COVALENT LABORATORIES PRIVATE LIMITED

CIN : U24230TG2002PTC039606

AN USFDA, WHO-GMP & ISO 14001:2004 Certified Company

Admin. Office : #8-3-677/18, 2nd Floor, S.K.D. Nagar,
Yellareddy Guda, Hyderabad - 500 073. Telangana, India
Ph : +91-40-49483333, Fax : +91-40-49483396
Email : info@covalentlab.com Web : www.covalentlab.com

Ref.:CLPL/MS_EAC/I.A.Ind-2/Jly-2017

The Member Secretary,
I.A Division., Industry 2, Govt. of India
Ministry of Environment, Forests & Climate Change,
Indira Paryavaran Bhawan, Aliganj,
Jorbagh Road, New Delhi – 110 003.

Date:18.07.2017

Dear Sir,

Sub: Request for Correction to the Amendment EC issued to our unit M/s.Covalent Laboratories Pvt. Ltd., Unit I - Expansion of bulk drugs & intermediate manufacturing unit-I along with CPP (3MW) at Sy.No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377A, Gundlamachanoor (v), Hatnoora (M), Sangareddy District (formerly Medak Dist.) Telangana State by M/s.Covalent Lab. Pvt. Ltd. – Reg.

Ref.: Environmental Clearance vide No.J-11011/375/2013-IA-II (I), Dated 23rd June, 2017.

In continuation to the above reference, we thank you for considering our request for amendment to the EC and issuing the Amended Environmental Clearance.

We would like to draw your attention to a typographical error from our end during preparation of the EMP and subsequently during the Presentation at the EAC meeting held on 18.04.2017.The typographical error was in the total plot area of the project, which in the EC issued on 30th December 2015 is correctly given as 155197Sq.Mtrs. as per our own submission.

In the process of requesting for amendment to the EC submitted by us on 07.04.2017, in the Form-1, on page 1, point No.5 and Layout copy shown on Slide No.7 ,it is correctly shown as 15.52Ha, i.e., 155197Sq.Mtrs. However in the EMP on page 1 in the first paragraph last word it is mentioned as 11.85Ha instead of 15.52Ha. This was purely due to oversight which we sincerely regret .

Arising out the above , the amended EC dated 23rd June 2017, also has a mention of Land permitted as 11.85Ha on page 5 point no. vii under Section C. This error was identified by the TSPCB Regional Office while processing our Consent Application.

Cont. 2

Copies of the previous EC issued on 30.12.2015 and the Form-I, EMP submitted on 07.04.2017, and presentation given on 18.04.2017 are herewith enclosed for your kind perusal.

Hence, we humbly request you to make necessary correction in the Amended EC (i.e., Total land permitted is 155197Sq.Mtrs or 15.52Ha) and issue the same at the earliest.

Thanking you,

Yours faithfully,

for COVALENT LABORATORIES PVT. LTD.,

M. Narayana Reddy
Managing Director

Encl.: As above Annexures:

I. EC Copy dated 30-12-2015
II. Form I Application with EMP submitted for EC Amendment
III. EC Amendment Presentation given 18-04-2017
IV. Amended EC dated 25-06-2017

Copy to: 1. The Member Secretary, TSPCB, Sanathnagar, Hyderabad
2. The Environmental Engineer, TSPCB, Sangareddy.

Annexures:

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 30th 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 ; 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 27th January, 2015.

Sir,

This has reference to your online proposal no. IA/TG/IND/26256/2013 dated 27th 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 30th 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^2, of which greenbelt will be developed in 55871 m^2 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)
Environmental Clearance (EC)		
1	Flucinazole	2.16

2	Nalidixic acid	14.4
3	Naproxen	36
Consent from APPCB		
1	Cefixime	24.00
2	Cefpodoxime Proxetil	11.99
3	Cefurosime Axetil	24.00
4	Cefuroxime Sodium	3.00
5	Ceftriaxone Sodium	6.00
6	Cefpirome	3.00
7	Cefdini	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	Cefurosime 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 Succunate	6
38	Tolterodine Tartrate	6
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thai-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7- AMCA)	12
40	7-Amino3-thiazole cephalosporanic acid (7-ATCA)	24
41	Lacosamide	120

42	Cinacalcet Hydrochloride	120
43	Fexofenadine Hydrochloride	120
44	Dronedarone Hydrochloride	120
45	Deferasirox	120
46	Silodosin	24
47	Fingolimod Hydrochloride	24
48	Sitaglinptin 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 Cilexitil	24
59	Febuxostat	24
60	Azilsartan medoxomil	24
61	Soilfenacin 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
Proposed By- Products from APIs & API Intermediates			
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

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_2. Fresh water requirement from ground water source /tanker supply will be increased from 53.5 m3/day to 457 m^3/day after expansion. Effluent generation will be increased from 9.2 m^3/day to 298 m^3/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 4th 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 29th - 30th January, 2014, 18th – 17th March, 2015 and 30th November, 2015-1st 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 8th 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 14th 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 30th 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 21st 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_2. 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 16th September, 2009. The levels of $PM_{2.5}$, PM_{10}, SO_2, NOx, 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^3/day and prior permission shall be obtained from the CGWA/SGWA.

x) Effluent generation shall not exceed 298 m^3/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 4th 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^2 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 31st 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, Banglore-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

FORM-I APPLICATION

for EC Amendment

(Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing unit)

Of

M/s. Covalent Laboratories Pvt. Ltd., Unit-I

Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V), Hatnoor (M),
Sangareddy District (formerly Medak District),
Telangana State

Submitted to

Ministry of Environment, Forest & Climate Change,
Paryavaran Bhavan,
New Delhi

COVALENT LABORATORIES PVT. LTD. HYDERABAD

April 2017

CONTENTS

APPENDIX I
(See paragraph – 6)
FORM 1

(I) Basic Information

S. No.	Item	Details
1.	Name of the Project	Covalent Laboratories Private Limited, Unit-I Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing unit along with 3 MW Captive Power Production.
2.	S.No. in the Schedule	5 (f)
3.	Proposed capacity / area / length / tonnage to be handled / command area / lease area / number of wells to be drilled	Existing unit Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load.
4.	New/ Expansion / Modernization	Existing unit Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load.
5.	Existing Capacity / Area etc.	Permitted capacity : 2400 TPA (Any 20 products out of 65 products will be manufactured at a time); Proposed for Amendment: 2420 TPA (with additional 20 TPA) (Any 20 products out of 45 products will be manufactured at a time); Existing total area: 15.52 Ha.
6.	Category of Project i.e., 'A' or 'B'	Category 'A'
7.	Does it attract the general Condition? If Yes, Please specify	No
8.	Does it attract the specific condition? If Yes, Please specify	No
9.	Location	
	Plot/Survey/Khasra No.	Sy.No.315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A
	Village	Gundlamachnoor
	Tehsil	Hatnoor
	District	Sangareddy District (formerly Medak District)
	State	Telangana
10.	Nearest railway station /	Shankerpalli – 22 km (aerial distance)

