

**F. No. J-11011/291/2013-IA-II(I)**  
**Government of India**  
**Ministry of Environment, Forest and Climate Change**  
**(Impact Assessment Division)**

**Indira Paryavaran Bhawan**  
**Aliganj, Jorbagh Road,**  
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Dated: 20<sup>th</sup> January, 2017

**To**

**The Managing Director**  
**(Dr. M. Sankara Reddy)**  
**M/s Sanorg Laboratories Pvt. Ltd.**  
**H.No. 8-8-112/1, Sri Ram Nagar Colony,**  
**Saroor Nagar (Post), R.R. District,**  
**Hyderabad, Telangana- 500 035**

**Sub: Expansion of Bulk Drugs Manufacturing Unit (from 8.925 MTPA to 745.2 MTPA) at Sy. No. 542, 538, 539, Village Chollair, Mandal Yadagirigutta, District Nalgonda, Telangana by M/s Sanorg Laboratories Pvt. Ltd.-Environmental Clearance- reg.**

**Ref: Online Proposal No. IA/TG/IND2/51225/2013 dated 05<sup>th</sup> May, 2016.**

Sir,

This has reference to your online proposal no. No. IA/TG/IND2/51225/2013 dated 05<sup>th</sup> May, 2016 along with project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report along with Public Hearing Report regarding the above mentioned project.

2. The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that the proposal is for expansion of bulk drugs manufacturing unit (from 8.925 MTPA to 745.2 MTPA) at Sy. No. 542, 538, 539, Village Chollair, Mandal Yadagirigutta, District Nalgonda, Telangana by M/s Sanorg Laboratories Pvt. Ltd. As informed by the Project Proponent (PP) and as per the documents submitted by the PP, the total plot area is 11.81 acres (47822.36 m<sup>2</sup>) of which greenbelt will be developed in 16327 m<sup>2</sup>. No additional land is required for the proposed project. Reserved Forests namely Mala



gutta RF-5.9 KMs (E) and Mallapa gutta RF -7 KMs(ENE) are located within 10 km distance from the manufacturing unit. The total cost of expansion of the project is Rs. 10.67 crores. The following products will be manufactured by the company:

Sl.No	Name of the product	CAS NO.	Application	Quantity in MT/Month
1	Fluconazole	86386-73-4	Antifungal	5.00
2	Gabapentin	60142-96-3	Anticonvulsant	5.00
3	Itraconazole	84625-61-6	Antifungal	1.00
4	Rosavastatin	287714-41-4	Antihyperlipidemic	1.00
5	Escitalopram oxalate	128196-01-0	Antidepressant	1.00
6	Domperidone	57808-66-9	Antiemetic	5.00
7	Tramadol Hydrochloride	46941-76-8	Analgesic	10.00
8	Omeprazole	73590-58-6	Antiulcer	5.00
9	Esomeprazole Magnesium trihydrate	217087-09-7	Antiulcer agent	1.00
10	Lansoprazole	103577-45-3	Gastric antisecretory agent	1.00
11	Pantoprazole sodium	138786-67-1	Proton Pump Inhibitor	2.50
12	Rabeprazole sodium	117976-90-6	Gastric antisecretory agent	2.50
13	Losartan potassium	124750-99-8	Antihypertensive	2.00
14	Telmisartan	144701-48-4	Antihypertensive	2.00
15	Valsartan	137862-53-4	Antihypertensive	1.00
16	Tamsulosin hydrochloride	106463-17-6	Anti-adrenergic	0.10
17	Duloxetine	116539-59-4	Antidepressant	5.00
18	Levo cetirizene Dihydrochloride	130018-87-0	Antihistamine	2.00
19	Ornidazole	16773-42-5	Anti amoebic agent	10.00
Total				62.10

3. All Synthetic organic chemicals industry projects (Bulk drugs and intermediates excluding drug formulations), located outside the notified industrial area/estate are listed at Sl.No. 5(f) of Schedule of Environmental Impact Assessment (EIA) Notification under Category 'A' and are appraised at Central Level by Expert Appraisal Committee (EAC).

4. The project proposal was considered by the Expert Appraisal Committee (Industry - 2) in its 15<sup>th</sup> Meeting held during 29<sup>th</sup>-30<sup>th</sup> January 2014, 9<sup>th</sup> meeting held on 27<sup>th</sup>-28<sup>th</sup> June, 2016 and 13<sup>th</sup> meeting held during 26<sup>th</sup>-27<sup>th</sup> September, 2016. The Project Proponent and the accredited consultant M/s Right Source Industrial Solutions Pvt. Ltd., Hyderabad, gave a

detailed presentation on the salient features of the project and proposed environmental protection measures to be undertaken, as per Terms of References (TORs) awarded in the 15<sup>th</sup> Meeting held during 29<sup>th</sup>-30<sup>th</sup> January 2014 for preparation of EIA-EMP report.

5. Public Hearing for the proposed project has been conducted by the Telangana State Pollution Control Board on 28<sup>th</sup> January, 2016. The concerns were raised regarding pollution control measures, employment and effect on agricultural land etc.

