



No. SEIAA/GUJ/EC/5(f)/ 949 /2022

Date: 16 APR 2022

By R P A D

Time Limit

Sub: Environment Clearance to M/s. Active Pharm Chemicals LLP for setting up manufacturing plant of 'Synthetic Organic Chemicals' [API & its Intermediates] at Plot No.- D-II-CH-151/1/3, Dahej-II Industrial Estate, Tal- Vagra- 392140, Dist: Bharuch, (Gujarat). In Category 5(f) of Schedule annexed with EIA Notification dated 14/09/2006.

Ref: Your Proposal No. SIA/GJ/IND2/243593/2021.

Dear Sir,

This has reference to your application along with Form-1 dated 23/12/2021 submitted to SEIAA, seeking Environmental Clearance under Environment Impact Assessment Notification, 2006.

The proposal is for Environmental Clearance to M/s. Active Pharm Chemicals LLP for setting up manufacturing plant of 'Synthetic Organic Chemicals' [API & its Intermediates] at Plot No.- D-II-CH-151/1/3, Dahej-II Industrial Estate, Tal- Vagra- 392140, Dist: Bharuch, (Gujarat). It is a proposed unit for manufacturing following products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

Sr. No.	Name of Product	CAS NO.	Quantity (MT/Month)	End Use	Remarks
1	Erithromycin	114-07-8	50.0	Antibiotic	Unit is proposed to mfg either individual or total production of (Product No.- 1 to 42) shall not exceed 50.0 MT/Month.
2	Erithromycin Ethyl Succinate	1264-62-6		Antibiotic	
3	Erithromycin Stearate	643-22-1		Antibiotic	
4	Erithromycin Estolate	3521-62-8		Antibiotic	
5	Azithromycin	117772-70-0		Antibiotic	
6	Clarithromycin	81103-11-9		Antibiotic	
7	Ofloxacin	82419-36-1		Antibiotic	
8	Levofloxacin	100986-85-4		Antibiotic	
9	Ciprofloxacin	85721-33-1		Antibiotic	
10	Norfloxacin	70458-96-7		Antibiotic	
11	Mefenamic Acid	61-68-7		Anti-Inflammatory	
12	Amoxicillin Tri Hydrate	61336-70-7		Antibiotic	
13	Albendazole	54965-21-8		Anti-helminthic	
14	Mebendazole	31431-39-7		Anti-helminthic	
15	Fenbendazole	43210-67-9		Anti-helminthic	
16	Triclabendazole	68786-66-3		Anti-helminthic	
17	Praziquantel	55268-74-1		Anti-helminthic	
18	Alendronate Sodium	121268-17-5		Bone Enhancers	
19	Losartan Potassium	124750-99-8		Anti hypertensive	
20	Telmisartan	144701-48-4		Anti hypertensive	
21	Valsartan	137862-53-4		Anti hypertensive	
22	Fexofenadine Hydrochloride	153439-40-8		Antihistamine	
23	Loratidine	79794-75-5		Antihistamine	
24	Cetirizine Hydrochloride	83881-51-0		Antihistamine	
25	Levocetirizine	130018-77-8		Antihistamine	
26	Chlorpheniramine Maleate	113-92-8		Antihistamine	
27	Phenylephrine Hydrochloride	61-76-7		Antihistamine	
28	Domperidone	57808-66-9		Antiemetic	
29	Glimepiride	93479-97-1		Antidiabetic agent	
30	Metformin	1115-70-4		Antidiabetic agent	
31	Lansoprazole	103577-45-3		Antiulcers	
32	Omeprazole	73590-58-6		Antiulcers	
33	Pantoprazole Sodium	138786-67-1		Antiulcers	
34	Rabeprazole Sodium	117976-90-6		Antiulcers	
35	Esomeprazole	73590-58-6		Antiulcers	
36	Atorvastatin Calcium	134523-03-8		Antilipemics	
37	Rosuvastatin Calcium	147098-20-2		Antilipemics	
38	Simvastatin	79902-63-9		Antilipemics	



39	Niacinamide	98-92-0		VitaminB/B 12	
40	LopramideHydrochloride	34552-83-5		Anti-Diarrheal	
41	Aceclofenac	89796-99-6		Pain killer	
42	DioclofenacSodium	15307-79-6		Pain killer	
43	R&D	--	0.1		
Total			50.1		