	airport along with distance in km.	Rajiv Gandhi International Airport, Shamshabad- 53 km (aerial distance)
11.	Nearest Town, City, District Headquarters along with distance in km.	Aerial distance Sangareddy – 8.5 km Hyderabad (ORR): 40 km (S)
12.	Village Panchayats, Zilla Parishad, Municipal Corporation, Local body (complete postal addresses with telephone nos. to be given)	**Village Panchayat address (local body):** Gram Panchayat Office, Gundla Machnoor (V), Hatnoora (M), Sangareddy District, Telangana State
13.	Name of the applicant	Mr. M. Narayana Reddy, Managing Director
14.	Registered Address	M/s. Covalent Laboratories Pvt. Ltd., 8-3-677/18, SKD Nagar, Yellareddyguda, Hyderabad- 500 073. Telangana
15.	Address for correspondence:	M/s. Covalent Laboratories Pvt. Ltd.
	Name	Mr. M. Narayana Reddy
	Designation (Owner/Partner/ CEO)	Managing Director
	Address	M/s. Covalent Laboratories Pvt. Ltd., 8-3-677/18, SKD Nagar, Yellareddyguda, Hyderabad- 500 073. Telangana
	Pin Code	500 073
	E-mail	kmsreddy@covalentlab.com info@covalentlabs.com
	Telephone No.	040-49483333
	Fax No.	040-49483396
16.	Details of Alternative Sites examined, if any, Location of these sites should be shown on a topo sheet.	Not Applicable as this application for EC amendment
17.	Interlinked projects	Nil
18.	Whether separate application of interlined project has been submitted	Not Applicable
19.	If yes, date of submission	Not Applicable
20.	If no, reason	Not Applicable as this application for EC amendment
21.	Whether the proposal involves approval/clearance under: if yes, details of the same and their status to be given (a) The Forest (Conservation)Act, 1980 (b) The Wildlife (Protection) Act, 1972 (c) The C.R.Z Notification, Act, 1991	Nil
22.	Whether there is any Government Order/Policy relevant/relating to the site	Nil
23.	Forest land involved (hectares)	Nil
24.	Whether there is any litigation pending against the project and / or land in which the project is propose to be set up	Nil

	(a) Name of the Court (b) Case No. (c) Orders / directions of the Court, if any and its relevance with the proposed project.	

** Capacity corresponding to sectoral activity (such as production capacity for manufacturing, mining lease area and production capacity for mineral production, area for mineral exploration, length for linear transport infrastructure, generation capacity for power generation etc.,)*

II) Activity

1. Construction, operation or decommissioning of the Project involving actions, which will cause physical changes in the locality (topography, land use, changes in water bodies, etc.)

S. No.	Information/Checklist confirmation	Yes/No	Details thereof (with approximate quantities /rates, wherever possible) with source of information data
1.1	Permanent or temporary change in land use, land cover or topography including increase in intensity of land use (with respect to local land use plan)	**No**	Form I Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load in the existing land. Please refer Plant layout is enclosed as **Annexure – VI of EMP.**
1.2	Clearance of existing land, vegetation and buildings?	**No**	Existing Industry having EC, CFE & latest CFO are presented in **Annexure – I, II & III of EMP.**
1.3	Creation of new land uses?	**No**	Not envisaged
1.4	Pre-construction investigations e.g. bore houses, soil testing?	**No**	Not envisaged.
1.5	Construction works?	**Yes**	The present proposal is for Amendment of additional 20 TPH coal fired Boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load. Only for Boiler in EC Permitted land. **Please refer** Annexure-VI in EMP **for Plant Layout.**
1.6	Demolition works?	**No**	Not envisaged.
1.7	Temporary sites used for construction works or housing of construction workers?	**No**	Construction workers are coming from the nearby villages. No accommodation for the construction workers.

S. No.	Information/Checklist confirmation	Yes/No	Details thereof (with approximate quantities /rates, wherever possible) with source of information data
1.8	Above ground buildings, structures or earthworks including linear structures, cut and fill or excavations	**Yes**	Form I Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load in the existing land. As per the drawing enclosed as Annexure – VI in EMP.
1.9	Underground works including mining or tunneling?	**No**	No Under Ground Works
1.10	Reclamation works?	**No**	Not envisaged.
1.11	Dredging?	**No**	Not envisaged.
1.12	Offshore structures?	**No**	Not envisaged.
1.13	Production and manufacturing processes?	**Yes**	Existing operating unit. Form I Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load in the existing land. Please refer **Table 2 of EMP** for proposed products details.
1.14	Facilities for storage of goods or materials?	**Yes**	Storage yard facility available. Form I Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load in the existing land.
1.15	Facilities for treatment or disposal of solid waste or liquid effluents?	**Yes**	Existing facilities available as per CFO.
1.16	Facilities for long term housing of operational workers?	**No**	Most of the workers are from nearby village and Towns
1.17	New road, rail or sea traffic during construction or operation?	**No**	Not envisaged
1.18	New road, rail, air waterborne or other transport infrastructure including new or altered routes and stations, ports, airports etc?	**No**	Not envisaged
1.19	Closure or diversion of existing transport routes or infrastructure leading to changes in traffic	**No**	Not envisaged

S. No.	Information/Checklist confirmation	Yes/No	Details thereof (with approximate quantities /rates, wherever possible) with source of information data
	movements?		
1.20	New or diverted transmission lines or pipelines?	**No**	Not envisaged
1.21	Impoundment, damming, culverting, realignment or other changes to the hydrology of watercourses or aquifers?	**No**	Not envisaged
1.22	Stream crossings?	**No**	Not envisaged
1.23	Abstraction or transfers of water form ground or surface waters?	**Yes**	Water requirement will be met ground water through private Tankers
1.24	Changes in water bodies or the land surface affecting drainage or run-off?	**No**	Not envisaged
1.25	Transport of personnel or materials for construction, operation or decommissioning?	**Yes**	Unit in Operation and submitting for EC amendment.
1.26	Long-term dismantling or decommissioning or restoration works?	**No**	Not envisaged
1.27	Ongoing activity during decommissioning which could have an impact on the environment?	**No**	Not envisaged. Form I Application for EC amendment of additional 20 TPH coal fired boiler for 2 MW CPP along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load in the existing land.
1.28	Influx of people to an area in either temporarily or permanently?	**No**	Unit in Operation and submitting for EC amendment.
1.29	Introduction of alien species?	**No**	Nil
1.30	Loss of native species or genetic diversity?	**No**	Nil
1.31	Any other actions?	**No**	**--**

2. Use of Natural resources for construction or operation of the Project (such as land, water, materials or energy, especially any resources which are non-renewable or in short supply):

S. No.	Information/checklist confirmation	Yes/No	Details thereof (with approximate quantities /rates, wherever possible) with source of information data
2.1	Land especially undeveloped or agricultural land (ha)	**No**	This application is for EC amendment Boilers and changing individual production capacity with marginal increase in total production capacity.
2.2	Water (expected source & competing users) unit: KLD	**Yes**	Water will be used from private tankers. Water Balance is presented as **Table 3 in EMP.**

2.3	Minerals (MT)	**Yes**	Coal for additional Boilers
2.4	Construction material – stone, aggregates, sand / soil (expected source – MT)	**Yes**	Construction materials for additional boilers only and procured from the local market and construction is based on the plant layout enclosed as **Annexure – VI in EMP.**
2.5	Forests and timber (source – MT)	**No**	-
2.6	Energy including electricity and fuels (source, competing users) Unit: fuel (MT), energy (MW)	**Yes**	Existing Operational unit for Amendment with additional boiler and change in individual production capacity with marginal increase in overall production capacity. Additional Coal will be 100 TPD.
2.7	Any other natural resources (use appropriate standard units)	**No**	**--**

3. Use, storage, transport, handling or production of substances or materials, which could be harmful to human health or the environment or raise concerns about actual or perceived risks to human health.

