

To,
The Director (IA division -II)
MoEF&CC,
Vayu Wing, 3rd Floor,
Ministry of Environment, Forest & Climate Change,
Jor Bagh Road,
New Delhi-110003

Date: 20.03.2020

Sir,

Sub: Submission of EIA/EMP report for obtaining Environmental clearance – reg.

Ref: 1. Application submitted to KSEIAA on 07.03.2019
2. 219th KSEAC meeting proceedings held on 27.03.2019
3. TOR received (File No SEIAA 10 IND 2019)(Proposal No: SIA/KA/IND2/32129/2019) dated 21.05.2019
4. EIA/EMP report submitted to KSEIAA on 04.11.2019
5. 180th SEIAA Proceedings held on 23.12.2019

- Vide ref (1), with reference to the above subject, we had submitted the application for the issue of TORs for the Proposed Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds located at No.49, F1 & F2, Bommasandra Industrial Area, Phase-I, Bengaluru.
- The project was placed in 219th KSEAC meeting held on 27.03.2019 for appraisal of TOR.
- Vide ref (2), the subject was recommended for issue of TOR to conduct the EIA studies. Based on the recommendation, collected the environmental baseline data from March 2019 to May, 2019.
- Vide ref (3), TORs for the project was issued vide ref SEIAA 10 IND 2019 dated: 21.05.2019
- Vide ref (4), Final EIA/EMP report submitted to KSEIAA on 04.11.2019. Later, the proposal was placed in 236th KSEAC meeting held on 18.12.2019 for EIA/EC appraisal.
- Vide ref (5), based on the SEIAA Proceedings, Authority opined as below:

The Authority noted the Jigani Industrial Area wherein the proposed project site is located has been identified as a critically polluted area vide the orders of Hon'ble National Green Tribunal. As per the mechanism brought out by the Ministry of Environment, Forest and Climate Change vide O.M dated 31st October 2019 in compliance to the orders of the Hon'ble NGT, all B1 category activities are to be appraised at the Central level.

The Authority in view of the above observations, decided to advise the proponent to approach the Ministry of Environment, Forest and Climate Change for Environmental

Anthem Biosciences Pvt. Ltd.

49, F1 & F2, Canara Bank Road,
Bommasandra Industrial Area, Phase - I
Bommasandra, Bengaluru - 560 099
Karnataka, India

CIN : U24233KA2006PTC039703

Tel : +91 80 6672 4000

Fax : +91 80 6672 4020

www.anthembio.com

Clearance under EIA Notification, 2006 amended from time to time. The Authority also decided to forward the concerned file of the Authority to MoEF&CC for further consideration as the EIA report has already been submitted in accordance with law.

Hence in view of the same, Bommasandra- Jigani KIADB Industrial Area being categorized as Critically Polluted Area (CEPI Score: 70.99 by CPCB), our proposal attracts General Condition of EIA Notification 2006 and its amendments, which needs to be appraised at Central level (MoEF&CC). Hence, we are herewith submitting EIA/EMP report for onward consideration of EC.

Kindly do the needful for Environmental Clearance process.

Thanking You,
Yours faithfully,
For M/s Anthem Biosciences Pvt Ltd.,


Authorized Signatory

Encl:

1. Hard and Soft copy of EIA/EMP report and annexures
2. 180th SEIAA Proceedings & TOR copy



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 10 IND 2019

Date: 21-05-2019

To,

Mr. Ajay Bhardhwaj
Chairman & Managing Director
M/s. Anthem Biosciences Pvt. Ltd
#49, F1 & F2, Bommasandra Industrial Area,
Phase-I,
Bengaluru-560 099

Sir,

Sub: Proposed Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds both from R&D and pilot plant at No.49, F1 & F2, Bommasandra Industrial Area, Phase-I, Bengaluru by M/s. Anthem Biosciences Pvt Ltd - issue of ToRs and additional ToRs -regarding.

Ref: Proceedings of the 219th SEAC meeting held on 27th March 2019.
Proceedings of the 167th SEIAA meeting held on 4th May 2019.

This has reference to your online application dated 7th March 2019 bearing proposal No.SIA/KA/IND2/32129/2019 addressed to SEIAA, Karnataka on the subject mentioned above along with Form-1, Form 1A, conceptual plan as per the EIA Notification, 2006.