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 located in notified industrial area, 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 09/03/2022 had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project based on its meeting held on 11/01/2022. The proposal was considered by SEIAA, Gujarat in its meeting held on 24/03/2022 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.
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. 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**].
5. 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.
6. Leak Detection and Repair (LDAR) program shall be prepared and implemented as per the CPCB guidelines. LDAR Logbooks shall be maintained.
7. All measure shall be taken to avoid soil and ground water contamination within premises.
8. R & D products shall be of similar chemistry in line with the EIA Notification vide S.O. 1223 (E) dated 27/03/2020 and the pollution load shall remain the same as committed. (b) Project proponent shall not take continuous/commercial production of the R & D materials. Necessary approvals shall be obtained from the concern authorities prior to commercial production of R & D materials. (c) Unit shall submit relevant details of R & D products like raw materials, its safety measures to the regulatory authority well before R & D activity. (d) Unit shall submit relevant details of R & D products like different wastes generated (Quantity & Quality) and its management to the regulatory authority within a month of R & D activity.
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 labour 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. PP shall not install storage tank for storage of Hazardous chemicals as proposed by project proponent and all Hazardous chemicals shall be stored in drums/ bags/ cylinders etc only.
- m. Unit shall provide effective fire hydrants, water monitors & foam application system at solvent storage tank farm area. 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.
- n. Unit shall Store Bromine Bottle in cool dry separate area, out of direct sunlight.
- o. Unit shall provide safety valve and rupture disc for Hydrogenation vessel safety.
- p. Unit shall provide safety valve and rupture disc, as well as auto dump or auto quench/, suppress system for nitration vessel safety.
- q. Unit shall provide water sprinkler to the ammonia storage cylinder.

A. 2 WATER:

10. Total water requirement for the project shall not exceed 69.30 KLD. Unit shall reuse 47.50 KLD of boiler condensate and treated effluent within premises. Hence, fresh water requirement shall not exceed 21.80 KLD and it shall be met through private water tanker supply only. Prior permission from concerned authority shall be obtained for withdrawal of water.
11. The industrial effluent generation from the project shall not exceed 25.70 KLD.
12. Industrial effluent shall be segregated and streamwise treated as follows,
 - **High COD effluent:-**
 - 14.5 KLD effluents {from Process (10.3), Washing (2.0), R&D (0.2) and RO Reject (2.0)} shall be treated into Primary ETP-1 plant and then treated effluent shall be send to Common MEE of M/s. BEIL through GPS fitted tanker, for evaporation.
 - **Low COD Effluent :**
 - 6.5 KLD Effluents {from Boiler (4.0), Cooling (0.5) & Other Scrubber (2.0)} shall be treated into Primary ETP plant-2 & RO Plant. About 4.5 KLD RO permit water shall be reused for utility purpose and 2.0 KLD RO Reject Water shall be sending to ETP-1 for further treatment & final disposal.
 - 6.7 KLD exhausted scrubbing media shall be sold to end users having Rule-9 permission or reused in process within plant as per Hazardous Waste Rules'2016.
13. Unit shall discharge wastewater to CMEE only after complying with norms prescribed by GPCB in order to achieve no adverse impacts on Environment and Human Health.
14. Domestic wastewater generation shall not exceed 2.50 KL/day for proposed project and it shall be treated in ETP. It shall not be disposed off into soak pit.
15. Unit shall provide buffer water storage tank of adequate capacity for storage of treated waste water during ant shut down of CMEE.
16. Unit shall provide ETP, RO and STP with adequate capacity.
17. The PP shall ensure to dispose off Waste water to the Common Facilities having valid CTO of GPCB.
18. The unit shall provide metering facility at the inlet and outlet of ETP, & RO and maintain records for the same.
19. Proper logbooks of ETP, & RO; reuse/ recycle of treated/ untreated effluent; chemical consumption in effluent treatment; quantity & quality of treated effluent sent to CMEE; power consumption etc. shall be maintained and shall be furnished to the GPCB from time to time

A. 3 AIR:

20. Unit shall not exceed fuel consumption for Boiler and D G Set 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)
1	Boiler (Cap. – 5.0 MT/hr)	30 M	Briquette of Bio Coal	10 MT/Day	PM SO ₂ NO _x	Multicyclone Separator Bag Filter & Water Scrubber
2	D.G. Sets (Stand by) (Cap. – 500 KVA x 2 Nos)	18 M	HSD	100 Liter/hr		Adequate Stack Height

21. Unit shall provide adequate APCM with flue gas generation sources to achieve the norms prescribed by GPCB.
22. Unit shall provide adequate APCM with process gas generation sources as mentioned below.