S. No.	Information/Checklist confirmation	Yes / No	Details thereof (with approximate quantities/rates, wherever possible) with source of information data
3.1	Use of substances or materials, which are hazardous (as per MSIHC rules) to human health or the environment (flora, fauna, and water supplies)	**Yes**	Hazardous chemicals and solvent used for proposed products shall be stored and handled in closed systems.
3.2	Changes in occurrence of disease or affect disease vectors (e.g. insect or water borne diseases)	**No**	Not envisaged
3.3	Affect the welfare of people e.g. by changing living conditions?	**No**	Unit in Operation and submitting for EC amendment.
3.4	Vulnerable groups of people who could be affected by the project e.g. hospital patients, children, the elderly etc.,	**No**	Not envisaged.
3.5	Any other causes	**No**	**-**

4. Production of solid wastes during construction or operation or decommissioning (MT/month)

S. No.	Information/Checklist confirmation	Yes / No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data
4.1	Spoil, overburden or mine wastes	**No**	Not applicable
4.2	Municipal waste (domestic and or commercial wastes)	**Yes**	The commercial waste from the administration building is generated and is sold to scrap venders.
4.3	Hazardous wastes (as per Hazardous Waste Management Rules)	**Yes**	Compliance as per CFO. Existing APIs manufacturing unit and submitting for EC amendment only. Please refer **Table 5 of EMP** for details of

			Hazardous wastes generated from the proposed products.
4.4	Other industrial process wastes	**Yes**	Existing Operational unit for Amendment with additional boiler and change in individual production capacity with marginal increase in overall production capacity. Please refer **Table 5 of EMP** for details of Hazardous wastes generated from the proposed products.
4.5	Surplus product	**No**	Production will be based on the market demand. Hence No surplus production will be generated.
4.6	Sewage sludge or other sludge from effluent treatment	**Yes**	Domestic wastewater is sent to Septic tank and over flow to ETP-ZLD. Please refer **Table 5 of EMP** for ETP Sludge generation details.
4.7	Construction or demolition wastes	**No**	Existing operating industry for EC amendment for new boiler. Construction is as per plant layout and ensures to reduce the construction or demolition waste.
4.8	Redundant machinery or equipment	**No**	Not envisaged
4.9	Contaminated soils or other materials	**No**	Not envisaged.
4.10	Agricultural wastes	**No**	Not envisaged.
4.11	Other solid wastes	**Yes**	Please refer **Table 5 of EMP** for details of other Industrial process wastes from the proposed products

5. Release of pollutants or any hazardous, toxic or noxious substances to air (Kg/hr)

S. No.	Information/Checklist confirmation	Yes / No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data
5.1	Emissions from combustion of fossil fuels from stationary or mobile sources	**Yes**	Existing operating industry for EC amendment for additional 20 TPH coal fired boiler. Additional coal used for additional Boiler of 20 TPH will be 100 TPD. Please refer **Table 8 of EMP** for Emission details
5.2	Emissions from production processes	**Yes**	Please refer **Table 7 of EMP** for Emissions from process reactions of the proposed products. Scrubbers are used for process emissions.
5.3	Emissions from materials handling including storage or transport	**No**	Pumps are being used for handling liquid raw materials and trolleys are used for Solid / Powder type raw materials. Vent condensers provided for storage tanks.
5.4	Emissions from construction activities including plant and	**No**	Not applicable.

S. No.	Information/Checklist confirmation	Yes / No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data
	equipment		
5.5	Dust or odours from handling of materials including construction materials, sewage and waste	**No**	Not envisaged
5.6	Emissions from incineration of waste	**No**	Not applicable/ Sending all Incinerable Hazardous waste to TSDF for incineration / TSPCB Authorized Cement Industries.
5.7	Emissions from burning of waste in open air (e.g. slash materials, construction debris)	**No**	Not envisaged.
5.8	Emissions from any other sources	**No**	Not envisaged.

6. Generation of Noise and Vibration, and Emissions of Light and Heat:

S. No.	Information/ Checklist confirmation	Yes/ No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data with source of information data
6.1	From operation of equipment e.g. engines, ventilation plant, crushers	**Yes**	DG Sets are with inbuilt acoustic enclosures and other utilities equipment are installed in separate room.
6.2	From industrial or similar processes	**Yes**	Noise generated from the pumps, motors, centrifuges etc., which are controlled by proper maintenance.
6.3	From construction or demolition	**No**	Unit in Operation and submitting for amendment of EC.
6.4	From blasting or piling	**No**	Not envisaged.
6.5	From construction or operational traffic	**Yes**	Unit in Operation and submitting for amendment of EC.
6.6	From lighting or cooling systems	**No**	Nil
6.7	From any other sources	**No**	Nil

7. Risks of contamination of land or water from releases of pollutants into the ground or into sewers, surface waters, groundwater, coastal waters or the sea:

S. No.	Information/Checklist confirmation	Yes/ No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data
7.1	From handling, storage, use or spillage of hazardous materials	**Yes**	Spillages such as wastewater / solid wastes / raw materials are possible and the risk of this would be limited to within the premises of the manufacturing facility. Precautionary measures are implemented in the industry for spillage control and to avoid contamination of land or water from the pollutants or raw materials.
7.2	From discharge of sewage or other	**Yes**	Process effluents are pumped to the above

S. No.	Information/Checklist confirmation	Yes/ No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data
	effluents to water or the land (expected mode and place of discharge)		ground level R.C.C lined tanks for storage and neutralization then sent to ETP – ZLD. In-house treatment (ZLD) with primary treatment, secondary treatment and Tertiary treatment. Domestic wastewater is sent to septic tank and the overflow to ETP- ZLD.
7.3	By deposition of pollutants emitted to air into the land or into water	**Yes**	Additional Boilers will be provided with ESP and Bag filter. Process emissions are controlled by multi stage scrubbers.
7.4	From any other sources	**No**	Nil
7.5	Is there a risk of long term build up of pollutants in the environment from these sources?	**No**	Not envisaged.

