

**F. No. J-11011/375/2013-IA II (I)**  
**Government of India**  
**Ministry of Environment, Forests and Climate Change**  
**(I.A. Division)**

**Indira Paryavaran Bhawan**  
**Aliganj, Jorbagh Road,**  
**New Delhi -110003**

**E-mail: lk.bokolia@nic.in**  
**Telefax: 011-24695313**  
**Dated 30<sup>th</sup> December, 2015**

To,  
Shri M. Narayan Reedy, Managing Director  
M/s Covalent Lab. Pvt. Ltd.  
8-3-677/18, SKD Nagar,  
Yellareddyguda,  
Hyderabad – 500073

**Email.: [info@covalentlabs.com](mailto:info@covalentlabs.com) ; Fax.: 040-49483396**

**Subject: Expansion of bulk drugs & intermediate manufacturing unit-I alongwith CPP (3MW) at Village Gundlamachanoor, Mandal Halnoor, District Medak, Telangana (Formerly in Andhra Pradesh) by M/s Covalent Lab. Pvt. Ltd. – Environmental Clearance reg.**

**Ref.: Your online proposal no. IA/TG/IND/26256/2013 dated 27<sup>th</sup> January, 2015.**

Sir,

This has reference to your online proposal no. IA/TG/IND/26256/2013 dated 27<sup>th</sup> January, 2015 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report alongwith Public Hearing Report regarding above mentioned project and subsequent submission of additional information vide letter dated 30<sup>th</sup> April, 2015.

2.0 The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that the proposal is for expansion of bulk drugs & intermediate manufacturing unit-I alongwith CPP (3MW) at Village Gundlamachanoor, Mandal Halnoor, District Medak, Telangana (Formerly in Andhra Pradesh) by M/s Covalent Lab. Pvt. Ltd. Cost of project is Rs. 212.94 crores. Out of which, Rs. 21.0 Crore and Rs. 6.0 Crore per annum towards capital cost and recurring cost per annum for implementation of environmental management plan. Nakka Vagu and Manjeera River is flowing at a distance of 1km and 2.5 Km respectively. It is reported that no ecological sensitive area or protected area as per wildlife protection Act, 1972 is located within 10 km distance. The said industry is located at a distance of 15 Km from the CEPI identified Patancheru-Bollaram stretch. Total plot area is 155197 m<sup>2</sup>, of which greenbelt will be developed in 55871 m<sup>2</sup> area. It is proposed to manufacture 65 bulk drugs and its intermediates on campaign basis with any 20 products manufactured at a time along with 3 MW Captive Power Plant. List of existing products being manufactured is given below:

S.N.	Product Name	Quantity (TPA)
<b>Environmental Clearance (EC)</b>		
1	Flucinaazole	2.16

js

2	Nalidixic acid	14.4
3	Naproxen	36
<b>Consent from APPCB</b>		
1	Cefixime	24.00
2	Cefpodoxime Proxetil	11.99
3	Cefuroxime Axetil	24.00
4	Cefuroxime Sodium	3.00
5	Ceftriaxone Sodium	6.00
6	Cefpirome	3.00
7	Cefdinir	6.00
8	Cefprozil	3.00
9	Cefepime	6.00

List of proposed products to be manufactured is as given below:

S.N.	Product Name	Quantity (TPA)
1	Cefixime Trihydrate	780
2	Cefpodoxime Proxetil	120
3	Cefuroxime Axetil	180
4	Cefuroxime Sodium	180
5	Cefdinir Monohydrate	72
6	Cefprozil Monohydrate	60
7	Meropenem	60
8	Doripenem Monohydrate	60
9	7-AVNA	60
10	MEAT (Thio Ester)	60
11	Cefuroxime Acid	36
12	Cefotaxime Sodium	36
13	Faropenem Sodium	36
14	7-APCA	36
15	Cefuroxime Sodium	24
16	Cefpirome Sulfate	12
17	Cefepime Dihydrochloride Monohydrate	12
18	Cefditoren Pivoxil	12
19	Ceftibuten Monohydrate	24
20	Cefazoline Sodium	12
21	Cefoperazone Sodium	12
22	Cefoxitin Sodium	6
23	Ceftazidime Pentahydrate	6
24	Ceftizoxime Sodium	12
25	Cephalothin Sodium	12
26	Cefpodoxime Acid	12
27	Cefcapene Pivoxil	9.6
28	Cefmetazole Sodium	12
29	Cefmetazole	12
30	Imipenem	24
31	Cilastatin Sodium	24
32	Ertapenem Sodium	12
33	Biapenem	12
34	Panipenem	12
35	Tebipenem Pivoxil	1.2
36	Darifenacin Hydrabromide	6
37	Solifenacin Succinate	6
38	Tolterodine Tartrate	6
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7- AMCA)	12
40	7-Amino-3-thiazole cephalosporanic acid (7-ATCA)	24
41	Lacosamide	120