Sr. No.	Stack attached to	Stack Height	Air Pollution Control System	Parameter
1	Process Vent -1 (Chlorination & Sulphonation) Mebendazole	11 M	Two stage (Water + Alkali) Scrubber	HCl SO ₂
2	Process Vent -2	11 M	Two Stage Water	NH ₃

	Omeprazole & its intermediate		Scrubber	
3	Process Vent -3 Valsartan	11 M	Two Stage Alkali Scrubber	HBr
4	Process Vent -4 Ofloxacin	11 M	Two Stage Alkali Scrubber	HF

23. 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.
24. Regular monitoring of Volatile Organic Compounds (VOCs) shall be carried out in the work zone area and ambient air.
25. 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.
26. 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.
27. Regular monitoring of ground level concentration of PM10, PM2.5, SO2, HCl, HBr, NH3, HF 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:

28. 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 & Schedule as per HW Rules.	Quantity (MT/ Annum)	Management of HW
1	ETP Sludge	ETP	SCH-I/35.3	75	Collection, Storage, Transportation and Disposal at common TSDF site.
2	Discarded Drums/Bags/ Liners	Raw Materials/ Products	SCH-I/33.1	20	Collection, Storage, Transportation, Decontamination & Sale to GPCB approved vendors/ reuse /send back to supplier.
3	Used/ Spent Oil	Machineries/Utility	SCH-I/5.1	1.8	Collection, Storage, Disposal by reuse in plant machinery as lubricant or transportation & Sale to GPCB registered re-processor.
4	Distillation Residue	Distillation	SCH-I/20.3	720	Collection, Storage, Transportation and sent for co-processing or Disposal at common incineration site.
5	Spent Solvent	Process	SCH-I/28.6	28808	Collections, Storage, distillation and reuse in plant premises.
6	Spent Carbon	Process	SCH-I/28.3	60	Collection, Storage, Transportation and sent for

					co-processing or Disposal at common incineration site.
7	Organic Residue	Process	SCH-I/28.1	1266	Collection, Storage, Transportation and sent for co-processing or Disposal at common incineration site.
8	Inorganic residue	Process	SCH-I/28.1	838	Collection, Storage, Transportation and Disposal at common TSDF Site.
9	Spent Catalyst	Process	SCH-I/28.1	84	Collection, Storage, reuse in the plant premises or Transportation and send to regenerator under Rule-9.
10	Sodium Bromide	Process (Albendazole) & Scrubber	SCH-I/28.1	552	Collection, Storage, Transportation and Sell to end user who is having Rule-9 Permission.
11	Spent Aluminum Chloride	Process (Mebendazole)	SCH-I/28.1	38	Collection, Storage, Transportation and Sell to end user who is having Rule-9 Permission.
12	Hydrochloric acid	Process (Amoxicillin Tri Hydrate)	SCH-I/28.1	400	Collection, Storage, Transportation and Sell to end user who is having Rule-9 Permission.
13	Dilute HCl (28%)	Scrubber	SCH- II / B 15	1496	Collection, Storage and reuse in plant premises. and Sell to end user who is having Rule-9 Permission.
14	Sodium bi sulphite (30%)	Scrubber	SCH- II / B 15	544	Collection, Storage, Transportation and Sell to end user who is having Rule-9 Permission.
15	Liq. Ammonia (25%)	Scrubber	SCH-I/28.1	224	Collection, Storage, Transportation and Sell to end user who is having Rule-9 Permission.
16	Sodium Fluoride (25 %)	Scrubber	SCH-I/28.1	90	Collection, Storage, Transportation and Sell to end user who is having Rule-9 Permission.
17	Off Specification Products	From mfg. Process (Batch failure)	SCH-I/28.4	10	Collection, Storage, Transportation and sent for co-processing or Disposal at common incineration site.
R&D					
18	ETP Sludge	ETP	SCH-I/35.3	2.0	Collection, Storage, Transportation & disposal at common TSDF site.
19	Residue from Distillation/ Organic Process Waste	R&D	SCH-I/28.1	4.0	Collection, Storage, Transportation and sent for co-processing or Disposal at common incineration site.
20	Discarded Drum	Raw Materials/Products	SCH-I/33.1	20	Collection, Storage, Transportation & Sell to GPCB authorized Vendor.
21	Discarded Bags / Liner	Raw Materials/Products	SCH-I/33.1	0.2	Collection, Storage, Transportation & Sell to GPCB authorized Vendor.
22	Off Specification Products	R&D	SCH-I/28.4	1.0	Collection, Storage, Transportation and sent for co-processing or Disposal at common incineration site.