8. Risk of accidents during construction or operation of the Project, which could affect human health or the environment

S. No.	Information/Checklist confirmation	Yes/ No	Details thereof (with Approximate quantities/rates, wherever possible) with source of information data
8.1	From explosions, spillages, fires etc. from storage, handling, use or production of hazardous substances	**Yes**	All safety precautions are taken by the industry to avoid such accidents.
8.2	From any other causes	**No**	**-**
8.3	Could the project be affected by natural disasters causing environmental damage (e.g. floods, earthquakes, landslides, cloudburst etc)?	**No**	Not envisaged.

9. Factors which should be considered (such as consequential development) which could lead to environmental effects or the potential for cumulative impacts with other existing or planned activities in the locality

S. No.	Information/Checklist confirmation	Yes/ No	Details thereof (with Approximate quantities/ rates, wherever possible) with source of information data
9.1	Lead to development of supporting facilities, ancillary development or development stimulated by the project which could have impact on the environment e.g.:		

S. No.	Information/Checklist confirmation	Yes/ No	Details thereof (with Approximate quantities/ rates, wherever possible) with source of information data
	• Supporting infrastructure (roads, power supply, waste or waste water treatment, etc.)	**No**	• Existing Unit in operation.
	• housing development	**No**	• All employees are coming from nearby villages.
	• extractive industries	**No**	• Not envisaged.
	• supply industries	**No**	• Existing operating unit
	• other	**No**	• Not envisaged.
9.2	Lead to after-use of the site, which could have an impact on the environment	**No**	Not envisaged.
9.3	Set a precedent for later developments	**No**	Not envisaged.
9.4	Have cumulative effects due to proximity to other existing or planned projects with similar effects	**No**	Existing API manufacturing unit and submitting for EC Amendment.

(III) Environmental Sensitivity

S. No.	Areas	Name/ Identity	Aerial distance (within 15 km.) Proposed project location boundary
1	Areas protected under international conventions, national or local legislation for their ecological, landscape, cultural or other related value	**No**	Not applicable. This application is for EC amendment only.
2	Areas which are important or sensitive for ecological reasons - Wetlands, watercourses or other water bodies, coastal zone, biospheres, mountains, forests	**No**	There are no wetlands near the plant site.
3	Areas used by protected, important or sensitive Species of flora or fauna for breeding, nesting, foraging, resting, over wintering, migration	**No**	NIL
4	Inland, coastal, marine or underground waters	**Yes**	Nakka Vagu(rivulet) - 1 km Manjeera River - 2.5 km (W)
5	State, National boundaries	**No**	NIL
6	Routes or facilities used by the public for access to recreation or other tourist, pilgrim areas	**Yes**	National Highway (NH)-65 (previously NH-9): 8 km (Hyderabad to Mumbai)
7	Defense installations	**No**	NIL
8	Densely populated or built-up area	**No**	Gundlamachanoor village is at a distance of 0.7 km from the industry.
9	Areas occupied by sensitive man-made land uses *(hospitals, schools, places of worship, community* *facilities)*	**No**	Hospitals, schools, temples and other general community facilities exist in the settlements in the study area.

S. No.	Areas	Name/ Identity	Aerial distance (within 15 km.) Proposed project location boundary
10	Areas containing important, high quality or scarce resources *(ground water resources, surface resources, forestry, agriculture, fisheries, tourism, minerals)*	**No**	Not applicable
11	Areas already subjected to pollution or environmental damage. *(those where existing legal environmental standards are exceeded)*	**No**	Not applicable. This application is for EC amendment.
12	Areas susceptible to natural hazard which could cause the project to present environmental problems (*earthquakes, subsidence, landslides, erosion, flooding or extreme or adverse climatic conditions*)	**No**	This is existing Bulk Drug (API) and API Intermediate manufacturing industry proposing for EC amendment.

(IV). Proposed Terms of Reference for EIA studies

Not applicable as this is Existing operating industry and submitting Form 1 application for Environmental Clearance amendment for EC issued in 2015.

I hereby given undertaking that the data and information given in the application and enclosures are true to the best of my knowledge and belief and I am aware that if any part of the data and information submitted is found to be false or misleading at any stage, the project will be rejected and clearance given, if any to the project will be revoked at our risk and cost.

Date : 03-04-2017
Place : Hyderabad

M/s.Covalent Laboratories Pvt. Ltd., Unit-I
Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A
Gundla Machanoor (V), Hatnoora (M),
Sangareddy District, Telangana State

COVALENT LABORATORIES PVT. LTD. HYDERABAD

Signature of the applicant
Name: **Mr. M. Narayana Reddy**
Designation: **Managing Director**

NOTE:

1. The project involving clearances under Coastal Regulation Zone Notification, 1991 shall submit with the application a CRZ map duly demarcated by one of the authorized agencies, showing the project activities, w.r.t. C.R.Z (at the stage of ToR) and the recommendations of the State Coastal Zone Management Authority (at the stage of EC). Simultaneous action shall also be taken to obtain the requisite clearance under the provisions of the C.R.Z. Notification, 1991 for the activities to be located in the CRZ.

2. The project 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-à-vis the project location and the recommendation or comments of the Chief Wildlife Warden thereon (at the stage of EC).

3. All correspondence with the Ministry of Environment & Forests including submission of application for TOR / Environmental Clearance, subsequent clarification, as may be required from time to time, participation in the EAC Meeting on behalf of the project proponent shall be made by the authorized signatory only. The authorized signatory should also submit a document in support of his claim of being an authorized signatory for the specific project.

Environmental Management Plan

for Amendment to EC

(Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing unit)

Of

M/s. Covalent Laboratories Pvt. Ltd., Unit-I

Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V), Hatnoor (M),
Sangareddy District (formerly Medak District),
Telangana State

Submitted to

Ministry of Environment, Forest & Climate Change,
Paryavaran Bhavan,
New Delhi

April 2017

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1.0 Introduction

M/s. Covalent Laboratories Pvt. Ltd., Unit-I, Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing facility located at Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A, Gundlamachanoor (V), Hatnoor (M), Sangareddy District (formerly Medak District), Telangana State with an area of 11.85 Ha.

- The industry was originally established in 1989 and obtained its first Environmental Clearance vide J -11011/88/2004-IA II (I) dated 30-11-2004.
- In 2015, industry proposed expansion of the unit and obtained its Environmental Clearance F.No. J-11011/375/2013-IA II (I) dated 30-12-2015 **(Annexure-I)** to manufacture on campaign basis any 20 products at a time out of 65 products with total production capacity of 2400 TPA (200 TPM) along with 3 MW coal based CPP. The Public Hearing for this project was conducted on 04-12-2014.
- Consent for Establishment vide order No. 01/TSPCB/CFE/RO-SR-I/HO/2016-1596 dated 29-09-2016 **(Annexure-II).**
- Consent to Operate vide order no. TSPCB/SRD/HO/CFO/2017-2861 dated 28-01-2017 valid upto 30-09-2021 **(Annexure-III).**

After the unit was put into operation in January 2017, it has come to the knowledge that the overall Steam Requirement was under estimated during the proposal submitted in 2015 for expansion by about 12 TPH. It was also identified that the Captive Power requirement is on the higher side compared to the earlier estimation. Hence, Covalent after thorough understanding of the requirement has proposed to request for Amendment to the Environmental Clearance from the Ministry of Environment, Forests & Climate Change for the installation of an additional boiler of 20 TPH capacity with 2 MW Captive Power generation along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load. The industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.

