8	0.004	0.000	0.004	Antipsychotic
30.	ProchloroPerazine Edisylate	API	1257-78-9	0.002	0.000	0.002	Antipsychotic
31.	Penicillamine	API	52-67-5	0.083	0.000	0.083	Treatment of rheumatoid arthritis, It helps to decrease pain/tenderness/swelling in the joints.
32.	Nitazoxanide	API	55981-09-4	0.050	0.000	0.050	Diarrhea
33.	Metyrosine	API	672-87-7	0.008	0.000	0.008	This medication is used to treat high blood pressure in people with a certain adrenal gland tumor (pheochromocytoma). Metyrosine is used to prevent high blood pressure before and immediately after surgery to remove the tumor.
34.	Clidinium Bromide	API	3485-62-9	0.004	0.000	0.004	This medication is a combination of 2 drugs, clidinium and chlordiazepoxide. It is used along with other medications to help treat stomach/intestinal disorders (such as ulcers, irritable bowel syndrome, bowel infections). Clidinium helps to reduce the symptoms of stomach and intestinal cramping
35.	Prazosine HCL	API	19216-56-9	0.004	0.000	0.004	Prazosin is used alone or in combination with other medications to treat high blood pressure.
36.	Chlordiazepoxide HCL	API	438-41-5	0.004	0.000	0.004	Used to treat anxiety and acute alcohol withdrawal. It is also used to relieve fear and anxiety before surgery.
	Clomipramine HCL	API	303-49-1	0.004	0.000	0.004	Used to treat obsessive compulsive disorder (OCD). It helps decrease persistent/unwanted thoughts (obsessions).
38.	Vigabatrin	API	60643-86-9	0.008	0.000	0.008	Vigabatrin powder is used to control infantile spasms in babies 1 month to 2 years of age. Vigabatrin is in a class of medications called anticonvulsants.
39.	Tipracil HCL	API	183204-72-0	0.002	0.000	0.002	Metastatic colorectal cancer
40.	Cariprazine HCL	API	1083076-69-0	0.002	0.000	0.002	Used for treatment of schizophrenia and bipolar disorder. It has a role as a second-generation antipsychotic, a dopamine agonist and a serotonergic antagonist.
41.	Deferasirox	API	201530-41-8	0.017	0.000	0.017	Used to treat adults and children 2 years of age and older who have too much iron in their body because they received many blood transfusions.
42.	Aminocaproic Acid	API	60-32-2	0.167	0.000	0.167	Fibrinolysis agent
43.	Calcium Gluconate	API	299-28-5	0.417	0.000	0.417	Hypocalcemia, Hypocalcemic tetany and Osteoporosis
44.	Potassium Phosphate (Dibasic)	API	7758.11.4	0.125	0.000	0.125	Used as an electrolyte replenisher and with radio-protective activity. Upon oral administration, potassium phosphate is able to block the