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. STP sludge shall be collected and used as manure in gardening activity or send to TSDF site for landfilling.
33. 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.
34. 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:

35. The project proponent shall carry out the entire activities [Solar street light set with battery backup (18W -15 Nos.) in Suva and Galenda Village & construct 1,00,000/- Liter RCC collection tank with filtration facility for rain water harvesting in Suva Village] 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.
36. 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:

37. Water demand during construction shall be reduced by use of curing agents, super plasticizers and other best construction practices.
38. 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.
39. All required sanitary and hygienic measures shall be provided before starting the construction activities and to be maintained throughout the construction phase.
40. First Aid Box shall be made readily available in adequate quantity at all the times.
41. 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.
42. 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.
43. 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.
44. Safe disposal of waste water and municipal solid wastes generated during the construction phase shall be ensured.
45. All topsoil excavated during construction activity shall be used in horticultural / landscape development within the project site.
46. 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.
47. 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.
48. 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.
49. "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.
50. "No uncovered vehicles carrying construction material and waste shall be permitted."
51. "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."
52. Roads leading to or at construction site must be paved and blacktopped (i.e. - metallic roads).
53. No excavation of soil shall be carried out without adequate dust mitigation measures in place.
54. Dust mitigation measure shall be displayed prominently at the construction site for easy public viewing.
55. Grinding and cutting of building materials in open area shall be prohibited.
56. Construction material and waste should be stored only within earmarked area and road side storage of construction material and waste shall be prohibited.
57. 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:

58. The water meter shall be installed and records of daily and monthly water consumption shall be maintained.

59. 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:

60. 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 & its 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.
61. 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.
62. Stack/Vents (Whichever is applicable) of adequate height shall be provided as per the prevailing norms for flue gas emission/Process gas emission.
63. 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.
64. All the reactors / vessels used in the manufacturing process shall be closed to reduce the fugitive emission.

B.2.3 HAZARDOUS/SOLID WASTE:

65. 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.
66. 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.
67. The unit shall obtain necessary permission from the nearby TSDF site and CHWIF. (Whichever is applicable)
68. 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.
69. The design of the Trucks/tankers shall be such that there is no spillage during transportation
70. All possible efforts shall be made for Co-Processing of the Hazardous waste prior to disposal into TSDF/CHWIF.
71. 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:

72. The occupier/manager shall strictly comply the provisions under the Factories Act 1948 and the Gujarat Factories Rules 1963
73. 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.
74. Main entry and exit shall be separate and clearly marked in the facility.
75. Sufficient peripheral open passage shall be kept in the margin area for free movement of fire tender/ emergency vehicle around the premises.
76. Storage of flammable chemicals shall be sufficiently away from the production area.
77. Sufficient number of fire extinguishers shall be provided near the plant and storage area.
78. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of toxic / hazardous chemicals.
79. 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.
80. The project management shall ensure to comply with all the environment protection measures, risk mitigation measures and safeguards mentioned in the Risk Assessment report.
81. Only flame proof electrical fittings shall be provided in the plant premises.
82. 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.
83. 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.
84. Handling and charging of the chemicals shall be done in closed manner by pumping or by vacuum transfer so that minimal human exposure occurs.
85. Tie up shall be done with nearby health care unit / doctor for seeking immediate medical attention in the case of emergency.
86. Personal Protective Equipments (PPEs) shall be provided to workers and its usage shall be ensured and supervised.
87. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity.
88. Training shall be imparted to all the workers on safety and health aspects of chemicals handling.