42	Cinacalcet Hydrochloride	120
43	Fexofenadine Hydrochloride	120
44	Dronedaron Hydrochloride	120
45	Deferasirox	120
46	Silodosin	24
47	Fingolimod Hydrochloride	24
48	Sitagliptin Phosphate	24
49	Prasugrel Hydrochloride	24
50	Venlafaxine Hydrochloride	24
51	Pregabalin	24
52	Diacerein	24
53	Linezolid	24
54	Ropinirole Hydrochloride	24
55	D-Cycloserine	24
56	Clopidogrel Hydrogen Sulfate	24
57	Bosentan	24
58	Candesartan Cilexetil	24
59	Febuxostat	24
60	Azilsartan medoxomil	24
61	Soifenacin Succinate	24
62	Darifenacin Hydrobromide	24
63	Trospium Chloride	24
64	Tolterodine Tartrate	24
65	Valsartan	24
Total production capacity 2400TPA (Maximum 20 Products at a time) with 3MW coal based CPP		

S.N.	By-Product	TPA	By product from the product
<b>Proposed By- Products from APIs &amp; API Intermediates</b>			
1.	Triphenylphosphine oxide	565.5	CefiximeTrihydrate
		159.94	Cefdinir Monohydrate
		62.4	Cefprozil Monohydrate
		17.16	CefditorenPivoxil
		4.2	CeftazidimePentahydrate
		88.78	7-AVNA
		60.0	MEAT (Thio Ester)
		52.94	7-APCA
		34.32	7-Amino3-thiazole cephalosporanic acid (7-ATCA)
2.	2-Mercaptobenzothiazole	280.8	CefiximeTrihydrate
		57.6	CefpodoximeProxetil
		3.84	Cefpirome Sulfate
		88.46	Cefdinir Monohydrate
		3.6	CefepimeDihydrochloride Monohydrate
		6.0	CefditorenPivoxil
		4.8	CeftazidimePentahydrate
		100.8	Cefotaxime Sodium
		6.0	Ceftizoxime Sodium
		6.47	Cefpodoxime Acid
36.36	MEAT (Thio Ester)		
3.	Sodium Acetate	549.82	Cefuroxime Axetil

ME

3.0 Electrostatic precipitator (ESP) and the stack of adequate height will be provided to coal fired boiler (30 TPH) and Multi cyclone dust collector followed by Bag filter with a adequate height will be provided 10 TPH Coal fired boiler (standby) and 4 TPH & 15 lac K.cal/hr Thermic Fluid heater (standby) for controlling the particulate matter and effective dispersion of flue gases. Scrubber will be provided to control process emissions viz. HBr, HCl, HF and SO<sub>2</sub>. Fresh water requirement from ground water source /tanker supply will be increased from 53.5 m<sup>3</sup>/day to 457 m<sup>3</sup>/day after expansion. Effluent generation will be increased from 9.2 m<sup>3</sup>/day to 298 m<sup>3</sup>/day after expansion. Industrial effluent will be segregated into low and high strength streams based on characteristics of wastewater viz. TDS, COD etc. High TDS/COD effluent stream will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS/COD effluent stream will be treated in the effluent treatment plant (ETP) based biological treatment process followed by reverse osmosis (RO). No effluent will be discharged outside the premises and 'Zero' effluent discharge concept will be adopted. Evaporation salt, process inorganic salts and sludge from wastewater pre-treatment will be sent to TSDF. Process organic residues, spent carbon, spent mixed solvents will be sent cement manufacturers. Fly ash will be sent to cement plant. Catalyst, waste oil and used batteries will be sent to authorized recyclers.