							uptake of the radioactive isotope phosphorus P 32
45.	Potassium Phosphate (monobasic)	API	7778-77-0	0.083	0.000	0.083	Used to prevent calcium kidney stones. It is also used to decrease the amount of ammonia in urine, thereby reducing odor and skin irritation caused by high-ammonia urine.
46.	Sodium Acetate	API	127-09-3	0.033	0.000	0.033	Used in the textile industry to neutralize sulfuric acid waste streams and also as a photoresist while using aniline dyes.
47.	Sodium Phosphate (Monobasic)	API	10049-21-5	0.017	0.000	0.017	It is used in beverages, cheese and soft drink formulations.
48.	Sodium Phosphate (Dibasic)	API	7558-79-4	0.017	0.000	0.017	Used as a saline laxative to treat constipation or to clean the bowel before a colonoscopy.
49.	Crisaborole	API	179324-69-7	0.017	0.000	0.017	Used to treat eczema (atopic dermatitis; a skin condition which causes the skin to be dry and itchy and to sometimes develop red, scaly rashes) in adults and children 3 years of age and older. Crisaborole is in a class of medications called phosphodiesterase inhibitors
50.	VelbenazineDitosylate salt and its premix	API	1639208-54-0	0.167	0.000	0.167	Used in trials studying the treatment and basic science of Tourette Syndrome and Tardive Dyskinesia.
51.	R&D/Pilot Scale/New Product development quantity	API		0.417	0.000	0.417	
52.	Magnesium Aluminum Silicate	API	1327-43-1	0.167	0.000	0.167	Used as an over-the-counter antacid for the self-treatment of heartburn, sour stomach, or acid indigestion
53.	Benazepril Hydrochloride	API	86541-74-4	0.083	0.000	0.083	Used alone or in combination with other medications to treat high blood pressure. Benazepril is in a class of medications called angiotensin-converting enzyme (ACE) inhibitors.
54.	ZiprasidoneMesylate	API	199191-69-0	0.083	0.000	0.083	Used to treat occurrences of severe agitation in patients with schizophrenia. It works by helping to restore the balance of certain natural substances (neurotransmitters) in the brain.
55.	Chlorthalidone	API	77-36-1	0.083	0.000	0.083	a 'water pill,' is used to treat high blood pressure and fluid retention caused by various conditions, including heart disease.
56.	Pyridostigmine Bromide	API	101-26-8	0.083	0.000	0.083	Used for more than 40 years in the routine treatment of myasthenia gravis and may be used following surgery in the reversal of neuromuscular blockade
57.	Hydroxyzine pamoate	API	10246-75-0	0.083	0.000	0.083	Used to treat itching caused by allergies. It is an antihistamine and works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. Hydroxyzine may also be used short-term to treat anxiety or to help you feel sleepy/relaxed before and after

							surgery.
58.	Azathioprine	API	446-86-6	0.083	0.000	0.083	Used to prevent organ rejection in people who have received a kidney transplant, also used to treat rheumatoid arthritis.
59.	Clopidogrelbisulfate	API	120202-66-6	0.083	0.000	0.083	Thienopyridine class of drug that inhibits platelet aggregation and thus inhibits aspects of blood clotting used to treat patients with acute coronary syndrome, myocardial infarction (MI), peripheral vascular disease and some stroke (ischemic type) patients.
60.	Pregabalin	API	148553-50-8	0.542	0.000	0.542	Is an anti-epileptic drug, also called an anticonvulsant. It works by slowing down impulses in the brain that cause seizures. Pregabalin also affects chemicals in the brain that send pain signals across the nervous system.
61.	Doxepin hydrochloride	API	1668-19-5	0.083	0.000	0.083	Used to treat mental/mood problems such as depression and anxiety.
62.	Pantoprazole sodium	API	138786-67-1	1.250	0.000	1.250	Used to treat damage from gastroesophageal reflux disease (GERD).
63.	Lactulose	API	4618-18-2	0.083	0.000	0.083	Lactulose is a synthetic sugar used to treat constipation
64.	Tigabine hydrochloride monohydrate	API	145821-57-4	0.083	0.000	0.083	Used for the treatment of epilepsy. It has a role as an anticonvulsant and a GABA reuptake inhibitor.
65.	Sodium Benzoate	API	532-32-1	0.083	0.000	0.083	Is a preservative, with the E number E211. It is most widely used in acidic foods such as salad dressings
66.	Sodium Phenyl Acetate	API	114-70-5	0.083	0.000	0.083	Sodium phenylacetate and benzoate injection combination is used to treat hyperammonemia
67.	Prochlorperazine disylate	API	1257-78-9	0.042	0.000	0.042	This leads to a reduction in psychotic symptoms, including hallucinations and delusions, its antiemetic activity by blocking the dopamine and histamine receptors in the chemical trigger zone (CTZ) in the brain, thereby relieving nausea and vomiting.
68.	Deflazacort	API	14484-47-0	0.000	0.417	0.417	Used to treat Duchenne muscular dystrophy (DMD; a progressive disease in which the muscles do not function properly) in adults and children 2 years of age and older.
69.	HydroxyChloroquine sulphate	API	747-36-4	0.000	0.417	0.417	Is in a class of drugs called antimalarials. It works by killing the organisms that cause malaria. Hydroxychloroquine may work to treat rheumatoid arthritis
70.	Prochloroperazine maleate	API	84-02-6	0.000	0.417	0.417	Used to treat severe nausea and vomiting from certain causes (for example, after surgery or cancer treatment)
71.	Ramdesivir	API	1809249-37-3	0.000	0.417	0.417	Sars-cov-2, infection who had an oxygen saturation of 94% or less while they were breathing ambient air or who were receiving oxygen support.

