

ENVIRONMENTAL
CLEARANCE



Government of India
Ministry of Environment, Forest and Climate Change
(Issued by the State Environment Impact Assessment
Authority(SEIAA), Andhra Pradesh)

To,

The Director
ANDHRA MEDI PHARMA INDIA PVT LTD
Andhra Medi Pharma India Pvt. Ltd. Sy. No. 263, Veeravalli Village,
Bapulapadu Mandal, Krishna District, Andhra Pradesh -521110

Subject: Grant of Environmental Clearance (EC) to the proposed Project Activity
under the provision of EIA Notification 2006-regarding

Sir/Madam,

This is in reference to your application for Environmental Clearance (EC)
in respect of project submitted to the SEIAA vide proposal number
SIA/AP/IND2/173127/2020 dated 14 Sep 2020. The particulars of the environmental
clearance granted to the project are as below.

- | | |
|---|--|
| 1. EC Identification No. | EC22B058AP151533 |
| 2. File No. | AP KRI IND 09 2020 2151 |
| 3. Project Type | Expansion |
| 4. Category | B2 |
| 5. Project/Activity including Schedule No. | 5(f)-API |
| 6. Name of Project | Expansion of Active Pharma Ingredients (Bulk Drugs and Intermediates) manufacturing unit by Andhra Medi Pharma India Pvt. Ltd |
| 7. Name of Company/Organization | ANDHRA MEDI PHARMA INDIA PVT LTD |
| 8. Location of Project | Andhra Pradesh |
| 9. TOR Date | N/A |

The project details along with terms and conditions are appended herewith from page
no 2 onwards.

Date: 09/02/2022

(e-signed)
DR. P.V.CHALAPATHI RAO
Member Secretary
SEIAA - (Andhra Pradesh)

*Note: A valid environmental clearance shall be one that has EC identification
number & E-Sign generated from PARIVESH. Please quote identification
number in all future correspondence.*

This is a computer generated cover page.

PARIVESH

(Pro-Active and Responsive Facilitation by Interactive,
and Virtuous Environmental Single-Window Hub)



REGD.POST WITH ACK.DUE

Order No. SEIAA/AP /KRI/IND/09/2020/2151/152.19&145.19

Sub: SEIAA, A.P. – M/s. Andhra Medi Pharma India Pvt. Ltd. Sy.Nos. 263, Veeravalli Village, Bapulapadu Mandal, Krishna District, Andhra Pradesh - Environmental Clearance - Expansion - Issued - Reg.

- I. This has reference to your EC application submitted through online on 14.09.2020 (Proposal No.SIA/AP/IND2/173127/2020), seeking Environmental Clearance for manufacturing of **Bulk Drugs and Intermediates Manufacturing Unit at Sy.Nos. 263, Veeravalli Village, Bapulapadu Mandal, Krishna District** in favour of **M/s. Andhra Medi Pharma India Pvt. Ltd.** The nearest human habitation viz., Narayanapuram (V) exists at a distance of 1.8 km from the premises. The total area of the site is 5 Acres. The capital cost for expansion of the project is Rs.3.0 Crores. The details of the production capacities of the project is as follows:

List of existing products and Quantities as per MoEF EC order dt.24.01.2011:

| Sl.No. | Phase | Products | Capacity | |
|--------------|-------|-----------------------------|--------------|-------------|
| | | | TPM | Kg/day |
| 1. | I | Glucosamine Hydrochloride | 30.0 | 1200 |
| 2. | | Chondroitin Sulphate Sodium | 3.0 | 120 |
| 3. | II | Losartan Potassium | 3.0 | 120 |
| 4. | | Pantoprazole Sodium | 0.50 | 20 |
| 5. | | Topiramate | 3.0 | 120 |
| 6. | | Rabeprazole Sodium | 0.50 | 20 |
| 7. | | Valsartan | 0.50 | 20 |
| 8. | | Levetiracetam | 3.0 | 120 |
| Total | | | 43.50 | 1740 |

List of Proposed products and Quantities (After expansion):

| S.No. | Name of the Product | Capacity (TPM) |
|------------------------|-----------------------------|----------------|
| Group - A | | |
| 1 | Glucosamine Hydrochloride | 186 |
| Total Group - A | | 186 |
| Group - B | | |
| 1 | Glucosamine Hydrochloride | 100 |
| 2 | Chondroitin Sulphate Sodium | 3 |
| 3 | Losartan Potassium | 3 |
| 4 | Pantoprazole Sodium | 0.5 |

| | | |
|--|--------------------|--------------|
| 5 | Topiramate | 3 |
| 6 | Rabeprazole Sodium | 0.5 |
| 7 | Valsartan | 0.5 |
| 8 | Levetiracetam | 3 |
| Total Group - B | | 113.5 |
| Any one group will be manufactured at any point of time on campaign basis | | |

List of by-products and Quantities (After expansion):

| Sl.No. | Name of Product | Name of by-Product | Stage | Quantity (kg/day) |
|------------------|--------------------|--------------------|-------|-------------------|
| Group - A | | | | |
| 1. | Glucosamine HCl | Acetic Acid | I | 1726.2 |
| Group - B | | | | |
| 1. | Glucosamine HCl | Acetic Acid | I | 928.1 |
| 2. | Losartan Potassium | Benzoic Acid | II | 104 |
| | | Tritanol | IV | 77.2 |

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 **10.11.2020**. The Proposal of **M/s. Andhra Medi Pharma India Pvt. Ltd.**, is for Environmental Clearance for expansion of production quantities **of bulk drugs and intermediates from 43.5 TPM to 186 TPM**. The project proponent and their Consultant M/s.Team Labs and Consultants, have attended the Online 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.*" Further it is extended up to 30th March, 2021 vide S.O. No. 3636(E), dated 15.10.2020. 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 the existing unit is Bulk Drug & Intermediates manufacturing unit. Now, the PP has proposed the Bulk Drug & Intermediates manufacturing unit with expansion of production capacity: from 43.5 TPM to 186 TPM. The project proponent has submitted the EMP, PFR, Risk Assessment Report and certified compliance report of EC order of existing Industry. The Committee observed that the industry is complying the norms. The Committee after examining the project proposals, presentations and deliberations recommended for issue of Environmental Clearance for expansion of production of Bulk Drug and intermediates with production quantity - **from 43.5 TPM to 186 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 **08.12.2020** 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 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 CPCBand 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 and 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. The industry shall send hazardous waste to the authorized cement industries/ TSDF/ authorized recyclers by properly maintaining the system.