2. It is a proposal seeking Environmental clearance for the proposed Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds both from R&D and pilot plant at No.49, F1 & F2, Bommasandra Industrial Area, Phase-I, Bengaluru by M/s. Anthem Biosciences Pvt. Ltd . This is a project covered under Sl.No.5(f) of the Schedule Under of EIA Notification 2006 and amendments made there on.

3. It is inter-alia, noted that M/s. Anthem Biosciences Pvt. Ltd. have taken Environmental Clearance form Authority vide letter no. SEIAA 6 IND 2013 dated 3rd October 2013 for Expansion of Existing R &D unit into a manufacvturing unit of 16 bulk drug and drug intermediates.

4. It is inter-alia, noted that M/s. Anthem Biosciences Pvt. Ltd. have proposed for Expansion of Manufacturing drug and drug intermediates, fermentation based products and custom synthesis of organic compounds of a total quantity of 3771 kg/month both from R & D and pilot plant project on a land area of 20,222 sqmt. The

State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

total builtup area is 8659.36 sqm. The water requirement for the proposed project is 144 KLD, The total power supply required for the proposed project is 2980 KVA.

5. The State Expert Appraisal Committee (SEAC), Karnataka has considered the proposal during its meeting held on 27th March 2019. Based on the consideration of the documents submitted and the presentation made by you and the environment consultant M/s EHSC Pvt. Ltd., the Committee prescribed the following Terms of Reference (ToR) for preparing EIA/EMP report with at least one season baseline data for the above mentioned project.

6. The SEIAA Karnataka after due consideration of the relevant documents submitted by the project proponent, and the recommendation of the SEAC have in its meeting held on 4th May 2019 and decided to accord the Standard Terms of Reference (TOR) along with additional Terms of Reference, in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments made there on.

A. STANDARD TERMS OF REFERENCE

- 1) Executive Summary
- 2) Introduction
 - i. Details of the EIA Consultant including NABET accreditation
 - ii. Information about the project proponent
 - iii. Importance and benefits of the project
- 3) Project Description
 - i. Cost of project and time of completion.
 - ii. Products with capacities for the proposed project.
 - iii. If expansion project, details of existing products with capacities and whether adequate land is available for expansion, reference of earlier EC if any.
 - iv. List of raw materials required and their source along with mode of transportation.
 - v. Other chemicals and materials required with quantities and storage capacities.
 - vi. Details of Emission, effluents, hazardous waste generation and their management.
 - vii. Requirement of water, power, with source of supply, status of approval, water balance diagram, man-power requirement (regular and contract)
 - viii. Process description along with major equipments and machineries, process flow sheet (quantative) from raw material to products to be provided.
 - ix. Hazard identification and details of proposed safety systems.
 - x. Expansion/modernization proposals:
 - a. Copy of all the Environmental Clearance(s) including Amendments thereto obtained for the project from MOEF/SEIAA shall be attached as an Annexure. A certified copy of the latest Monitoring Report of the

State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

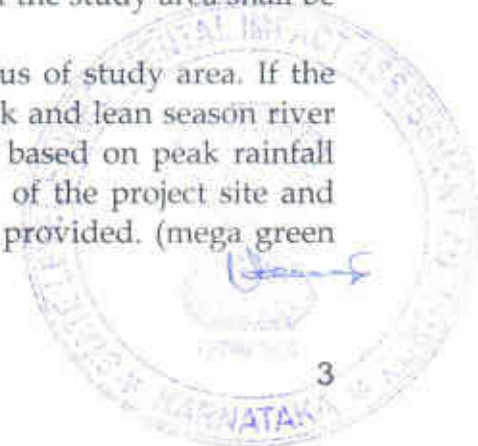
Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

Regional Office of the Ministry of Environment and Forests as per circular dated 30th May, 2012 on the status of compliance of conditions stipulated in all the existing environmental clearances including Amendments shall be provided. In addition, status of compliance of Consent to Operate for the ongoing /existing operation of the project from SPCB shall be attached with the EIA-EMP report.