72.	Selegiline HCL	API	14611-52-0	0.000	0.417	0.417	Usually used in combination with other medicines (e.g., levodopa, carbidopa). Selegiline is an enzyme blocker (MAO inhibitor) that works by slowing the breakdown of certain natural substances in the brain
73.	Indomethacin	API	53-86-1	0.000	0.417	0.417	Used to relieve moderate to severe pain, tenderness, swelling, and stiffness caused by osteoarthritis, rheumatoid arthritis
74.	Meta Chloro Anisole	Intermediate	2845-89-8	0.000	20.833	20.833	Intermediate
75.	Diethyl Dipropylmalonate	Intermediate	6065-63-0	0.000	20.833	20.833	Intermediate
Total				77.76	44.17	121.93	--

Brief Note of Product Profile:

1. **No of Manufacturing Plants:** 01 nos.
2. **Brief Note regarding number of Products to be manufactured considering plant capacity:** With the available and proposed capacity at a time 20 Products can be manufactured and in a year all the products 75 Nos. can be produced

The project activity is covered in 5(f) and is of 'B' Category. Since, the proposed project is categorized as B2 category project by SEAC and as per the MoEF&CC's amended EIA Notification vide S.O. 1223(E) dated 27.03.2020, public consultation is not required as per paragraph 7(i) (III) (i) (b)&(e) of the Environment Impact Assessment Notification-2006.

The SEAC, Gujarat vide their letter dated 25/06/2021 had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project based on its meeting held on 25/06/2021. The proposal was considered by SEIAA, Gujarat in its meeting held on 26/06/2021 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 conditions of any subsequent amendment or expansion or change in product mix, after the 30th September 2020, considered as per the provisions in force at that time as mentioned in the Notification vide S.O. 1223 (E) dated 27/03/2020 and its amendment.
2. PP shall carry out proposed project/activities in respect of Active Pharmaceutical Ingredients (API) as per the amended EIA Notification vide S.O. 1223 (E) dated 27/03/2020 and any subsequent amendments.
3. PP shall submit six monthly compliance report of Environmental Clearance without fail and the same shall be critically assessed by the regulatory authority.
4. Total number of products manufacturing shall not exceeding twenty at a given point of time as per the plant capacity shown in plant layout.
5. 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].
6. 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.
7. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained.
8. All measures shall be taken to avoid soil and ground water contamination within premises.
9. **Safety & Health:**
 - a. PP shall obtain PESO permission for the storage and handling of hazardous chemicals.
 - 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 labor within premises.
 - i. Flame proof electrical fittings shall be provided in the plant premises, wherever applicable.
 - 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. Unit shall provide water sprinkler to the ammonia storage cylinder.
10. Unit shall comply with all the orders passed by the Hon'ble National Green Tribunal (NGT), New Delhi in Original Application No. 1038/2018 dated 10/07/2018.
 11. Unit shall stand in compliance to Office Memorandum (OM) vide Letter No. F. No. 22-23/2018 – IA.III (Pt) dated 31/10/2019 regarding Compliance of Hon'ble National Green Tribunal (NGT) order dated 19.08.2019 (Published on 23/08/2019) in Original Application No. 1038/2018.
 12. No project/activity in contradiction to the orders passed by the Hon'ble National Green Tribunal (NGT), New Delhi in Original Application No. 1038/2018 dated 10/07/2018 shall be carried out else the granted Environment Clearance shall stand cancelled.
 13. Close loop solvent recovery system with adequate condenser system shall be provided to recover solvent vapors in such a manner that recovery shall be maximum and recovered solvent shall be reused in the process within premises. (If there is in-house solvent recovery and in-house distillation)
 14. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained
 15. Unit shall explore the possibilities for environment friendly methods for disposal of Incinerable & land fillable wastes before sending to CHWIF/TSD sites respectively.
 16. Unit shall install CEMS 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. [Whichever (Air emission & Effluent discharge) is applicable as per the prevailing guidelines of GPCB/CPCB]
 17. All measures shall be taken to prevent soil and ground water contamination.
 18. 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.
 19. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G. S. R. 608 (E) dated 21/07/2010 and amended from time to time shall be followed.
 20. 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.
 21. Unit shall provide CCTV camera at strategic locations within premises with web link facility for the continuous monitoring and recording to ensure that there is no discharge from the premises. (As per the prevailing guidelines of GPCB).
 22. Third party monitoring of the functioning of the EMS along with its efficiency shall be carried out once in a year through a GPCB recognized auditors.