The Gross investment for the proposed project would increase from the originally estimated Rs.212.94 crores to Rs.225 Crores.

1.1 The Details of the proposal are given hereunder:

M/s. Covalent Laboratories Pvt. Ltd., Unit-I, Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing facility located at Sy. No. 345, 346, 358, 359, 374, 375, 376, 315/E, 377/A, Gundlamachanoor (V), Hatnoor (M), Sangareddy District (formerly Medak District), Telangana State. This site is at a distance of about 15 km (aerial distance) from Hyderabad ORR, 0.7 km from

Gundlamachanoor village and 8 km from the NH-65 (previously NH-9) (Hyderabad-Mumbai Highway).

General location, Google map showing the Co-ordinates and revised Plant layout of the project showing the proposed facilities are presented at **Annexures- IV, V & VI.**

M/s. Covalent Laboratories Pvt. Ltd., Unit-I, has been permitted to manufacture 20 products at a time from total 65 permitted products with total production capacity of 2400 TPA (200 TPM) along with 3MW Captive Power Plant using 30TPH Coal Fired Boiler.

Covalent Unit-I proposes to request for Amendment to the Environmental Clearance from the Ministry of Environment, Forests & Climate Change for the installation of an additional boiler of 20 TPH capacity with 2 MW Captive Power generation along with permitted 3MW Captive Power Plant using 30 TPH coal fired boiler. The industry has also identified about 20 Products to be dropped out of the permitted 65 products and retain 45 products. The industry proposes to marginally revise the individual production capacities of 3 products out of the 45 products thereby marginally increasing the overall production capacity and pollution load of the industry. The industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.

Industry has identified certain by-products from the permitted products manufactured which were disposed as waste in either effluent or in solid waste, that can be reused within the industry or disposed of as by-product. After thorough R&D on these by-products, industry now proposes to recover them in pure form with better yields. Some of these by-products are either utilized back as raw material or sold as by-product to other parties where it can be reused. The additional capacity of the boiler will be utilized to make up the under estimated 12TPH and balance steam will be used in the process for recovery of by-products from waste streams, purification of by-products by adding additional stage and recovery of additional solvents.

The permitted and proposed products with its production capacities are presented in **Tables 1 & 2** respectively.

Table 1: List and Quantities of the Proposed and retained permitted Products and its status

Sl. No.	Product name	Permitted Quantity (Kg/day)	Proposed Quantity (TPA)	No. of Stages	Status
1	**Cefixime Trihydrate**	**2166.7**	780.0	3	Increased
2	**Cefpodoxime Proxetil**	**333.3**	120.0	2	Increased
3	**Cefuroxime Axetil**	**500**	180.0	3	Increased
4	Cefuroxime Sodium	66.7	24.0	1	Retained
5	**Ceftriaxone Sodium**	**500**	180.0	1	Retained
6	Cefpirome Sulfate	33.3	12.0	3	Retained
7	**Cefdinir Monohydrate**	**200**	72.0	4	Retained

Sl. No.	Product name	Permitted Quantity (Kg/day)	Proposed Quantity (TPA)	No. of Stages	Status
8	**Cefprozil Monohydrate**	**166.7**	60.0	3	Retained
9	Cefepime Dihydrochloride Monohydrate	33.3	12.0	2	Retained
10	**Cefuroxime Acid**	**100**	36.0	2	Retained
11	Cefditoren Pivoxil	33.3	12.0	3	Retained
12	Ceftibuten Monohydrate	66.7	24.0	2	Retained
13	Cefazoline Sodium	33.3	12.0	3	Retained
14	Cefoperazone Sodium	33.3	12.0	3	Retained
15	Cefoxitin Sodium	16.7	6.0	4	Retained
16	Ceftazidime Pentahydrate	16.7	6.0	6	Retained
17	**Cefotaxime Sodium**	**100**	36.0	2	Retained
18	Ceftizoxime Sodium	33.3	12.0	1	Retained
19	Cephalothin Sodium	33.3	12.0	2	Retained
20	Cefpodoxime Acid	33.3	12.0	1	Retained
21	Cefcapene Pivoxil	26.7	9.6	2	Retained
22	Cefmetazole Sodium	33.3	12.0	3	Retained
23	Cefmetazole	33.3	12.0	2	Retained
24	**Meropenem**	**166.7**	60.0	2	Dropped
25	Imipenem	66.7	24.0	3	Dropped
26	Cilastatin Sodium	66.7	24.0	3	Dropped
27	Ertapenem Sodium	33.3	12.0	2	Dropped
28	**Doripenem Monohydrate**	**166.7**	60.0	3	Dropped
29	Biapenem	33.3	12.0	2	Dropped
30	**Faropenem Sodium**	**100**	36.0	5	Dropped
31	Panipenem	33.3	12.0	2	Dropped
32	Tebipenem Pivoxil	3.3	1.2	2	Dropped
33	Darifenacin Hydrobromide	16.7	6.0	6	Dropped
34	Solifenacin Succinate	16.7	6.0	5	Dropped
35	Tolterodine Tartrate	16.7	6.0	4	Dropped
36	**7-AVNA**	**166.7**	60.0	2	Retained
37	**MEAT (Thio Ester)**	**166.7**	60.0	1	Retained
38	**7-APCA**	**100**	36.0	2	Retained
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	12.0	1	Retained
40	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**66.7**	24.0	1	Retained

Sl. No.	Product name	Permitted Quantity (Kg/day)	Proposed Quantity (TPA)	No. of Stages	Status
41	**Lacosamide**	**333.3**	120.0	1	Dropped
42	Silodosin	66.7	24.0	1	Dropped
43	Fingolimod Hydrochloride	66.7	24.0	1	Dropped
44	**Cinacalcet Hydrochloride**	**333.3**	120.0	1	Dropped
45	**Fexofenadine Hydrochloride**	**333.3**	120.0	1	Dropped
46	Sitagliptin Phosphate	66.7	24.0	1	Decreased
47	Prasugrel Hydrochloride	66.7	24.0	2	Decreased
48	Venlafaxine Hydrochloride	66.7	24.0	1	Dropped
49	Pregabalin	66.7	24.0	1	Decreased
50	Diacerein	66.7	24.0	2	Decreased
51	**Dronedarone Hydrochloride**	**333.3**	120.0	1	Dropped
52	Linezolid	66.7	24.0	1	Decreased
53	Ropinirole Hydrochloride	66.7	24.0	1	Decreased
54	D-Cycloserine	66.7	24.0	1	Decreased
55	Clopidogrel Hydrogen Sulfate	66.7	24.0	1	Decreased
56	Bosentan	66.7	24.0	1	Decreased
57	Candesartan Cilexitil	66.7	24.0	1	Decreased
58	**Deferasirox**	**333.3**	120.0	1	Dropped
59	Febuxostat	66.7	24.0	1	Decreased
60	Azilsartan medoxomil	66.7	24.0	1	Decreased
61	Solifenacin Succinate	66.7	24.0	1	Decreased
62	Darifenacin Hydrobromide	66.7	24.0	1	Decreased
63	Trospium Chloride	66.7	24.0	1	Decreased
64	Tolterodine Tartrate	66.7	24.0	1	Decreased
65	Valsartan	66.7	24.0	1	Decreased