89. 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.
90. Transportation of hazardous chemicals shall be done as per the provisions of the Motor Vehicle Act & Rules.
91. The company shall implement all preventive and mitigation measures suggested in the Risk Assessment Report.
92. 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:

93. 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 conform to the standards prescribed under The Environment (Protection) Act, 1986 & Rules.

B.2.6 CLEANER PRODUCTION AND WASTE MINIMISATION:

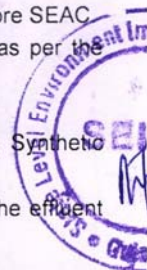
94. The unit shall undertake the Cleaner Production Assessment study through a reputed institute / organization and shall form a CP team in the company. The recommendations thereof along with the compliance shall be furnished to the GPCB.
95. The company shall undertake various waste minimization measures 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:

96. 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.
97. Drip irrigation / low-volume, low-angle sprinkler system shall be used for the green belt development within the premises.
98. The PP shall develop green belt (1683Sq. m i.e. 33 % of the total plot area) as per the undertaking 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.

B.3 OTHER CONDITION:

99. The project proponent shall comply and abide with the undertaking submitted that the proposed project falls in Synthetic Organic Chemical (API & Its intermediates) i.e category 5(f)-B2.
100. Project proponent shall install all environment management systems as per the CPCB/GPCB directives regarding the effluent discharge and air emission in working condition.
101. Project proponent shall display the copy of Environment Clearance at the site prominently.
102. Project proponent shall prepare and follow regular and preventive maintenance plan. The copy of same shall be submitted to SEIAA.
103. Project Proponent will have to display the safety procedure in working area.
104. The project proponent shall obtain all required permissions for safety, health and fire from competent authorities like PESO/Fire Authority etc. and intimate SEIAA.
105. 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.
106. Extra care will be taken by PP to avoid any accidental blast in boiler, reactor or any machinery in the plant.
107. Environment monitoring, training and disaster management plan should be undertaken and complied at regular interval.
108. Integrated Regional Office of MoEF&CC, Gandhinagar and GPCB will monitor all environment, safety & health norms as per the prevailing rules.
109. 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 legal action in the cases of non compliance.
110. 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).
111. 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.



112. 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).
113. 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.
114. 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.
115. The area earmarked as green area shall be used only for plantation and shall not be altered for any other purpose.
116. 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.
117. 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.
118. 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.
119. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any statutory authority.
120. 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.
121. Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
122. Leakages from pipes, pumps shall be minimal and if occurs, shall be arrested promptly.
123. 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.
124. 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.
125. 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.
126. 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.
127. 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.
128. 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.
129. 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.
130. 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.
131. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
132. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
133. 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.
134. 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.
135. This environmental clearance is valid for seven years from the date of issue.
136. 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.
137. 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:

138. 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.
139. 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.
140. Designated key person shall submit six monthly compliance report to SEIAA/SEAC, MOEF&CC, GPCB and Nodal Department of the Government.
141. 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.
142. 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.
143. 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.
144. All complains and public grievance or representations may be addressed to SEIAA/SEAC in the email addresses (a) msseiaagj@gmail.com & (b) seacgujarat@gmail.com

S. J. Pandit

(S. J. PANDIT)
Member Secretary

Issued to:

M/s. Active Pharm Chemicals LLP
Plot No.- D-II-CH-151/1/3, Dahej-II Industrial Estate,
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Copy to:-

1. The Secretary, SEAC, C/O. G.P.C.B. Gandhinagar - 382010.
2. The Additional Chief Secretary, Forests & Environment Department, Govt. of Gujarat, Block 14, 8th floor, Sachivalaya, Gandhinagar-382010.
3. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD -cum-Office Complex, East Arjun Nagar, New Delhi-110032
4. Scientist C, Integrated Regional Office, Ministry of Environment and Forests, Aranya Bhavan, Sector-10, Gandhinagar - 382010.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.
6. The Member Secretary, Gujarat Pollution Control Board, Paryavaran Bhavan, Sector-10 A, Gandhinagar-382010
7. Select File

