State Level Environment Impact Assessment Authority (SEIAA)
Telangana State
Government of India
Ministry of Environment, Forests & Climate Change
A-3, Industrial Estate, Sanathnagar, Hyderabad - 500 018.

REGD.POST WITH ACK.DUE

Order No. SEIAA/TS/OL/SRD-181/2020- **Dt:02.02.2021.**

Sub: **SEIAA, TS – M/s. Covalent Laboratories Pvt. Ltd., Unit-I, Sy.No. 315/EE, 337/A, 337/AA, 345/A, 346/A1, 358/1A, 359/AA, 374/A, 374/AA, 375, 376, 377/A, 377/A1, 377/EE/1, 324/EE, 324/E, 336/AA, 328/EE, 329/A, 329/AA, 336/A, 335/A, 335/AA, Gundlamachnoor (V), Hathnoora (M), Sangareddy District – Environmental Clearance (Expansion) - Issued - Reg.**

Ref:
1. EC Order No. F.No.J-11011/88/2004-IA.II(I) dt.30.11.2004.
2. EC Expansion Order No. F.No.J-11011/375/2013-IA II (I) dt.30.12.2015
3. EC (Amendment) Order dt.23.06.2017 and EC (Corrigendum) dt.19.12.2017
4. Application submitted online (proposal no.SIA/TG/IND2/155716/2020) on 14.08.2020 received on 18.07.2020

I. Earlier, the industry obtained Environmental Clearance vide reference 1st cited from MoE&F, GoI. Subsequently, the industry obtained EC (Expansion), EC (Amendment) & EC (Corrigendum) vide reference 2nd & 3rd to manufacture Bulk Drug.

II. Now, vide reference 4th cited for seeking Environmental Clearance for the proposed expansion of **Active Pharmaceutical Ingredients (APIs) and API Intermediates** under **Synthetic Organic Chemicals manufacturing unit** & 5 MW Captive Power Plant in the name of **M/s. Covalent Laboratories Pvt. Ltd., Unit-I, Sy.No. 315/EE, 337/A, 337/AA, 345/A, 346/A1, 358/1A, 359/AA, 374/A, 374/AA, 375, 376, 377/A, 377/A1, 377/EE/1, 324/EE, 324/E, 336/AA, 328/EE, 329/A, 329/AA, 336/A, 335/A, 335/AA, Gundlamachnoor (V), Hathnoora (M), Sangareddy District.** The nearest human habitation viz., Gundlamachnur (V) exists at a distance of 0.58 km and nearest water body is NakkaVagu exists at a distance of 0.88 km from the project site. The total area of the site is 29.57 Ha. Out of that, area earmarked for development of Green belt is 11.87 Ha. (40.14%). The total cost of the project after proposed expansion is Rs. 299.5 Crores and the production capacity of the project after expansion is as follows:

List of Products:

S.No	Name of Product	Capacity	
		Kg/day	TPM
1	Cefixime Trihydrate	4166.7	125.0
2	Cefpodoxime Proxetil	833	25.0
3	Cefuroxime Axetil	2000	60.0
4	Cefuroxime Sodium	66.7	2.0
5	Ceftriaxone Sodium	500	15.0
6	Cefpirome Sulfate	33.3	1.0
7	Cefdinir Monohydrate	200	6.0
8	Cefprozil Monohydrate	166.7	5.0
9	Cefepime Dihydrochloride Monohydrate	33.3	1.0
10	Cefuroxime Acid	100	3.0
11	Cefditoren Pivoxil	33.3	1.0
12	Ceftibuten Monohydrate	66.7	2.0
13	Cefazoline Sodium	33.3	1.0
14	Cefoperazone Sodium	33.3	1.0
15	Cefoxitin Sodium	16.7	0.5
16	Ceftazidime Pentahydrate	16.7	0.5
17	Cefotaxime Sodium	100	3.0
18	Ceftizoxime Sodium	33.3	1.0
19	Cephalothin Sodium	33.3	1.0

