



State Level Environment Impact Assessment Authority (SEIAA)
Andhra Pradesh
Ministry of Environment, Forests & Climate Change
Government of India

D.No.33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamavari Street, Kasturibaipet, Vijayawad-520010

REGD.POST WITH ACK.DUE

Order No. SEIAA/AP/IND/KRI/03/2021/3044/164.19/161.18 01/09/2021

Sub:SEIAA, A.P. – M/s. Eamani Pharma Laboratories Pvt. Ltd at R.S. No's. 4/1A, 4/1B, 4/1C & 4/2A, Pochampally Village, Jaggaiahpet Mandal, Krishna District, Andhra Pradesh - Environmental Clearance - Issued - Reg.

1. This has reference to your EC application submitted through online on 24.03.2021 (SIA/AP/IND2/204992/2021), seeking Environmental Clearance for **Bulk Drugs & Intermediates Manufacturing Unit at R.S. No's. 4/1A, 4/1B, 4/1C & 4/2A, Pochampally Village, Jaggaiahpet Mandal, Krishna District, Andhra Pradesh** in favour of **M/s. Eamani Pharma Laboratories Pvt. Ltd.** The nearest human habitation viz., Gauravaram (V) exists at a distance of about 3.08 Km from the premises. The total area is 13.34 Acres. The capital cost of the project is Rs.30.0 Crores. The details of the production capacities of the project is as follows:

List of proposed products with Quantities:

S.No.	Name of the Product	Quantity in TPM
1.	(2-(N-Triphenyl methylTetrazolyl)-4-Bromo methyl biphenyl (TTBB)	10.00
2.	2-(4, (4-chlorobutanoyl) phenyl)-2-methyl propyl acetate)	10.00
3.	2,4-Dichloro acetophenone	10.00
4.	4-Bromo Methyl Biphenyl Carbonitrile (OTBN)	10.00
5.	Cis Bromo Benzoate	10.00
6.	Cis- Mesylate	10.00
7.	Cis -Tosylate	10.00
8.	Fexofenadine hydrochloride	10.00
9.	Fluconazole	10.00
10.	Itraconazole	10.00
11.	Levocetirizine hydrochloride	10.00
12.	Losartan Potassium	10.00
13.	Montelukast Sodium	10.00
14.	Olmesartan	10.00
15.	Pantoprazole Sodium	10.00
16.	Sertraline hydrochloride	10.00
17.	Sitagliptin	10.00
18.	Tadalafil	10.00
19.	Telmisartan	10.00

20.	Valsartan	10.00
Total		200.00

List of By-products with quantities:

S. No	Name of the product	Name of the By-Product	Quantity in Kg/Day
1.	2-(4,(4-chlorobutanoyl) phenyl)-2-methyl propyl acetate)	Aluminium chloride solution (25%)	666.70
2.	4-Bromo Methyl Biphenyl Carbonitrile	Magnesium hydroxide	99.00
3.	Cis Bromo Benzoate (Ketoconazole intermediate)	Hydrobromic acid solution (23%)	354.80
4.	Cis-Mesylate (Itraconazole Intermediate)	Potassium Bromide	131.40
		Sodium Benzoate	159.10
		Triethylamine Hydrochloride	130.60
5.	Cis-Tosylate (Ketoconazole Intermediate)	Benzoic acid	116.60
6.	Fexofenadine hydrochloride	Boric acid	51.75
		Sodium methoxide	45.20
7.	Fluconazole	Aluminium Hydroxide solution (33%)	518.00
		Ammonium nitrate	132.60
8.	Itraconazole	Triethylamine Hydrochloride	83.80
9.	Levocetirizine Dihydrochloride	Tri ethyl amine hydrogen chloride	137.60
10.	Losartan potassium	Succinimide	108.80
		Trityl alcohol	248.75
		Sodium bromide	98.30
11.	Pantoprazole Sodium	Potassium sulphate	462.00
		Sodium acetate	142.10
12.	Sertraline Hydrochloride	Ammonium Chloride	70.30
13.	Telmisartan	Sodium Bromide	86.10
		Sodium acetate	80.40
14.	Valsartan	Potassium chloride	81.00
		Potassium Bromide	129.20