- b. In case the existing project has not obtained environmental clearance, reasons for not taking EC under the provisions of the EIA Notification 1994 and/or EIA Notification 2006 shall be provided. Copies of Consent to Establish/No Objection Certificate and Consent to Operate (in case of units operating prior to EIA Notification 2006, CTE and CTO of FY 2005-2006) obtained from the SPCB shall be submitted. Further, compliance report to the conditions of consents from the SPCB shall be submitted.

4) Site Details

- i. Location of the project site covering village, Taluka/Tehsil, District and State, Justification for selecting the site, whether other sites were considered.
- ii. A toposheet of the study area of radius of 10km and site location on 1:50,000/1:25,000 scale on an A3/A2 sheet. (including all eco-sensitive areas and environmentally sensitive places)
- iii. Details w.r.t. option analysis for selection of site
- iv. Co-ordinates (lat-long) of all four corners of the site.
- v. Google map-Earth downloaded of the project site.
- vi. Layout maps indicating existing unit as well as proposed unit indicating storage area, plant area, greenbelt area, utilities etc. If located within an Industrial area/Estate/Complex, layout of Industrial Area indicating location of unit within the Industrial area/Estate.
- vii. Photographs of the proposed and existing (if applicable) plant site. If existing, show photographs of plantation/greenbelt, in particular.
- viii. Landuse break-up of total land of the project site (identified and acquired), government/ private - agricultural, forest, wasteland, water bodies, settlements, etc shall be included. (not required for industrial area)
- ix. A list of major industries with name and type within study area (10km radius) shall be incorporated. Land use details of the study area
- x. Geological features and Geo-hydrological status of the study area shall be included.
- xi. Details of Drainage of the project upto 5km radius of study area. If the site is within 1 km radius of any major river, peak and lean season river discharge as well as flood occurrence frequency based on peak rainfall data of the past 30 years. Details of Flood Level of the project site and maximum Flood Level of the river shall also be provided. (mega green field projects)



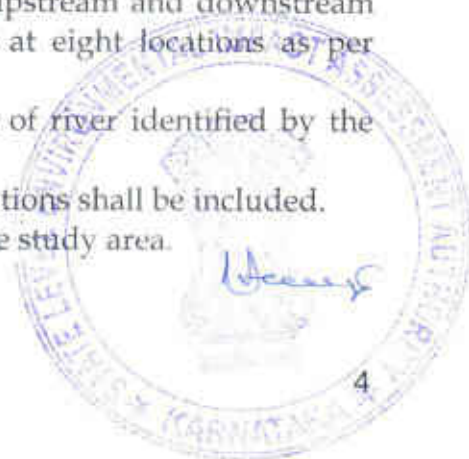
State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

- xii. Status of acquisition of land. If acquisition is not complete, stage of the acquisition process and expected time of complete possession of the land.
- xiii. R&R details in respect of land in line with state Government policy.
- 5) Forest and wildlife related issues (if applicable):
 - i. Permission and approval for the use of forest land (forestry clearance), if any, and recommendations of the State Forest Department. (if applicable)
 - ii. Landuse map based on High resolution satellite imagery (GPS) of the proposed site delineating the forestland (in case of projects involving forest land more than 40 ha)
 - iii. Status of Application submitted for obtaining the stage I forestry clearance along with latest status shall be submitted.
 - iv. The projects to be located within 10 km of the National Parks, Sanctuaries, Biosphere Reserves, Migratory Corridors of Wild Animals, the project proponent shall submit the map duly authenticated by Chief Wildlife Warden showing these features vis-a-vis the project location and the recommendations or comments of the Chief Wildlife Warden-thereon.
 - v. Wildlife Conservation Plan duly authenticated by the Chief Wildlife Warden of the State Government for conservation of Schedule I fauna, if any exists in the study area.
 - vi. Copy of application submitted for clearance under the Wildlife (Protection) Act, 1972, to the Standing Committee of the National Board for Wildlife.
- 6) Environmental Status
 - i. Determination of atmospheric inversion level at the project site and site-specific micrometeorological data using temperature, relative humidity, hourly wind speed and direction and rainfall.
 - ii. AAQ data (except monsoon) at 8 locations for PM10, PM2.5, SO2, NOX, CO and other parameters relevant to the project shall be collected. The monitoring stations shall be based CPCB guidelines and take into account the pre-dominant wind direction, population zone and sensitive receptors including reserved forests.
 - iii. Raw data of all AAQ measurement for 12 weeks of all stations as per frequency given in the NAQQM Notification of Nov. 2009 along with - min., max., average and 98% values for each of the AAQ parameters from data of all AAQ stations should be provided as an annexure to the EIA Report.
 - iv. Surface water quality of nearby River (100m upstream and downstream of discharge point) and other surface drains at eight locations as per CPCB/MoEF&CC guidelines.
 - v. Whether the site falls near to polluted stretch of river identified by the CPCB/MoEF&CC, if yes give details.
 - vi. Ground water monitoring at minimum at 8 locations shall be included.
 - vii. Noise levels monitoring at 8 locations within the study area.
 - viii. Soil Characteristic as per CPCB guidelines.