S.No	Name of Product	Capacity	
		Kg/day	TPM
20	Cefpodoxime Acid	33.3	1.0
21	Cefcapene Pivoxil	26.7	0.83
22	Cefmetazole Sodium	33.3	1.0
23	Cefmetazole	33.3	1.0
24	7-AVNA	166.7	5.0
25	MEAT (Thio Ester)	166.7	5.0
26	7-APCA	100	3.0
27	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	1.0
28	7-Amino3-thiazole cephalosporanic acid (7-ATCA)	66.7	2.0
29	Cefaclor Monohydrate	666.7	20.0
Maximum any 20 campaign products out of 29 products		**9533**	**286**
Captive Power Generation		**5 MW (3 MW + 2 MW)**	

List of By-products:

S.No	Name of the Product	Name of the By product	Capacity	
			Kg/day	TPM
1	2-Mercaptobenzothiazole	Cefixime Trihydrate	1499.76	45.0
		Cefpodoxime Proxetil	399.84	12.0
		Cefpirome Sulfate	10.64	0.32
		Cefdinir Monohydrate	245.96	7.4
		Cefepime Dihydrochloride Monohydrate	10.05	0.3
		Cefditoren Pivoxil	16.50	0.5
		Ceftazidime Pentahydrate	13.28	0.4
		Cefotaxime Sodium	49.00	1.5
		Ceftizoxime Sodium	16.70	0.5
		Cefpodoxime Acid	18.04	0.54
		MEAT (Thio Ester)	101.00	3.03
2	Ethyl-3-oxobutanoate	Cefaclor Monohydrate	246.05	7.4
3	Phenylacetic acid	Cefixime Trihydrate	1249.80	37.5
		7-AVNA	102.00	3.1
4	Sodium Salts as Recovered By-product (Sodium Bromide+ Sodium Chloride)	Cefixime Trihydrate	1899.07	57.0
		7-AVNA	154.99	4.65
5	Sodium Bromide	Cefuroxime Axetil	441.51	13.24
		Cefdinir Monohydrate	200.20	6.0
6	Sodium Sulfite	Cefixime Trihydrate	4166.00	125.0
7	Triphenylphosphine Oxide	Cefixime Trihydrate	3020.35	90.64
		Cefdinir Monohydrate	444.73	13.34
		Cefprozil Monohydrate	173.16	5.2
		Cefditoren Pivoxil	47.19	1.42
		Ceftazidime Pentahydrate	11.62	0.35
		7-AVNA	246.50	7.4
		MEAT (Thio Ester)	166.65	5.0
		7-APCA	147.00	4.41
		7-Amino3-thiazole cephalosporanic acid (7-ATCA)	95.81	2.9
8	HCl (12%)	Cefixime Trihydrate	7457.14	223.72

III. In the process, synthetic organic chemicals are produced by using various chemicals, solvents, etc.,

IV. 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 proposal in its meetings held on **09.09.2020 & 07.12.2020.** The Sub-Committee constituted by the SEAC in its meeting held on **09.09.2020** inspected the site on **11.09.2020** and submitted the report. Based on the information furnished, presentation made by the proponent and the consultant M/s. KKB Envirocare Consultants Pvt. Ltd., Hyderabad; Report of the Sub-Committee; The SEAC noted that the proponent has submitted self certified compliance report on earlier EC conditions; G.O.Ms. No. 95, dt. 21.09.2007 of the EFS&T Dept., GoAP; G.O.Ms. No. 64, dt. 25.07.2013 of the EFS&T Dept., G.O. Ms. No. 24, dt. 24.04.2019 of the EFS&T Dept.; S.O.1223 (E), dt.27.03.2020 of MoEF&CC, GoI; The Committee considered the project proposal and recommended for issue of Environmental Clearance. The State Level Environment Impact Assessment Authority (SEIAA) in its meeting held on **19.01.2021** examined the proposal and recommendations of SEAC for issue of Environmental Clearance. Accordingly, after discussions in the matter and considering the recommendations of SEAC, the SEIAA, Telangana hereby accords Environmental Clearance to the project for Expansion 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:

A. Specific Conditions:

i. Air pollution:

i The emissions from the existing Coal fired Boilers of capacity 1 x 30 TPH; 1 x 20 TPH; 1 x 10 TPH (standby) and 1 x 4 TPH (standby) shall be routed through APCE i.e., ESP & Multicyclone separator followed by Bag filter and disposed through separate Stacks of height 55m, 45m, 30m & 30m respectively. The concentration of particulates in the emission shall not exceed 50 mg/Nm^3. Thermic fluid heater (1 x 15 lakh kcal/hr) (Coal fired) shall be provided with a stack of height 30m. Sampling Port with removable dummy of not less than 30m diameter in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc., shall be provided to monitor stack emissions. Stack of adequate height shall be provided for D.G. Sets of capacity 5 x 1010 kVA & 1 x 320 kVA (Existing), 1 x 1010 kVA (Proposed) installed with Acoustic Enclosures & Silencers as per CPCB norms.

ii The process emissions containing Hydrogen Chloride& Hydrogen Fluoride are to be routed through Multi Stage Scrubber system. The process emissions containing derivatives of Carbon dioxide and Oxygen gas shall be safely dispersed into the atmosphere. Further, the process emissions containing derivatives of Hydrogen are to be safely dispersed into the atmosphere through water column. The industry shall also provide online pH monitoring system for scrubber. The industry shall meet the emission standards notified by the MoEF&CC.

iii National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.

iv Necessary measures shall be taken to control odour as far as possible. Chillers (brine solution) shall be installed to reduce solvent evaporation losses into the atmosphere. All the solvent storage tanks shall be connected to vent condensers. Regular monitoring of the VOCs shall be carried out using sensors.

v The solvents shall be recovered by installing fractional distillation columns. The recovered solvents shall be reused in the process or sold to authorized end users as raw material. The volatile vapours generated during process shall be routed through condensers and the condensate shall be reused in the plant.

vi As proposed, greenbelt of 11.87 Ha. (40.14%) 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 the road sides etc., Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.

vii Raw materials shall be transported in covered trucks. Raw materials shall be stored under sheds. All the belt conveyors shall be covered with G.I. sheets. Appropriate dust suppression system shall be provided all around the stockpiles and conveyor system. All the roads in the plant area shall be asphalted / concreted and water shall be sprinkled to suppress the dust.

viii The industry shall monitor VOCs in ambient air with online VOC analyzer and connect the data to the server of SPCB.

ix The project proponent shall install 24x7 continuous emission monitoring system at stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB & CPCB online servers and calibrate these system from time to time according to equipment supplier specification through labs recognized under Environment (Protection) Act, 1986 or NABL accredited laboratories.

x The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognized under Environment (Protection) Act, 1986.

xi To control source and the fugitive emission suitable pollution control devices shall be installed to meet the prescribed norms and / or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.

xii Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.

xiii Acoustic enclosure shall be provided to DG set for controlling the noise pollution.

xiv 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.

xv The ambient noise levels should conform to the standards prescribed under E(P)Act, 1986 viz., 75 dB(A) during day time and 70 dB(A) during night time.

xvi The Industry shall provide energy sources for lighting purpose shall preferably be LED based.

xvii Ambient air quality including ambient noise levels must not exceed the standards stipulated under Notification dt. 16.11.2009 issued by the MoEF&CC, GoI. Monitoring of ambient air quality and stack emissions shall be carried out regularly in consultation with TSPCB.

b) Water Pollution:

i The source of water is from Ground water. The total water requirement after expansion shall not exceed 1197 KLD (i.e., Fresh Water of 799 KLD & Recycled treated water of 398 KLD). Quantity of water used for: Process is 262 KLD; Washings is 30 KLD; Boiler feed is 240 KLD; QC & R& D is 5 KLD; Cooling tower makeup is 450 KLD; Scrubber is 10 KLD; Domestic purposes is 55 KLD & Gardening is 145 KLD.

ii The total waste water generated after expansion shall not exceed 451 KLD. Out of that, 294 KLD (HTDS) & 157 KLD (LTDS); 284 KLD are from Process; 30 KLD is from Washings; 5 KLD is from QC & R& D; 40 KLD is from Boiler blow down; 38 KLD is from cooling tower bleed off; 10 KLD is from Scrubber; 44 KLD is from Domestic section.

iii The high TDS and low TDS effluents generated from the process are to be separated and treated separately. The high TDS effluents shall be disposed into stripper followed by MEE and ATFD. The condensate shall be reused in cooling towers after necessary treatment. The LTDS effluents including domestic effluents shall be treated in Biological