A. 2 WATER :

23. Total water requirement for the project shall not exceed 227 KLD. Unit shall reuse 37.60 KLD of treated industrial effluent within premises. Hence, fresh water requirement shall not exceed 189.40 KLD and it shall be met through GIDC water supply only. Prior permission from concerned authority shall be obtained for withdrawal of water.
24. The industrial effluent generation from the project shall not exceed 89 KLD after expansion.
25. Industrial effluent shall be segregated into two streams (1) High COD and TDS effluent (2) Low COD and TDS effluent and it shall be managed as below.
 - **High COD and TDS effluent (14 KLD)**
 - 14 KLD, High COD and TDS effluent from process shall be treated in ETP-1 consists of Primary treatment units followed by solvent stripper. Then treated effluent shall be evaporated in in-house MEE cum ATFD and 37.60 KLD, MEE condensate shall be reused within premises.
 - **Low COD and TDS effluent (75 KLD):**
 - 75 KLD, Low COD effluent from process, utility and scrubber shall be treated in ETP-2 and RO plant. 60 KLD, RO permeate shall be discharged into GIDC Dahej –Vilayat underground pipeline. 24 KLD RO reject shall be

evaporated in in-house MEE cum ATFD.

26. Treated waste water shall be discharged into GIDC Dahej-Vilayat underground pipeline leading to deep sea only after complying with the norms prescribed by GPCB to ensure no adverse impact on Human Health and Environment.
27. Unit shall feed wastewater to in-house MEE only after ensuring content of effluent for COD/VOC so as not to get air borne during evaporation in order to achieve no adverse impacts on Environment and Human Health.
28. Domestic wastewater generation shall not exceed 9 KL/day for proposed project and it shall be treated in ETP. It shall not be disposed off through soak pit/ septic tank.
29. Unit shall provide buffer water storage tank of adequate capacity for storage of treated waste water during any shut down of in-house MEE.
30. The unit shall provide metering facility at the inlet and outlets of ETP, MEE and maintain records for the same.
31. Proper logbooks of ETP; chemical consumption in Effluent treatment; quantity & quality of effluent discharge to MEE and GIDC pipeline; quantity & quality of effluent recycle back in process, power consumption etc shall be maintained and shall be furnished to the GPCB from time to time.

A.3 AIR:

32. Unit shall not exceed fuel consumption for steam boiler, thermo pack, Incinerator and D. G. Sets as mentioned below:

Sr. no.	Source of emission With Capacity	Stack Height (meter)	Type of Fuel	Quantity of Fuel MT/Day	Type of emissions i.e., Air Pollutants	Air Pollution Control Measures (APCM)
Existing:						
1	*Steam Boiler- (Ton/hrs.) – 2.00 x 2 nos.	30	Bio Coal/Agrowaste	750.00 Kgs/hrs.	PM SO ₂ NO _x	Bag Filter and Adequate stack height
2	*D.G. Set - 500 KVA (1 Nos.)	11	HSD/LDO	70.00 & 250.00 Lit/Hr.		Adequate stack height
3	Incinerator	30	Natural Gas/LDO	375 SCM/hr.	PM HCl, SO ₂ CO TOC, HF, NO _x TDF Cd + Th + Their compounds Hg and its compounds Sb + As + Pb + Cr + Co + Cu + Mn + Ni + V + Their compounds	Two stage Alkali scrubber.