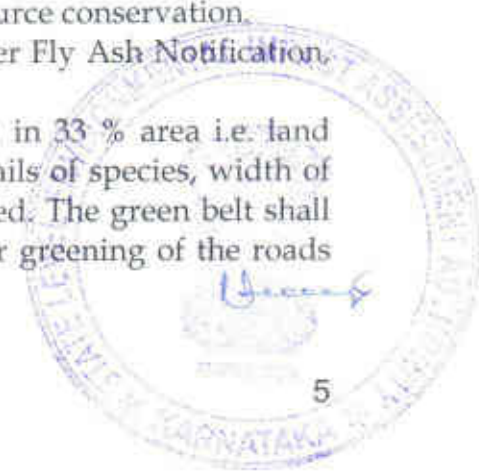
State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

- ix. Traffic study of the area, type of vehicles, frequency of vehicles for transportation of materials, additional traffic due to proposed project, parking arrangement etc.
 - x. Detailed description of flora and fauna (terrestrial and aquatic) existing in the study area shall be given with special reference to rare, endemic and endangered species. If Schedule-I fauna are found within the study area, a Wildlife Conservation Plan shall be prepared and furnished.
 - xi. Socio-economic status of the study area.
- 7) Impact and Environment Management Plan
- i. Assessment of ground level concentration of pollutants from the stack emission based on site-specific meteorological features. In case the project is located on a hilly terrain, the AQIP Modelling shall be done using inputs of the specific terrain characteristics for determining the potential impacts of the project on the AAQ. Cumulative impact of all sources of emissions (including transportation) on the AAQ of the area shall be assessed. Details of the model used and the input data used for modelling shall also be provided. The air quality contours shall be plotted on a location map showing the location of project site, habitation nearby, sensitive receptors, if any.
 - ii. Water Quality modelling - in case of discharge in water body
 - iii. Impact of the transport of the raw materials and end products on the surrounding environment shall be assessed and provided. In this regard, options for transport of raw materials and finished products and wastes (large quantities) by rail or rail-cum road transport or conveyor-cum-rail transport shall be examined.
 - iv. A note on treatment of wastewater from different plant operations, extent recycled and reused for different purposes shall be included. Complete scheme of effluent treatment. Characteristics of untreated and treated effluent to meet the prescribed standards of discharge under E(P) Rules.
 - v. Details of stack emission and action plan for control of emissions to meet standards.
 - vi. Measures for fugitive emission control
 - vii. Details of hazardous waste generation and their storage, utilization and management. Copies of MOU regarding utilization of solid and hazardous waste in cement plant shall also be included. EMP shall include the concept of waste-minimization, recycle/reuse/recover techniques, Energy conservation, and natural resource conservation.
 - viii. Proper utilization of fly ash shall be ensured as per Fly Ash Notification, 2009. A detailed plan of action shall be provided.
 - ix. Action plan for the green belt development plan in 33 % area i.e. land with not less than 1,500 trees per ha. Giving details of species, width of plantation, planning schedule etc. shall be included. The green belt shall be around the project boundary and a scheme for greening of the roads used for the project shall also be incorporated.