ETP followed by RO system. The permeate is to be re-used in the plant and rejects are to be sent to MEE system. The treated effluents shall be recycled completely. The project proponent shall achieve **Zero Liquid Discharge** and in no case the effluent shall be discharged outside the factory premises. The stripper distillate shall be distilled for recovery of solvents / sent to authorized cement plants for co-incineration.

iv The effluent discharged shall confirm to the standards prescribed under Environment (Protection) Rules, 1986 or as specified by the SPCB while granting Consent under the Air/Water Act, whichever is more stringent.

v The proponent shall provide separate storm water drains and harvest the rainwater from the rooftops to recharge the ground water.

vi The industry shall install & maintain separate water meters for recording water consumption for various purposes and also maintain daily records.

vii 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 SPCB and in the Industry's website.

viii The industry shall install IP Camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability and flow meters in the channel / drain provided for carrying the effluent within the premises of the unit.

ix Permission from the competent authority should be obtained for drawl of ground water, if any, required for this project.

x Regular monitoring of ground water level and quality should be carried out by establishing a network of existing wells by the project proponent in and around project area in consultation with Regional Director, CGWB, Southern Region, Hyderabad. Data thus collected should be sent at regular interval to MoEF, CGWA and CGWB, Southern, Region, Hyderabad.

xi Suitable conservation measures to augment groundwater resources in the area shall be planned and implemented in consultation with Regional Director, CGWB, Southern Region, Hyderabad. Suitable measures should be taken for rainwater harvesting.

c) Solid Waste :

i. Hazardous waste generated from the industry such as waste oils, used oils etc., shall be disposed as per the Hazardous Waste (Management, Handling, and Transboundary Movement) Rules, 2016, to the recyclers authorized by TSPCB.

ii. 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.

iii. Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc., Flame arresters shall be provided on tank farm and the solvent transfer through pumps.

iv. The company shall undertake waste minimization measures as: Metering and control of quantities of active ingredients to minimize waste; Reuse of by-products from the process as raw materials or as raw material substitutes in other processes; Use of automated filling to minimize spillage; Venting equipment through vapour recovery system; and Use of high pressure hoses for equipment clearing to reduce wastewater generation.

v. The proponent shall comply with the following w.r.t. solid waste generated:

S.No	Description	Quantity	Mode of Disposal
1	Process Organic residue	19.95 TPD	Sent to cement plants for co-incineration/TSDF
2	Spent Carbon	1.88 TPD	
3	Distillation Bottom Residue	0.7 TPD	
4	Inorganic & Evaporation Salts	31.4 TPD	Sent to TSDF
5	ETP Sludge	1.3 TPD	
6	Evaporation salt (Non-process)	3 TPD	
7	Boiler Ash	75 TPD	Sent to brick manufacturers
8	a) Detoxified Container / Liners drums b) HDPE Carboys/ Drums c) Fibre drums and its rings d) MS Tins	500No. s/ month 1400 Nos/month 13500 kg/month 350 Nos/month	Disposed to TSPCB Authorized agencies after complete detoxification
9	PP Bags	6000 kg/month	Sent to authorized agencies after complete detoxification
10	Spent Mixed solvents	72 KLD	Sent to Authorized cement plants for co-incineration / end users to use as raw materials
11	Waste oils & Grease	20Kl/year	Sent to authorized agencies
12	Used Lead acid Batteries	100No.s/year	Sent to suppliers on buy back basis
13	Misc. Waste (spill control waste)	Lumpsum	TSDF
14	Rejects	Lumpsum	
15	E- waste	Lumpsum	Authorized re-processor or TSDF
16	Waste papers & other types of packing scrap	Lumpsum	Sold to scrap vendors
17	Canteen waste	Lumpsum	Composted on site and reused for greenbelt
18	PVC Scrap	1000 kg/month	Disposed to SPCB Authorized agencies after complete detoxification
19	Used Aluminium cable scrap	500 kg/month	
20	Carton box scrap	1800 kg/month	

B. General Conditions:

i **This order is valid for a period of 7 years.**

ii "Consent for Establishment" shall be obtained from Telangana State Pollution Control Board under Air and Water Act before the start of any activity / construction work at site and also obtain CFO before commencing operations.