Proposed:

1	Steam Boiler- (Ton/hrs.) – 3.00 x 1 nos. & 6.00 x 1 nos.	32	Bio Coal/Agrowaste	750.00 & 1500.00 Kgs/hrs.	PM SO ₂ NO _x	Multi Cyclone Separator with Bag Filter and Adequate stack height
2	Thermic fluid heater- (Lack K. Cal/hr.) – 2.00 x 1 nos. & 4.00 x 1 nos.	32	HSD/LDO	75.00 Lit/Hr.		Adequate stack height
3	D.G. Set - 750 KVA (1 Nos.) & 1500 KVA (1 Nos.)	11	HSD/LDO	250.00 & 500.00 Lit/hrs.		Adequate stack height

Note: * The Existing Boiler and Existing D.G. Set will be used as a standby.

33. Unit shall provide adequate APCM with flue gas generation sources as mentioned above.
34. Unit shall provide adequate APCM with process gas generation sources as mentioned below:

Sr. no.	Specific Source of emission (Name of the Product & Process)	Type of emission	Stack/Vent Height (meter)	Air Pollution Control Measures (APCM)
Existing:				
1	Process Reactor– 1	HCl	11	Two stage Alkali scrubber.
2	Process Reactor	NH ₃	11	Phosphoric acid scrubber.

35. The fugitive emission in the workzone 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.

36. Regular monitoring of Volatile Organic Compounds (VOCs) shall be carried out in the work zone area and ambient air.

37. 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.

38. Solvent management shall be carried out as follows:

- ✓ Measures shall be taken to reduce the process vapours 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 vapours 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.

39. Regular monitoring of ground level concentration of PM10, PM2.5, SO2, NOx, HCl, and VOC 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.

4.4 SOLID / HAZARDOUS WASTE:

40. All the hazardous waste management shall be taken care as mentioned below:

Sl. 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
				Existing	Proposed	Total	
1	ETP Waste	ETP Operation	Sch.I:35.3	24.00	20.00	44.00	Collection, Storage, Transportation and Disposal at TSDF site
2	Used oil	From plant and machinery	Sch.I:5.1	300.00	0.00	300.00	Collection, Storage, Transportation, Disposal by selling to refiners.
3	Discarded Carboys/ Drum/ Containers/Line rs/Bags	Raw Materials	Sch.I:33.1	2400.00	2600.00	5000.00	Collection, Storage, decontamination, Transportation and disposal by selling to authorized vendor.
4	Process Residue & Waste	Distillation and manufacturing process of all products.	Sch.I:28.1	20.00	106.00	126.00	Collection, Storage, Transportation, Disposal by in-house incineration.
5	Spent carbon	Mfg. Process	Sch.I:28.3	0.00	100.00	100.00	Collection, Storage, Transportation, Disposal at Co-processing /GPCB Approved facility.
6	Off specification products	Mfg. Process	Sch.I:28.4	10.00	0.00	10.00	Collection, Storage, Transportation and disposal by in-house incineration.
7	Date-expired products	Mfg. Process	Sch.I:28.5	10.00	0.00	10.00	
8	Spent Solvent	From Solvent recovery plan	Sch.I:28.6	25.00	1500.00	1525.00	Collection, Storage, Transportation and Disposal either by send it to co-processing or by common incineration facility or sell out to authorized end-users who is having Rule-9 permission and after making
9	Spent Acid	Manufacturing process		0.00	100.00	100.00	