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

- x. Action plan for rainwater harvesting measures at plant site shall be submitted to harvest rainwater from the roof tops and storm water drains to recharge the ground water and also to use for the various activities at the project site to conserve fresh water and reduce the water requirement from other sources.
 - xi. Total capital cost and recurring cost/annum for environmental pollution control measures shall be included.
 - xii. Action plan for post-project environmental monitoring shall be submitted.
 - xiii. Onsite and Offsite Disaster (natural and Man-made) Preparedness and Emergency Management Plan including Risk Assessment and damage control. Disaster management plan should be linked with District Disaster Management Plan.
- 8) Occupational health
- i. Plan and fund allocation to ensure the occupational health & safety of all contract and casual workers
 - ii. Details of exposure specific health status evaluation of worker. If the workers' health is being evaluated by pre designed format, chest x rays, Audiometry, Spirometry, Vision testing (Far & Near vision, colour vision and any other ocular defect) ECG, during pre placement and periodical examinations give the details of the same. Details regarding last month analyzed data of above mentioned parameters as per age, sex, duration of exposure and department wise.
 - iii. Details of existing Occupational & Safety Hazards. What are the exposure levels of hazards and whether they are within Permissible Exposure level (PEL). If these are not within PEL, what measures the company has adopted to keep them within PEL so that health of the workers can be preserved,
 - iv. Annual report of health status of workers with special reference to Occupational Health and Safety.
- 9) Corporate Environment Policy
- i. Does the company have a well laid down Environment Policy approved by its Board of Directors? If so, it may be detailed in the EIA report.
 - ii. Does the Environment Policy prescribe for standard operating process / procedures to bring into focus any infringement / deviation / violation of the environmental or forest norms / conditions? If so, it may be detailed in the EIA.
 - iii. What is the hierarchical system or Administrative order of the company to deal with the environmental issues and for ensuring compliance with the environmental clearance conditions? Details of this system may be given.
 - iv. Does the company have system of reporting of non compliances / violations of environmental norms to the Board of Directors of the company and / or shareholders or stakeholders at large? This reporting



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

mechanism shall be detailed in the EIA report

- 10) Details regarding infrastructure facilities such as sanitation, fuel, restroom etc. to be provided to the labour force during construction as well as to the casual workers including truck drivers during operation phase.
- 11) Enterprise Social Commitment (ESC)
 - i. Adequate funds (at least 2.5 % of the project cost) shall be earmarked towards the Enterprise Social Commitment based on Public Hearing issues and item-wise details along with time bound action plan shall be included. Socio-economic development activities need to be elaborated upon.
- 12) Any litigation pending against the project and/or any direction/order passed by any Court of Law against the project, if so, details thereof shall also be included. Has the unit received any notice under the Section 5 of Environment (Protection) Act, 1986 or relevant Sections of Air and Water Acts? If so, details thereof and compliance/ ATR to the notice(s) and present status of the case.
- 13) A tabular chart with index for point wise compliance of above TOR.

B. SPECIFIC TERMS OF REFERENCE

1. Details on solvents to be used, measures for solvent recovery and for emissions control.
2. Details of process emissions from the proposed unit and its arrangement to control.
3. Ambient air quality data should include VOC, other process-specific pollutants* like NH₃*, chlorine*, HCl*, HBr*, H₂S*, HF*, etc., (*-as applicable)
4. Work zone monitoring arrangements for hazardous chemicals.
5. Detailed effluent treatment scheme including segregation of effluent streams for units adopting 'Zero' liquid discharge.
6. Action plan for odour control to be submitted.
7. A copy of the Memorandum of Understanding signed with cement manufacturers indicating clearly that they co-process organic solid/hazardous waste generated.
8. Authorization/Membership for the disposal of liquid effluent in CETP and solid/hazardous waste in TSDF, if any.
9. Action plan for utilization of MEE/dryers salts.
10. Material Safety Data Sheet for all the Chemicals are being used/will be used.
11. Authorization/Membership for the disposal of solid/hazardous waste in TSDF.
12. Details of incinerator if to be installed.
13. Risk assessment for storage and handling of hazardous chemicals/solvents. Action plan for handling & safety system to be incorporated.
14. Arrangements for ensuring health and safety of workers engaged in handling of toxic materials.