iii The industry shall not manufacture any other products and exceeding capacities except those mentioned in this order, without permission.

iv Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as safe drinking water, fuel for cooking, mobile toilets, mobile STP, medical health care, crèche etc., The housing may be in the form of temporary structures to be removed after the completion of the project. The safe disposal of wastewater and solid wastes generated during the construction phase should be ensured.

v No change in the process technology and scope of working should be made without prior approval of the SEIAA, TS. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA, TS/ MoEF&CC, GoI, New Delhi, as applicable.

vi The environment safeguards contained in the EMP Report should be implemented in letter and spirit. The responsibility of implementation of environmental safeguards rests fully with the proponent ie., **M/s. Covalent Laboratories Pvt. Ltd., Unit-I.**

vii The project proponent shall abide by all commitments and recommendations made in the EIA/EMP report, commitment made during their presentation to the Expert Appraisal Committee.

viii All the conditions, liabilities and legal provisions contained in the EC shall be equally applicable to the successor management of the project in the event of project proponent transferring the ownership, maintenance of management of the project to any other entity.

ix The proponent shall submit half-yearly compliance reports in respect of the terms and conditions stipulated in this order in hard and soft copies to the SEIAA; and CCF, Regional office of MoEF&CC, GoI, Chennai on 1st June and 1st December of each calendar year.

x Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone for RSPM, SPM, PM_{10}, $PM_{2.5}$, SO_2, NOx monitoring. 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.

xi Data on ambient air quality (PM_{10}, $PM_{2.5}$, SO_2, NO_2) should be regularly submitted to the Ministry including its Regional Office located at Chennai and the State Pollution Control Board/ Central Pollution Control Board once in six months.

xii Usage of Personnel Protection Equipments by all employees / workers shall be ensured.

xiii 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.

xiv Occupational health surveillance program of the workers should be undertaken periodically to observe any contractions due to exposure to dust and take corrective measures, if needed.

xv Emergency preparedness plan based on the Hazardous identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented.

xvi The Industry 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 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.

xviii The funds earmarked for environmental protection measures (Capital cost is Rs. 2491.0 Lakhs and Recurring Cost is Rs. 2400.0 Lakhs/annum; Budget for CER to be spent is Rs. 49.0 lakhs within 5 years and also the funds earmarked for Corporate Social Responsibility (CSR) activities, should be kept in separate account and should not be diverted for other purpose. The budget allocated for the EMP shall be subsequently increased if the project cost increases at the time of CFO. Year wise expenditure should be reported to the SEIAA, Ministry and its Regional Office located at Chennai.

xix The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned SPCB as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.

xx Officials from the TSPCB and Regional Office of MoEF&CC, GoI, Chennai who would be monitoring the compliance of the stipulated conditions and 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, GoI, Chennai.

xxi The project proponent shall submit the copies of 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.

xxii 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, Telangana. This order shall be displayed in the website of the project proponent.

xxiii 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.

xxiv The company shall undertake eco-development measures including community welfare measures in the project area.

xxv The proponent shall obtain all other mandatory clearances from respective departments.

xxvi Concealing the factual data or failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.

xxvii The SEIAA may revoke or suspend the order, if implementation of any of the above conditions is not satisfactory. The SEIAA reserves the right to alter/modify the above conditions or stipulate any further condition in the interest of environment protection.

xxvii The above conditions will be enforced inter-alia, under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

xxix Grant of EC is also subject to circulars issued under the EIA Notifications 2006, which are available on the MoEF&CC website: www.parivesh.nic.in

Sd/-	**Sd/-**	**Sd/-**
MEMBER SECRETARY	**MEMBER**	**CHAIRMAN,**
SEIAA, T.S.	**SEIAA, T.S.**	**SEIAA, T.S.**

To

Sri M. Narayana Reddy (Managing Director)
M/s. Covalent Laboratories Pvt. Ltd., Unit-I
8-3-677/18, S K D Nagar, Yellareddyguda,
Hyderabad-500073
Ph.No. 040-49483250
Email.id: kmsreddy@covalentlab.com

//T.C.F.B.O//

Joint Chief Environmental Engineer