12	Used Filter Cloths	Mfg. Process (From most of the products)	Sch.I:33.2	0.00	1.00	1.00	MoU industries. Collection, Storage, Transportation and disposal by in-house incineration.
13	Scrubber Bleed off	From Scrubber	Sch.I: 28.1	2920.00	0.00	2920.00	Collection, Storage, To In house ETP-2 for further treatment.
14	Mixed Solvents	From Solvent Stripper	Sch.I:28.6	0.00	73.00	73.00	Collection, Storage, Transportation and disposal at GPCB approved facility /co-processing or by common incineration facility.
15	MEE Salt	From MEE-ATFD Plant	Sch.I:37.3	0.00	100.00	100.00	Collection, Storage, Transportation, and disposal at GPCB approved TSDF facility.

41. 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.
42. 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.
43. 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. 5 OTHER:

44. The project proponent shall allocate the separate fund of Rs. 109.61 Lakhs as committed before SEAC. The entire activities proposed under CER 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.
45. All the environmental protection measures and safeguards proposed in the Form-1 & PFR submitted by the project proponent and commitments made in their application shall be strictly adhered to in letter and spirit.

B. GENERAL CONDITIONS:

B.1 CONSTRUCTION PHASE:

46. Water demand during construction shall be reduced by use of curing agents, super plasticizers and other best construction practices.
47. 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.
48. All required sanitary and hygienic measures shall be provided before starting the construction activities and to be maintained throughout the construction phase.
49. First Aid Box shall be made readily available in adequate quantity at all the times.
50. 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.
51. 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.
52. 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.
53. Safe disposal of waste water and municipal solid wastes generated during the construction phase shall be ensured.
54. All topsoil excavated during construction activity shall be used in horticultural / landscape development within the project site.
55. 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.
56. 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.
57. 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.
58. "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.
59. "No uncovered vehicles carrying construction material and waste shall be permitted."

60. "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."
61. Roads leading to or at construction site must be paved and blacktopped (i.e. – metallic roads).
62. No excavation of soil shall be carried out without adequate dust mitigation measures in place.
63. Dust mitigation measure shall be displayed prominently at the construction site for easy public viewing.
64. Grinding and cutting of building materials in open area shall be prohibited.
65. Construction material and waste should be stored only within earmarked area and road side storage of construction material and waste shall be prohibited.
66. 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:

67. Industry should provide separate dedicated washing area for hand washing/bathing of worker and the waste water generated from the same should be taken into ETP.
68. The water meter shall be installed and records of daily and monthly water consumption shall be maintained.
69. 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.

B.2.2 AIR:

70. 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.
71. 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.
72. Stack/Vents (Whichever is applicable) of adequate height shall be provided as per the prevailing norms for flue gas emission/Process gas emission.
73. 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.
74. All the reactors / vessels used in the manufacturing process shall be closed to reduce the fugitive emission.
75. Adequate Air Pollution Control Measures [APCM] shall be provided.
76. The unit shall adhere to Sector specific guidelines/ SOP published by GPCB / CPCB from time to time for effective fugitive emission control. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognized under Environment (Protection) Act, 1986.
77. Unit shall take adequate measures to control odor nuisance from the industrial activities which may include measures like-use of masking agent with atomizer system (water curtain), closed / automatic material handling system, containment of the odor vulnerable areas etc.
78. Unit shall provide Wall to Wall carpeting in vehicle movement areas within premises to avoid dusting.

B.2.3 HAZARDOUS/SOLID WASTE:

79. 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.
80. 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.
81. The unit shall obtain necessary permission from the nearby TSDF site and CHWIF. (Whichever is applicable)
82. 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.
83. The design of the Trucks/tankers shall be such that there is no spillage during transportation
84. All possible efforts shall be made for Co-Processing of the Hazardous waste prior to disposal into TSDF/CHWIF.
85. 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.
86. Unit shall carry out transportation of hazardous wastes through GPS mounted vehicles only for disposal at TSDF/CHWIF, co-processing and end-users having Rule-9 permission.
87. The by-products which fall under the purview of the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016 shall be handled as per the said rules and necessary permissions from the concern authority shall be obtained.
88. Unit shall submit the list of authorized end users of above mentioned wastes along with MoU signed with them at least two

months in advance prior to commencement of production. In absence of potential buyers of these items, the unit shall restrict the production of respective item.