This proposal has been referred to SEAC, A.P along with all the documents submitted by the proponent for their appraisal and for their specific recommendations on EC aspect. The proposal has been examined and processed in accordance with EIA Notification, 2006 and its amendments thereof. The State Level Expert Appraisal Committee (SEAC) examined the application in its meetings held on **26th July, 2021**. The Proposal of **M/s. Eamani Pharma Laboratories Pvt. Ltd.**, is for Environmental Clearance for production quantities **of the bulk drug & Intermediates – 200 TPM**. The project proponent and their consultant M/s. Right Source Industrial Solutions Pvt Ltd has attended the meeting. MoEF&CC, GoI, New Delhi

issued notification vide S.O. No. 1223(E), dated 27.03.2020 and MoEF&CC Office Memorandum dated 13.04.2020, wherein " *All proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API), received up to the 30th September 2020, shall be appraised , as Category 'B2' projects provided that any subsequent amendment or expansion or change in product mix, after the 30th September 2020, shall be considered as per the provisions in force at that time.*" and extended up to 30th March, 2021 vide S.O. No. 3636(E), dated 15.10.2020. Further extended up to 31st December, 2021 vide S.O. No. 2859(E), dated 16.07.2021. The proposed project falls under Item 5(f) of the schedule of the EIA Notification 2006- Synthetic organic chemicals industry (dyes & dye intermediates & bulk drug and intermediates). The Committee noted that this is a bulk drug & intermediates manufacturing unit. Now, the PP has proposed the Bulk Drug & Intermediates manufacturing unit with production capacity: **200 TPM**. The project proponent has submitted the EMP, PFR, Risk Assessment Reports, affidavit for TSDF Membership, affidavit for CER budget allocation and activities. The project proponent has submitted an affidavit on the drugs proposed to be manufactured and informed to the committee that, the drugs are related to the symptoms of the ailments like Covid 19 and other post-Covid symptoms. The Committee after examining the project proposals, presentations and deliberations recommended for **issue of Environmental Clearance** for manufacture of **Bulk Drug and Intermediates with production quantity – 200 TPM**. The committee in the appraisal report clearly stated that they have approved the Form-I/II, PFR/DPR and EMP for compliance by the proponent. The State Level Environment Impact Assessment Authority (SEIAA), in its meeting held on **28.08.2021** examined the proposal and the recommendations of SEAC and decided to accept SEAC recommendations aforesaid for strict compliance by the proponent and to issue EC. The SEIAA, A.P **hereby accords Environmental Clearance to the project** as mentioned at Para no. I under the provisions of the EIA Notification 2006 and its subsequent amendments issued under Environment (Protection) Act, 1986 subject to implementation of the following specific and general conditions:

III.a **Part A: Special Conditions:**

1. The proposal shall not attract the following Acts & Rules:
 - a. Forest Act 1980,
 - b. Wild life (Protection) Act,1972;
 - c. CRZ Notification, 2011;
 - d. The Eco sensitive areas as notified under Environment (Protection) Act,1986;
 - e. Critically polluted areas as notified by CPCB
and also shall not harm live stocks and human beings and disturb their activities.
2. The industry shall adopt appropriate pollution control system to achieve Zero Liquid Discharge (ZLD) and ensure that there will be no discharge from the unit.
3. The industry shall segregate effluents into different streams i.e. High TDS and High COD, High COD and Low TDS, Low COD and High TDS, Low COD and Low TDS in case of the industry sending the effluent to CETP.
4. The industry shall implement monitoring of waste factors for different streams of effluent sand solid waste.
5. The industry shall establish suitable scrubbing system in consultation with the APPCB.
6. The industry shall provide effective solvent recovery system.
7. The industry shall provide hazardous waste container (drums) cleaning/washing system (Container detoxification).

8. The industry shall provide flow meter to measure quantity of steam consumed for MEE system.
9. The industry shall provide magnetic tamper proof flow meters to measure quantity of different streams of effluents generated and routed through the treatment systems.
10. The industry shall provide steam stripping system to handle volatile matter in the effluents.
- 11.10. The industry shall send hazardous waste to the authorized cement industries/ TSDF/authorized recyclers by properly maintaining the system.

Part B: Specific Conditions:

Air & Noise Environment:

1. The emissions from the Coal fired boiler of capacity 2 x 5.0 TPH shall be routed through cyclones separator followed by bag filters with the stack type and height fixed in consultation with the APPCB. Proposed 1 x 4 Lakh K.Cal/hr Diesel fired Thermic fluid heater. Adequate stack height shall be provided for D.G. Sets 1 x 500 KVA & 1 x 380 KVA as per CPCB norms.
2. The process emissions containing the HBr, HCl, NH₃, HF, H₂S and Mercaptans shall be routed through two stages scrubber system. The packing media in the scrubber is 25 mm poly propylene rings. Scrubbed liquid shall be treated and reused or subjected to MEE.
3. Strict measures shall be taken to control odour with appropriate odour abatement methods. Sub coolers for brine circulation shall be installed to reduce solvent evaporation losses into the atmosphere. All the solvent storage tanks shall be connected to vent condensers with chilled water circulation to minimize the solvent loss. The proponent shall install VOC meter in the plant to monitor.
4. The solvents shall be recovered by installing fractional distillation columns. The recovered solvents shall be reused in the process or sold to recyclers authorized by APPCB. The volatile vapours generated during process shall be routed through condensers and the condensate shall be reused in the plant
5. The area of the greenbelt shall not be less than 33% of the total area of the site. Greenbelt with tall growing trees shall be developed along the boundary of the site.
6. Fugitive emissions from storage tanks shall be avoided by providing air condensers.
7. The proponent should provide appropriate PPE to the persons working in the unit and suitable to their work place environment.
8. The proponent shall establish adequate number of air monitoring stations, including one online station, in consultation with the APPCB and take appropriate measures to ensure that the GLC shall comply with the NAAQM norms notified by MoEF&CC, GoI on 16.11.2009.
9. Measures shall be taken to comply with the provisions made under "Noise pollution

(Regulation and control) Amendment Rules 2010 dated 11-01-2010 issued by MoEF.

Water Environment:

10. The total water requirement shall not exceed 308.07 KLD, which includes for Process – 52.07 KLD; Washings – 7.0 KLD, Boilers Make-up – 58.0 KLD, Cooling tower Makeup – 144.0 KLD, Scrubbing system – 8.0 KLD; Domestic – 11.50 KLD & Gardening – 27.50 KLD.

Waste water generation:

11. The total waste water generation is 107.86 KLD. Out of that; 58.86 KLD is from Process, 7.0 KLD from Washings; 8.0 KLD is from Boiler blow down; 16.0 KLD is from Cooling tower bleed off; 8.0 KLD is from scrubbing system and 10.0 KLD from Domestic.
12. Zero discharge concepts shall be adopted. High COD & Low TDS shall be sent to incinerator, Low COD & Low TDS shall be sent to conventional ETP and the Low COD & High TDS effluents are routed through Stripper with scrubber followed by MEE and rejects of MEE shall be sent to ATFD. The condensate of the MEE shall be sent to RO. The permeate from the RO plant shall be re-used in the plant and rejects to MEE. The domestic waste water shall be disposed into the septic tank followed by soak pit.
13. The proponent shall provide separate storm water drains and harvest the rainwater from the rooftops to recharge the ground water.
14. Regular monitoring of ground water level and quality should be carried out by establishing a network of existing wells in and around project area in consultation with the competent Ground Water Department. Data thus collected should be sent at regular intervals to MoEF&CC, CGWA and CGWB, Southern, Region, Hyderabad.
15. Suitable conservation measures to augment groundwater resources in the area shall be planned and implemented in consultation with GWB. Suitable measures should be taken for rainwater harvesting.
16. In case of Ground water usage, Permission from the competent authority should be obtained for drawl of ground water, if any, required for this project.

Hazardous / Solid Wastes:

17. Hazardous waste generated from the industry such as organic residue, salts, spent solvents waste oils, used oils etc., shall be disposed as per the Hazardous and other Wastes (Management and Transboundary movement) Rules, 2016 and its amendments thereof
18. The Hazardous / Solid waste and disposal: Organic Solid Waste (Process Residue) – 6808 Kg/Day, Spent Carbon – 165.0 Kg/Day; Solvent Distillation Residue – 1326 Kg/Day, Organic distillate from MEE Stripper – 1660 Ltrs/Day shall be sent to Cement Industries; Inorganic Solid Waste – 1734 kg/Day; ETP Sludge – 180 kg/day; MEE salts – 4549 kg/day shall be sent to TSDF; Used oils – 180 LPA shall be sent

to SPCB authorized agencies for reprocessing / recycling; Detoxified Containers / Container liners – 1500 Nos/Month shall be sent to SPCB authorized agencies after Detoxification; Used Lead Acid Batteries – 4 Nos/Annum shall send back to suppliers for buyback of new batteries. Ash from Boiler – 11.38 TPD shall be sent to brick manufactures.

19. The Organic and Inorganic solid wastes, Spent Carbon, process residues shall be sent to the authorized users or recyclers approved by the APPCB.
20. The proponent should strictly comply with the E-Waste Management Rules, 2016, and report compliance.