State Level Environment Impact Assessment Authority-Karnataka

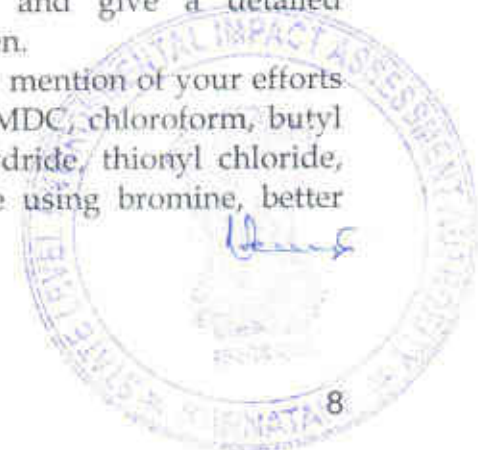
(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA-10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

C. ADDITIONAL TERMS OF REFERENCES

1. Submit the compliance to earlier EC conditions and CFO conditions.
2. Establish with layout plan the adoption of GMP for manufacturing products supported by P & ID.
3. Sketch showing the location of the additional infrastructure in the plan of the existing industrial site.
4. Give the details of disposal of debris generated during expansion.
5. Based on experimental data, detail the material balance / mass balance for each product with quantities of distillate residue, solvent loss and fugitive emissions. Also evaluate and present the ratio of (i) waste to product and (ii) raw material to product for each of the products proposed to be manufactured.
6. Enlist the raw materials with quantity with particular mention of any pyrophoric & highly reactive materials and precautions taken for their storage. Also mention any restricted/banned chemicals, if used in your product manufacture proposal.
7. Provide the solvents storage plan with quantity as per standard norms highlighting any special precautions adopted for storage.
8. Evaluate and present the quantity and quality of solid and gaseous waste generated and their scheme of disposal.
9. Evaluate and present the existing and proposed water balance based on expansion.
10. For the worst case scenario, evaluate and present the quantity and characteristics of effluent discharged and their scheme of disposal through ETP
11. Describe the measures proposed for in-house recovery of solvents mentioning the efficiency of recovery.
12. Identify and evaluate the steps in the manufacturing of your products that may represent risks to personnel or equipment and conduct a detailed investigation and present the hazop study along with risk assessment, disaster management for worst case scenario, all control equipment and mitigation measures adopted, emergency preparedness and onsite emergency plan.
13. Present the scheme proposed for separation of high TDS effluent and its treatment & disposal through MEE used, justifying the stages and design parameters.
14. Present the scheme proposed to isolate the lithium (if used) and other salts from MEE and explore the possibility of their disposal advantageously.
15. Evaluate the hydrogenation process (if adopted) and give a detailed description of the safety measures and precautions taken.
16. Highlight the green chemistry adopted with particular mention of your efforts to replace toxic solvents and reagents such as EDC, MDC, chloroform, butyl lithium, lithium aluminium hydride, sodium borohydride, thionyl chloride, THF etc wherever done and if bromination is done using bromine, better alternatives to bromine as brominating agent.



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 10 IND 2019

Expansion of manufacturing drugs and drug intermediates, fermentation based products and custom synthesis of organic compounds by M/s. Anthem Biosciences Pvt Ltd

17. Give the justification for categorizing the proposal under 'B' category in view of closeness to Bannerghatta National Park with necessary certificate from the competent authority regarding the exact distance from the project site.

The consultants involved in the preparation of EIA/EMP report after accreditation with Quality Council of India/National Accreditation Board of Education and Training (QCI/NABET) would need to include a certificate in this regard in the EIA/EMP reports prepared by them and the data provided by other Organization(s)/Laboratories including their status of approvals etc. In this regard Office Memorandum No. F. No. J-11013/77/2004-IA.II(I) dated 30th June, 2011 available on the MoEF, GoI website <http://www.moef.nic.in> may please be referred.

The Terms of Reference (ToR) prescribed by the State Expert Appraisal Committee (SEAC), Karnataka should be considered for the preparation of EIA / EMP report for the above mentioned project in addition to all the relevant information as per the Generic Structure of EIA given in Appendix III and IIIA in the EIA Notification, 2006.

The ToRs prescribed will be valid for a period of three years for submission of the EIA/EMP report.




Member Secretary,
State Level Environment Impact Assessment Authority,
Karnataka.

Copy to:-

1. Chairman, Karnataka State Pollution Control Board, KSPCB, Parisara Bhavan, 4th & 5th Floor, church street, Bangalore for information.
2. Guard File.