89. Industry shall dispose its hazardous wastes through co-processing, pre-processing to the extent possible prior its disposal to incineration/ landfill as per provisions of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

B.2.4 SAFETY:

90. The occupier/manager shall strictly comply the provisions under the Factories Act 1948 and the Gujarat Factories Rules 1963
91. 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.
92. Main entry and exit shall be separate and clearly marked in the facility.
93. Sufficient peripheral open passage shall be kept in the margin area for free movement of fire tender/ emergency vehicle around the premises.
94. Storage of flammable chemicals shall be sufficiently away from the production area.
95. Sufficient number of fire extinguishers shall be provided near the plant and storage area.
96. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of toxic / hazardous chemicals.
97. 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.
98. The project management shall ensure to comply with all the environment protection measures, risk mitigation measures and safeguards mentioned in the Risk Assessment report.
99. Only flame proof electrical fittings shall be provided in the plant premises.
100. 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.
101. 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.
102. Handling and charging of the chemicals shall be done in closed manner by pumping or by vacuum transfer so that minimal human exposure occurs.
103. Tie up shall be done with nearby health care unit / doctor for seeking immediate medical attention in the case of emergency.
104. Personal Protective Equipments (PPEs) shall be provided to workers and its usage shall be ensured and supervised.
105. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity.
106. Training shall be imparted to all the workers on safety and health aspects of chemicals handling.
107. Occupational health surveillance of the workers shall be done and its records shall be maintained. Pre-employment and periodical medical examination for all the workers shall be undertaken as per the Factories Act & Rules.
108. Transportation of hazardous chemicals shall be done as per the provisions of the Motor Vehicle Act & Rules.
109. The company shall implement all preventive and mitigation measures suggested in the Risk Assessment Report.
110. Necessary permissions from various statutory authorities like PESO, Factory Inspectorate and others shall be obtained prior to commissioning of the project.
111. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be maintained.
112. Effective safety precaution shall be taken for chemical storage, process handling and transportation hazard.
113. Unit shall prepare and Implement SOP for safe operation of the works.
114. Comply the statutory provision of safety audit & its compliance report.
115. Effective step shall be taken for prevention of fire, explosion & toxic release.

B.2.5 NOISE:

116. 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:

117. 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.

118. 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:

119. The PP shall develop green belt [24153 Sq m (36 %) of total plot area] as committed 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.

B.3 OTHER CONDITION:

120. 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).
121. The provisions of the Solid Waste Management Rules, 2016, e-Waste (Management) Rules, 2016, the Construction and Demolition Waste Management Rules, 2016 and the Plastics Waste Management Rules, 2016 shall be followed.
122. Rain water harvesting (Off-site) shall be undertaken 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. (Applicable for units consuming ground water $\geq$ 50 KLD in line with the prevailing guidelines of SPCB).
123. 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.
124. 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.
125. The area earmarked as green area shall be used only for plantation and shall not be altered for any other purpose.
126. 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.
127. 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.
128. 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.
129. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any statutory authority.
130. 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.
131. Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
132. Leakages from pipes, pumps shall be minimal and if occurs, shall be arrested promptly.
133. 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.
134. 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.
135. 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.
136. 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.
137. 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.
138. 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.

139. 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.
140. 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.
141. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
142. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
143. 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.
144. 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.
145. This environmental clearance is valid for seven years from the date of issue.
146. 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.
147. 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.

With regards,
Yours sincerely,


(S. J. PANDIT)
Member Secretary



Issued to:
M/s. Raks Pharma Private Limited
Plot. No. Z/111/A, Dahej-SEZ-II,
Taluka. Vagra,
Dist. Bharuch