Environment:

1. The Project Proponent shall ensure that the transportation activity of the unit should not cause any inconvenience to the public and comply with the local norms, if any;
2. The project shall implement the commitments, if any, made in the public hearing;

Part C: General Conditions:

1. **This order is valid for 7 years.**
2. No further expansion, increase in production; or change in product mix or technologies/land use shall be made without prior approval of the SEIAA
3. The project proponent shall submit the copies of the **Environmental Clearance** to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.
4. The project authorities should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the clearance letter informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with the State Pollution Control Board and SEIAA, A.P.
5. The **Prior Environmental Clearance** issued to this project along with the Approved Environmental Management Plan (EMP) and the Approved DPR should be uploaded in the project's web site and be made available in the public domain.
6. The PEC main contents be displayed on permanent boards at the main entry of the premises and at other prominent places.
7. The project proponent shall strictly adhere to its **Environmental Policy** approved by the SEIAA, and shall be made available in their web site.
8. A separate "**Environmental Management Unit**" (With a laboratory) shall be set up with all monitoring facilities.
9. A Separate Bank account need to be started for the budget allocated for the EMP and

the amount committed should be deposited before the project obtains CFE/CFO as the case may be. The amounts allocated should not be diverted for any other purpose.

10. The funds earmarked for environmental protection measures (**Capital cost Rs.264.0 Lakhs & Recurring cost of Rs.32.0 Lakhs/Annum**) should be kept in separate account and should not be diverted for other purpose. Year wise expenditure should be reported to the Ministry and its Regional Office located at Vijayawada.
11. The proponent before starting the operations, shall obtain all other mandatory clearances from respective departments, including the CFE and CFO from the APPCB.
12. The project proponent shall meticulously follow the **Form-1/2** of the application; and approved **EMP, for the purpose of all compliances.**
13. Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone. Location of the stations should be decided based on the meteorological data, topographical features and environmentally and ecologically sensitive targets and frequency of monitoring should be undertaken in consultation with the State Pollution Control Board.
14. Data on ambient air quality should be regularly submitted to the Ministry including its Regional Office located at Bangalore and the State Pollution Control Board/ Central Pollution Control Board once in six months.
15. Personnel working in the industry should be provided with protective respiratory devices and they should also be provided with adequate training and information on safety and health aspects.
16. Occupational health check up program for the workers should be undertaken periodically. A separate environmental management cell with suitable qualified personnel should be set-up under the control of a Senior Executive, who will report directly to the Head of the Organization.
17. The project proponent shall submit **Half-yearly** reports on the status of compliance of the stipulated **Environmental Clearance Conditions** including results of monitored data (both in hard copies as well as by e-mail) to the Ministry of Environment & Forests, its Regional Office, Vijayawada, SEIAA, A.P., Zonal Office of Central Pollution Control Board, Bangalore, and A.P. Pollution Control Board.
18. The proponent shall upload the status of compliance of the environmental clearance conditions including results of monitored data on their websites and shall update the same periodically.
19. Officials from the Regional Office of MoEF&CC, Vijayawada / The SEIAA, Andhra Pradesh through the Regional Offices of Andhra Pradesh Pollution Control Board, who would be monitoring the implementation of environmental safeguards, should be given full co-operation, facilities and documents/data by the project proponents during their inspection. A complete set of all the documents shall be submitted to the CCF, Regional Office to MoEF&CC, Vijayawada.
20. SEIAA reserves the right to cancel the EC issued at any time, if EC has been

obtained by the proponent through suppression of any information or furnishing false information upon which the project is appraised.

21. Concealing the factual data in the compliance reports, or failure to comply with any conditions mentioned above may result in withdrawal of the EC and attract action under the provisions of Environment (Protection) Act, 1986.
22. The SEIAA reserves the right to alter/modify the above conditions or stipulate any further conditions from time to time, in the interest of environment protection.
23. 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.

**MEMBER SECRETARY,
SEIAA, A.P.**

**MEMBER,
SEIAA, A.P.**

**CHAIRMAN,
SEIAA, A.P.**

Special Secretary To Govt

To
M/s. Eamani Pharma Laboratories Pvt. Ltd,
Sri Eamani Kranthi Reddy, Mg. Director,
R.S. Nos. 4/1A, 4/1B, 4/1C and 4/2A,
Pochampally Village, Jaggayyapeta,
Krishna District-521178, Andhra Pradesh,

Copy to:

1. The Chairman, SEAC, A.P. for kind information.
2. The Member Secretary, APPCB for kind information.
3. The EE, RO: Vijayawada, APPCB for information.
4. The Regional Officer, MOEF&CC, GOI, Vijayawada for kind information.
5. The Secretary, MOEF&CC, GOI New Delhi for kind information.
6. Monitoring cell, MoEF&CC, GOI, New Delhi for kind information.
7. The District Collector, Krishna District, Andhra Pradesh for kind information.

U.T.C.F.B.O

P. Muna Sreerany Nayak

Senior Environmental Engineer
State Environment Impact
Assessment Authority
Govt. Of Andhra Pradesh