6. The Project Proponent has informed the Expert Appraisal Committee (EAC) that the ambient air quality monitoring was carried out at 8 locations during March 2014 to May 2014. The baseline data indicates that ranges of concentrations of PM<sub>10</sub> (40.10 µg/m<sup>3</sup> to 59.8 µg/m<sup>3</sup>), PM<sub>2.5</sub> (8.10 µg/m<sup>3</sup> to 19.60 µg/m<sup>3</sup>), SO<sub>2</sub> (8.10 µg/m<sup>3</sup> to 12.5 µg/m<sup>3</sup>) and NO<sub>x</sub> (12.10 µg/m<sup>3</sup> to 16.5 µg/m<sup>3</sup>), respectively. Ambient Air Quality (AAQ) modeling study for point source emissions indicates that the maximum incremental ground level concentrations (GLCs) after the proposed project would be 0.76 µg/m<sup>3</sup>, 2.3 µg/m<sup>3</sup> and 2.97 µg/m<sup>3</sup> with respect to SPM, SO<sub>2</sub> and NO<sub>x</sub>. The resultant concentrations are within the National Ambient Air Quality Standards (NAAQS).

7. Bagfilter will be provided to additional Coal fired boilers (2.0 TPH and 5.0 TPH) to control particulate emissions. Two Scrubbers in two stages will be provided to control process emissions viz. HCl and SO<sub>2</sub>. The total water requirement will be 179 m<sup>3</sup>/day. Out of which, fresh water requirement will be 123.56 m<sup>3</sup>/day and remaining water requirement i.e. 55.44 m<sup>3</sup>/day will be met from the recycled water. The water requirement will be met from ground water source. The unit has proposed for ground water recharging in nearby Marrigudem Village open land, which is 2.2 km away from Industry site. It is proposed to construct good storm water channels to divert water from upstream side of open land which is 366 Mt-372 Mt at Mean Sea Level. It is suggested to adopt air cooled condenser instead of water cooling tower. Effluent generation would be 88 m<sup>3</sup>/day after re-estimation.

8. The EAC, in its 13<sup>th</sup> meeting held during 26<sup>th</sup>-27<sup>th</sup> September, 2016, has found that the final EIA/EMP report submitted by the PP is adequate. The EAC after detailed deliberations, on the basis of the information and presentation made by the PP, has recommended the project for environmental clearance with certain conditions.

9. Based on the proposal and information submitted by the Project Proponent, and based on the recommendation by the Expert Appraisal Committee (Industry-2), the Ministry of Environment, Forest and Climate Change hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14<sup>th</sup> September 2006, subject to the compliance of the following Specific and General Conditions:

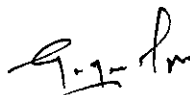
*A. J. P.*

#### **A. Specific Conditions:**

- i) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21<sup>st</sup> July, 2010 and amended time to time shall be followed by the unit.
- ii) Bag filter shall be provided to the coal fired boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.
- iii) Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubber with caustic lye media solution shall be provided to process vents to control SO<sub>2</sub>. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.
- iv) Solvent management shall be carried out as follows :
  - (a). Reactor shall be connected to chilled brine condenser system
  - (b). Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
  - (c). The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
  - (d). Solvents shall be stored in a separate space specified with all safety measures.
  - (e). Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - (f). Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
  - (g). All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- v) Total fresh water requirement from ground water source shall not exceed 123.56 m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA.
- vi) Effluent generation shall not exceed 88 m<sup>3</sup>/day. Trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream shall be treated in ETP and then passed through RO system. Condensate and recover water will be recycled/reused within factory premises.
- vii) 'Zero' effluent discharge shall be adopted and no effluent shall be discharged outside the premises.
- viii) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.
- ix) Air cooled condenser shall be used instead of cooling tower make up.



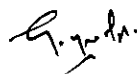
- x) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
- xi) As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers/cement industry.
- xii) The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from APPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
- xiii) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All Transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
- xiv) Fly ash should be stored separately as per CPCB guidelines so that it should not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust should be avoided.
- xv) The company shall undertake following waste minimization measures :-
  - (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 material substitutes in other processes.
  - (c). Use of automated filling to minimize spillage.
  - (d). Use of Close Feed system into batch reactors.
  - (e). Venting equipment through vapour recovery system.
  - (f). Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- xvi) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.
- xvii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xviii) As proposed, green belt over 33 % of the total project area shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.




- xix) All the commitment made regarding issues raised during the Public Hearing/ consultation meeting shall be satisfactorily implemented.
- xx) At least 5 % of the total cost of the project 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 prepared and submitted to the Ministry's Regional Office at Chennai.

**B. General Conditions:**


- i. The project authorities must strictly adhere to the stipulations made by the Telangana Pollution Control Board, State Government and any other statutory authority.
- ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- iii. The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- iv. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> November, 2009 shall be followed.
- v. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.
- vii. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- viii. The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.
- ix. The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.



- x. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
  - xi. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
  - xii. The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.
  - xiii. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad/Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.
  - xiv. The project proponent shall also submit six monthly 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 respective Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
  - xv. The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF&CC by e-mail.
  - xvi. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at <http://moef.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.
  - xvii. The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
10. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
11. The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.




12. The above conditions will be enforced, *inter alia* under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

  
(Yogendra Pal Singh)  
Scientist 'D'

**Copy to:-**

1. The Secretary, Department of Environment, Forests, Science and Technology, Government of Telangana, Hyderabad, Telangana
2. Additional Principal Chief Conservator of Forests (C), Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1<sup>st</sup> and 2<sup>nd</sup> Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, Chennai – 600034
3. The Chairman, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex East Arjun Nagar, Delhi - 110 032.
4. The Chairman, Telangana State Pollution Control Board, Plot No A 3, Paryavaran Bhawan, Sanath Nagar, Hyderabad - 500018, Telangana.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, Jor Bhag, New Delhi- 110 003.
6. Guard File/Monitoring File/Website/Record File.

  
(Yogendra Pal Singh)  
Scientist 'D'