4.0 Public hearing/consultation meeting was held on 4<sup>th</sup> December, 2014.

5.0 All Synthetic Organic Chemicals Industry located outside the notified industrial area/estate are listed at S.N. 5(f) under category 'A' and appraised at Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry) in its meetings held during 29<sup>th</sup> - 30<sup>th</sup> January, 2014, 16<sup>th</sup> - 17<sup>th</sup> March, 2015 and 30<sup>th</sup> November, 2015- 1<sup>st</sup> December, 2015 respectively. Project Proponent and the EIA Consultant namely M/s KKB Envirocare Consultants Pvt. Ltd. have presented EIA / EMP report as per the TOR. EAC has found the EIA / EMP Report and additional information to be adequate and in full consonance with the presented TORs. The Committee recommended the proposal for environmental clearance. M/s Covalent Lab. Pvt. Ltd. has passed a resolution in a meeting of the Board of Directors held on 8<sup>th</sup> July, 2015 that violation of the Environmental (Protection) Act, 1986 will not be repeated. A copy of Board Resolution is submitted. Collector & District Magistrate, Medak has filed case against the unit at Addl. Judge First Class Magistrate Narsapur on 19.08.2015 for violation of provisions of the EIA Notification, 2006.

7.0 Based on the information submitted by the project proponent, the Ministry of Environment and Forests hereby accords environmental clearance to 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. SPECIFIC CONDITIONS:**

- i) Compliance to all the environmental conditions stipulated in the environmental clearance letter no. J-11011/88/2004-IA II(I) dated 30<sup>th</sup> November, 2004 shall be satisfactorily implemented and compliance reports submitted to the Ministry's Regional Office at Bangalore.
- ii) 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.
- iii) Electrostatic precipitator (ESP) and the stack of adequate height shall be provided to coal fired boiler (30 TPH) and Multi cyclone dust collector followed by Bag filter with a adequate height shall be provided 10 TPH Coal fired boiler (standby) and 30m combined stack for 4 TPH & 15 lac K.cal/hr Thermic Fluid heater (standby) for controlling the particulate matter and effective dispersion of flue gases.

- iv) Scrubber shall be provided to control process emissions viz. HBr, HCl, HF and 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.
- v) Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> September, 2009. The levels of PM<sub>2.5</sub>, PM<sub>10</sub>, SO<sub>2</sub>, NO<sub>x</sub>, VOC, CO, HBr, HCl and HF shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MOEF, the respective Zonal office of CPCB and the State Pollution Control Board (SPCB).
- vi) In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the SPCB. Odour management plan shall be implemented.
- vii) The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
- viii) Solvent management shall be carried out as follows :
- i. Reactor shall be connected to chilled brine condenser system
  - ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
  - iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
  - iv. Solvents shall be stored in a separate space specified with all safety measures.
  - v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
  - vii. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- ix) Total fresh water requirement from ground water source and tanker supply shall not exceed 457 m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA.
- x) Effluent generation shall not exceed 298 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. 'Zero' effluent discharge shall be adopted and no effluent will be discharged outside the premises.
- xi) 'Zero' effluent discharge shall be adopted and no effluent shall be discharged outside the premises.
  - xii) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.
  - xiii) Automatic /online monitoring system (24 x 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed. The data to be made available to the respective SPCB and in the Company's website.
  - xiv) 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.
  - xv) 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.
  - xvi) 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 TPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
  - xvii) 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.
  - xviii) 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 alongwith the storm water. Direct exposure of workers to fly ash & dust should be avoided.
  - xix) 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.
  - xx) 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.
  - xxi) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
  - xxii) All the issues raised during the Public Hearing/consultation meeting held on 4<sup>th</sup> December, 2014 shall be satisfactorily implemented and adequate budget provision shall be made accordingly.

- xxiii) 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 Bangalore. Implementation of such program shall be ensured accordingly in a time bound manner.
- xxiv) As proposed, green belt of 55871 m<sup>2</sup> 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.
- xxv) Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.

## **B. GENERAL CONDITIONS:**

- i. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board (SPCB), 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 and Forests. 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 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).
- v. 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.
- vi. 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.
- vii. Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.
- 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. As proposed, the company shall earmark sufficient funds towards capital cost and recurring cost/annum to implement the conditions stipulated by the Ministry of Environment and Forests 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, Zila Parisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who 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, the respective Zonal Office of CPCB and the AP Pollution Control Board. 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 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://envfor.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.

8.0 The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

9.0 The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

10.0 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.



**(Lalit Bokolia)**  
**Additional Director**

Copy to :-

1. The Principal Secretary, Department of Environment, Forest, Science & Technology, Government of Telangana, Hyderabad, A.P.
2. The Chief Conservator of Forests, Regional Office (Southern Zone, Bangalore) Kendriya Sadan, 4th Floor, E&F Wing, II Block Koramangala, Bangalore-560034.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, Telangana Pollution Control Board, Paryavaran Bhawan, A-III, Industrial Estate, Sanath Nagar, Hyderabad - A.P.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, *Jorbagh Road*, New Delhi.
6. Guard File/Monitoring File/Record File.



**(Lalit Bokolia)**  
**Additional Director**