Table 2: List and Quantities of the Proposed Products and Therapeutic Category

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	Therapeutic Category / API Intermediate
1	**Cefixime Trihydrate**	**3055**	**1100**	Antibiotic
2	**Cefpodoxime Proxetil**	**833**	**300**	
3	**Cefuroxime Axetil**	**833**	**300**	
4	Cefuroxime Sodium	**66.7**	**24**	
5	**Ceftriaxone Sodium**	**500**	**180**	
6	Cefpirome Sulfate	33.3	12	
7	**Cefdinir Monohydrate**	**200**	**72**	
8	**Cefprozil Monohydrate**	**166.7**	**60**	
9	Cefepime Dihydrochloride Monohydrate	33.3	12	
10	**Cefuroxime Acid**	**100**	**36**	Anti-Infective
11	Cefditoren Pivoxil	33.3	12	Antibiotic
12	Ceftibuten Monohydrate	**66.7**	**24**	Anti-Infective
13	Cefazoline Sodium	33.3	12	Anti-Infective
14	Cefoperazone Sodium	33.3	12	Antibiotic
15	Cefoxitin Sodium	16.7	6	
16	Ceftazidime Pentahydrate	16.7	6	
17	**Cefotaxime Sodium**	**100**	**36**	
18	Ceftizoxime Sodium	33.3	12	
19	Cephalothin Sodium	33.3	12	
20	Cefpodoxime Acid	33.3	12	Antibacterial
21	Cefcapene Pivoxil	26.7	10	Antibiotic
22	Cefmetazole Sodium	33.3	12	
23	Cefmetazole	33.3	12	
24	**7-AVNA**	**166.7**	**60**	Cefixime Intermediate Cefdinir Intermediate Cefprozil Intermediate Cefpodoxime Proxetil Intermediate Cefditoren Pivoxil Intermediate
25	**MEAT (Thio Ester)**	**166.7**	**60**	
26	**7-APCA**	**100**	**36**	
27	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	12	
28	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**66.7**	**24**	
29	Sitagliptin Phosphate	**50**	**18**	Antidiabetic
30	Prasugrel Hydrochloride	**50**	**18**	Anti-Hypertensive
31	Pregabalin	**50**	**18**	Anti-Convulsant
32	Diacerein	**50**	**18**	Anti-inflammatory
33	Linezolid	**50**	**18**	Antibiotic
34	Ropinirole Hydrochloride	**50**	**18**	Antidyskinetic

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	Therapeutic Category / API Intermediate
35	D-Cycloserine	50	18	Antituberculosis
36	Clopidogrel Hydrogen Sulfate	50	18	Anti-thrombotic
37	Bosentan	50	18	Anti-Hypertensive
38	Candesartan Cilexitil	50	18	Anti-Hypertensive
39	Febuxostat	50	18	Antigout
40	Azilsartan medoxomil	50	18	Anti-Hypertensive
41	Solifenacin Succinate	50	18	Antimuscarinic Agent
42	Darifenacin Hydrobromide	50	18	Anticholinergic
43	Trospium Chloride	50	18	Antispasmodic
44	Tolterodine Tartrate	50	18	Antimuscarinic Agent
45	Valsartan	50	18	Anti-Hypertensive
	Total (Any 20 products at a time)	**6721**	**2420**	

2.0 Project Description

The manufacturing process of APIs consists of chemical synthesis and multiple stages of processing extending to maximum of 6 stages involving different types of chemical reactions. Typical process description with process details for all 45 products is enclosed at **Annexure-VII**.

2.1 Raw Materials

- Additional coal of about 100 TPD will be used in the additional 20 TPH coal fired boiler for 2 MW CPP with total coal of about 250 TPD.
- The chemicals (raw materials) required for the manufacture of proposed products is presented at **Annexure -VIII** and Hazardous chemicals list is presented at **Annexure-IX.**

3.0 Environmental Management Plan

The environmental management plan (EMP) is delineated based on scientific assessment of pollution generation, its handling, treatment and disposal for gaseous, liquid, and solid wastes.

3.1 Water requirement and Wastewater Generation and their Management / Disposal

The water requirement and wastewater generation for proposed products on regular/campaign basis is presented in **Table 3**.

Table 3: Proposed Water Balance

Sl. No.	Description	Input (KLD)		Output (KLD)		Segregation type of Wastewater	Treatment and Reuse Method
		Fresh Water	Recycled water	Evaporation / Handling Loss	Total Wastewater		
1	Process	162	-	-14	176	HCOD/HTDS	Segregation, Collection and Treatment separately in ETP with ZLD System for reusing the treated effluent in cooling towers
2	Washings (reactors, centrifuges, nutch filters, containers, floor moping, etc.)	25	-	-	25	LTDS/LCOD	
3	Boiler (30 & 20 TPH)	240	-	200	40	LTDS/LCOD	
4	Cooling Towers (5000 TR)	21	279	275	25	LTDS/LCOD	
5	DM Regeneration	12	-	-	12	HTDS/LCOD	
6	Scrubber	8	-	-	8	HTDS/LCOD	
7	Q.C and R&D	5	-	-	5	LTDS/LCOD	
8	Domestic	30	-	5	25		
9	Gardening	50	-	50	-		
Total		**553**	**279**	**516**	**316**	**Reuse:**	Total reuse is 279 KLD
		832		**832**			

The sources of wastewater generation are from the process, floor & reactor washings, utilities, Q.C, R&D, scrubber and plant domestic waste. Total proposed wastewater will be 316 KLD. The effluent will be segregated in to HTDS/ HCOD, HTDS from scrubber and other utilities, LTDS/LCOD and collected by gravity into collection tank separately and the details are presented in **Table 4.** This individual effluent will be pumped to the above ground level R.C.C lined tanks for storage and neutralization. The effluents segregated quantity, characteristics and treatment flow is briefly presented in **Table 4.**

Table 4: Effluent Treatment Flow as per Segregation

Effluent	Qty. (KLD)	pH	TDS (mg/l)	COD (mg/l)	Treatment Flow
HTDS/ HCOD & HTDS	196	2 to 12	<100000	<30000	Collection → Equalization → Neutralization → Settling → Holding → Steam stripper → MEE along with HTDS effluent → Condensate to ETP(biological treatment) → Concentrate to ATFD ATFD Condensate to ETP (Biological Treatment) along with domestic wastewater (septic tank overflow) → Pressure Sand Filter → Activated Carbon Filter → R.O → R.O rejects to MEE.