Part B. Specific Conditions:

1) Air & Noise Environment:

1. The emissions from the existing Coal fired boiler of capacity 2 x 2.0 TPH shall be routed through multi cyclone separator with the stack type and height fixed in consultation with the APPCB. Proposed a 1 x 2 Lakh K.Cal/hr Thermic fluid heater. Adequate stack height shall be provided for D.G. Sets 2 x 250 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 after expansion shall not exceed 206.5 KLD (Group-A – Fresh water is 65.9 KLD & Recycled water is 30 KLD and Group-B – Fresh water is 72.6 KLD & Recycled water is 38 KLD) which includes for Process - Group A - 11.9 KLD & Group B - 15.6 KLD, Washings – Group A - 2.0 KLD & Group B - 2.0 KLD, Scrubber - Group A - 2.0 KLD & Group B - 5.0 KLD, Boiler feed – Group A - 12.0 KLD & Group B - 12.0 KLD, Cooling Tower - Group A - 58.0 KLD & Group B - 66.0 KLD, DM / RO Rejects – Group A - 3.0 KLD & Group B - 3.0 KLD, Domestic – Group A - 3.0 KLD & Group B - 3.0 KLD & for Greenbelt – Group A - 4.0 KLD & Group B - 4.0 KLD.

Waste water generation:

11. The total waste water generation is existing – 70.9 KLD (Group A - 31.7 KLD & Group B - 38.5 KLD). **The HTDS effluent** generation is existing - 15.2 KLD, Group A - 12.4 KLD & Group B - 16.9 KLD from process, existing - 3.0 KLD, Group A - 2.0 KLD & Group B - 2.0 KLD from washings, existing - 1.0 KLD, Group A - 2.0 KLD & Group B - 5.0 KLD from Scrubber, Group A - 3.0 KLD & Group B - 3.0 KLD from RO / DM Plant Rejects. The HTDS shall be sent to Group A: Forced Evaporation system followed by biological treatment plant. Group B: Sent to Stripper. Stripper condensate shall be disposed to cement industries for co-processing/TSDF. Stripper bottom is sent to MEE followed by AFTD. Condensate from MEE shall be sent to biological treatment plant followed by RO. RO rejects are sent to

MEE and permeate is reused in utility make-up and rejects sent to MEE. **The LTDS effluent** generation is existing - 2.0 KLD, Group A - 1.5 KLD & Group B - 1.5 KLD from Boiler Blow downs, existing - 1.5 KLD, Group A - 8.0 KLD & Group B - 8.0 KLD from Cooling tower Blow downs, and existing - 4.0 KLD, Group A - 2.8 KLD & Group B - 2.8 KLD from Domestic shall be sent to biological treatment system followed by RO. RO permeates reused for utility make-up. RO rejects are sent to MEE.

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.

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 Tran boundary movement) Rules, 2016 and its amendments thereof.
18. The Process residue – Existing - 2.216 TPD, Group A - 1.46 TPD & Group B - 1.95 TPD, Solvent Residue - existing - 0.56 TPD, Group A - 0.31 TPD & Group B - 0.56 TPD shall be sent to TSDF / Cement industries for co processing, Spent Carbon - existing - 212 kg/day, Group A - 174.6 kg/day & Group B - 125.6 kg/day, Hyflow - existing - 4.0 kg/day shall be sent to TSDF, Spent solvent - Group A - 1.6 TPD & Group B - 13.0 TPD shall be sent to recovered within the plant and reused, Mixed Solvents - Group A - 0.2 TPD & Group B - 1.6 TPD shall be sent to authorized recovery units/Cement plants for co-incineration, Evaporation Salts - existing - 420.0 kg/day, Group A - 40.0 kg/day & Group B - 755.3 kg/day shall be sent to TSDF, ETP Sludge - existing - 50.0 kg/day, Group A - 250.0 kg/day & Group B - 300.0 kg/day, Process inorganic residue - existing - 115.0 kg/day & Group B - 95.9 kg/day shall be sent to TSDF, Ash from Boiler - existing - 1.0 TPD, Group A - 1.0 TPD & Group B - 1.0 TPD shall be sold to brick manufacturers, Detoxified containers & Liners - existing - 200 Nos/year, Group A - 400 Nos/year & Group B - 600 Nos/year shall be sold to authorized vendors and Waste Oil - existing - 50 LPA, Group A - 50 LPA & Group B - 50 LPA shall be sent to authorized recyclers.

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.142.6 Lakhs & Recurring cost of Rs.169.0 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, Vijayawada, 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 anytime, 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.**

To

Sri K. Sri Narayanan, Director - Technical,
M/s. Andhra Medi Pharma India Pvt. Ltd.
Door No.40-25-35/1, Opposite Kesava Towers,
Patamatalanka, Asramam street,
Vijayawada, Andhra Pradesh – 520 010,
Ph.91 9866472222

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.