					R.O Permeate & Condensate to Boiler ATFD Salts to TSDF and stripped solvents to SPCB authorized cement industries
LTDS / LCOD	95	6-10	< 5000	< 3000	Collection → Equalization → Neutralization →ETP (Biological Treatment) along with MEE condensate.
Domestic	25	6-9	< 2000	< 1000	Septic tank→Overflow to Biological treatment of ETP

ETP – ZLD facility consists of primary treatment (equalization and neutralization), secondary treatment (stripper with MEE, ATFD & biological) and tertiary treatment (Pressure sand filter, Activated carbon filter & Reverse Osmosis) will be provided. Domestic wastewater will be sent to septic tank and the overflow to ETP (biological treatment). Concentrate from MEE system will be sent to ATFD and the salts from the evaporation system will be collected and sent to TSDF for safe disposal. Industry also proposes for another MEE.

3.2 Hazardous / Solid Waste Generation, Handling and their Disposal

Solid waste mainly segregated into process organic residues, inorganic salts, boiler ash spent mixed unrecoverable solvents and spent carbon. Hazardous / Solid waste will be segregated, detoxified and collected in the HDPE drums / bags and will be stored in the covered and raised platform with Leachate collection system. The proposed solid waste and other waste generated, handling and disposal method from the various stages of APIs & API intermediates manufacturing plant is presented in the **Table 5**.

Table 5: Hazardous / Solid Waste Generation from the Proposed Products

Sl. No.	Description	Proposed Quantity (TPD)	Handling Method	Disposal
1.	Process Organic	9.8	HDPE Bags / Drums	Sent to SPCB Authorized Cement industries / TSDF
2.	Spent carbon	1		
3.	Distillation residue	Lumpsum		
4.	Inorganic & Evaporation salt (Process)	16.3	HDPE Bags	
5.	Evaporation salt (Non-Process)	2.5		
6.	ETP Sludge	1		
7.	Boiler Ash	75	Stored in covered area	Sold to Cement Brick Manufacturers
Other Hazardous Waste generation from the Plant				
8.	Detoxified Container / Liners	200 Nos./ month	Designated covered	Disposed to SPCB Authorized agencies after complete

Sl. No.	Description	Proposed Quantity (TPD)	Handling Method	Disposal
	drums, HDPE Carboys, Fiber Drums, PP Bags	1000 Nos/month 500 nos/month 500 kg/month	area	detoxification
9.	Spent Mixed solvents	6 KLD	Stored Tanks/ Drums	Sent to SPCB Authorized Recyclers / Cement industries
10.	Waste oils & Grease	2 KL/annum	MS Drums	Sent to SPCB Authorized agencies for reprocessing / recycling.
11.	Used Lead acid Batteries	100 nos/month	Designated covered area	Sent to suppliers on buy-back basis.
12.	E- waste	0.001	Designated covered area	Send to authorized e-waste Collection centers/ registered dismantlers/ authorized recyclers/ return back to manufacturers
13.	Canteen food waste	Lumpsum	HDPE Bags	Disposed to Village authorized agencies
14.	Paper waste & Misc.	Lumpsum	HDPE Bags	Scrap Venders
15.	Misc. Waste (spill control waste)	Lumpsum	Stored in Drums	TSDF

Note: Solid waste quantities maximum on various combinations i.e., 20 products on campaign products at a point of time and R&D products

The overall comparison of various combinations of pollutants from permitted and proposed products are presented in **Table 6**.

Table 6: Comparison of Pollution Loads for the Permitted and Proposed Products

Sl. No.	Description	Permitted	Revised Pollution load (proposed)
1.	Total Production Capacity (TPM)	200	201.67
2.	Water Input for Process (KLD)	161	162
3.	Total Process Effluent (KLD)	171	176
4.	TDS (kg/day)	15518	16348
5.	COD (kg/day)	7153	6567
6.	Fresh Water requirement	457	553
7.	Total Effluent (KLD)	298	316
8.	Organic Residue (kg/day)	9357	9758
9.	Inorganic & Eva. Salts (kg/day)	15519	16339
10.	Spent Carbon (kg/day)	989	992
11.	Total Solid Waste (kg/day	25138	26842
12.	Process Emissions (kg/day)	1712	1507

3.3 Process Emissions Management

Manufacturing of APIs and APIs intermediate will result in gaseous emissions. Maximum process emissions for proposed products are given in **Table 7.** Proposed gaseous emissions will be scrubbed in two stages with water and caustic solution based on the characteristics of gases.

Table 7: Maximum Quantity of Process Emissions from Proposed Products

Name of the Gas	*Quantity (kg/day)	Treatment
CO_2	1316.27	Dispersed into atmosphere
HCl	61.07	Scrubber with water / caustic solution
HF	29.38	Scrubber with caustic sol.
H_2	1.87	Diffused with flame arrestor
SO_2	40.34	Scrubber with caustic solution
HBr	0.02	Scrubber with caustic sol.

3.4 Fugitive emissions

- Solvents used in the manufacturing process are stored in drums and bulk quantities are stored in underground/ above ground storage tanks.
- Solvents are handled in closed conditions thereby reducing the losses in the form of evaporation.
- Proper earthing will be provided to all the electrical equipment and the joints / connections wherever solvent handling is done.
- Reactor and solvent handling pump will have mechanical seals to prevent leakage.
- The industry will take measures for reduction of fugitive emissions and for further reduction industry will provide vent condensers to the tanks.
- Chilled brine circulation will be carried out to condensate the solvent vapour and to the receivers of the solvent vapors which ensures the maximum recovery.
- Solvent vapours from the Centrifuge and Catch pots will be connect to vent condensers.
- The height of the solvent receiver tank vent is above production block roof level and the diameter is 20 mm.
- Flame proof fitting / equipments / pumps / lighting will be used wherever solvents are used. The solvent storage tanks will be provided with breather valve to prevent losses
- Industry has proposed solvent recovery unit with 32 (existing 22 & proposed 10) simple and fractional distillation columns ranging from 2 KL to 8 KL capacity batch / continuous columns height ranging from 12 m to 20 m with Primary and Secondary condenser facility. Industry also proposes additional solvent recovery units.

Solvent Input	Solvent Loss in Effluent	Solvent Loss in Org. residue	Solvent Loss (Handling)	Solvent Recovery	Solvent Recovery
(KLD)	(KLD)	(KLD)	(KLD)	(KLD)	(%)
326	3.1	2.7	13.6	306.5	94

3.5 Emissions–Utilities

Industry has already installed 30 TPH coal fired boiler for 3 MW CPP. Proposes an additional 20 TPH coal fired boiler for 2 MW CPP. Existing 10 TPH, 4 TPH coal fired boilers and 15 lac K.cal/hr coal fired thermic fluid heater will remain standby and will be used during the maintenance. Existing DG sets of 320 KVA and 5x1010 KVA DG sets will be utilized only in case of power failure.

Additional 20 TPH boiler is to meet the steam requirement for recovery of by-products from waste streams, purification of by-products by adding additional stage and recovery of additional solvents.

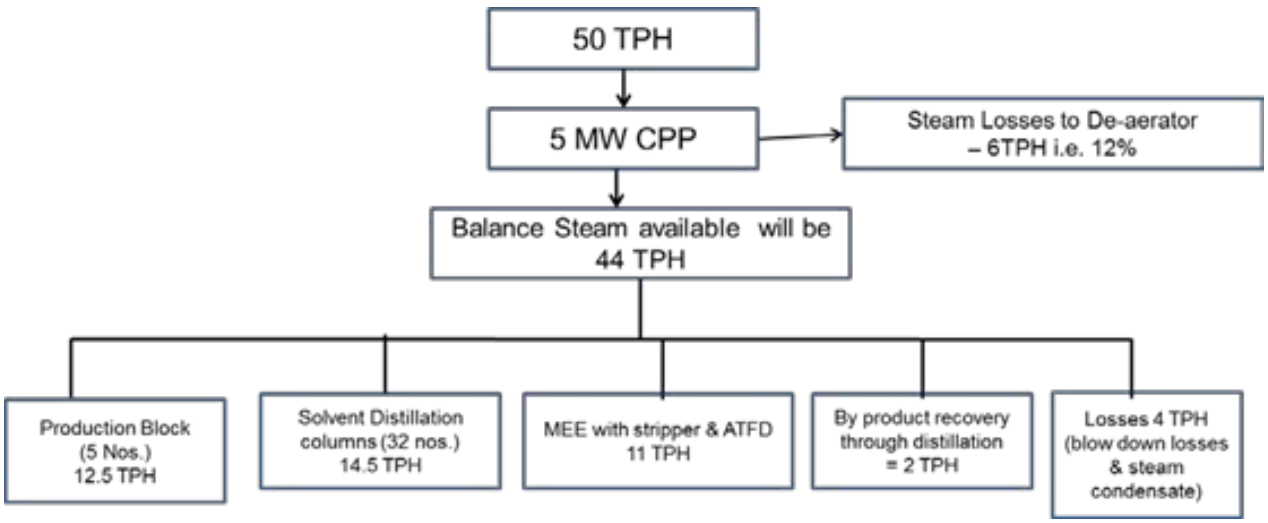
Table 8: Stack Emission Details

Source	Stack Height (m)	Diameter (m)	Temperature (°C)	Flue Gas Flow rate (m^3/hr)	Exit Gas Velocity (m/sec)	PM	SO_2	NOx
						kg/hr		
Coal Fired Boiler								
Additional 20 TPH	45	1.1	150	55440	16.2	2.93	35.42	26.24
Existing 30TPH	55	1.3	150	82404	17.3	4.32	56.23	39.38

The various measures proposed to minimize the pollution from the boiler are as follows:

- Electrostatic Precipitator (ESP) will be installed to control the particulate (PM) emissions within statutory limit of 115 mg/Nm^3. To facilitate wider dispersion of pollutants, 45 m height stack will be installed for 20 TPH Boiler.
- The NOx emissions from the boilers will be controlled by controlling combustion measures, which will be approached by way of low NOx burners or by air stagging in boiler. The NOx emissions will be restricted to below 500 mg/Nm^3.
- Fugitive dust are controlled by adopting dust extraction and dust suppression measures and development of greenbelt along the periphery of the proposed Boiler area.

Boiler Steam Distribution:



3.6 Waste Minimization

Industry proposed to purify some crude by-products using mixed solvents and reusing them in the products and recover some by-products out of waste, thereby minimizing the waste from the products manufactured.

4.0 Conclusions

After thoroughly verifying the requirements and approvals given to the industry, it was identified that the steam and power requirement has been underestimated by industry. Hence proposed to install an additional 20 TPH boiler for 2 MW Captive Power generation along with the permitted 3MW Captive Power Plant using 30 TPH coal fired boiler to meet the underestimated steam requirements of the industry. Industry also felt that about 20 products added does not have good market and hence proposed to drop 20 products from the total 65 products. Thereby total products reduced to 45 and modified production capacity marginally increased by 20 TPA. The industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.

Following points are identified from the above EMP:

1. Total production capacity marginally increased from 200 TPM to 201.67 TPM.
2. Overall process effluent marginally increased from 171 KLD to 176 KLD.
3. Overall solid waste has marginally increased from 25138 kg/day to 26842 kg/day.
4. Overall solvent recovery improved from 93% to 94%.
5. Overall reduction in gaseous emissions from 1712 kg/day to 1507 kg/day.
6. Spent Mixed solvents are used for purification and recovery of by-products that was previously included in Hazardous waste is now recovered.

Industry humbly requests the MoEF&CC and EAC to consider the above Amendments to Environmental Clearance and issue us the EC Amendment.

Welcome

To

The Hon'ble Expert Appraisal Committee (Industry-2)

Ministry of Environment , Forests & Climate Change, Govt. of India

The Presentation on amendment in EC

For

Covalent Laboratories Pvt. Ltd., Unit-I

Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A
Gundlamachanoor (V), Hatnoor(M), Sangareddy District (formerly Medak District), Telangana State.

18-04-2017

Project Proponent
M/s. Covalent Laboratories Pvt. Ltd., Unit-I
Hyderabad

Consultant
M/s KKB Envirocare Consultants Pvt. Ltd
Hyderabad
Sl. No. 91 NABET website as on 10-04-2017

Chronological status

S.No.	Activity	Date
1	First EC order vide No. J -11011/88/2004-IA II (I)	30-11-2004
2	Industry proposed for expansion and obtained its EC vide F.No. J-11011/375/2013-IA II (I)	30-12-2015
3	CFE from TSPCB vide order No. 01/TSPCB/CFE/RO-SR-I/HO/2016-1596	29-09-2016
4	CFO from TSPCB vide order No. TSPCB/SRD/HO/CFO/2017-2861	28-01-2017
4	Acknowledgment for EC Amendment Application	07-04-2017
5	Acceptance for EC Amendment Application	08-04-2017

 # Date of Public Hearing Conducted on 04-12-2014

Salient Features of the Project

ANNEXURE - III

Name of the Project	Permitted Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing Unit **2400 TPA (200 TPM) along with 3MW Captive Power Plant using 30TPH Coal Fired Boiler.** (any **20 products at a time from total 65 permitted products** on campaign basis) by **M/s. Covalent Laboratories Pvt. Ltd., Unit-I**
Project Location	Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A, Gundlamachanoor (V), Hatnoor (M), Sangareddy District (formerly Medak District), Telangana State.
Environmental Clearance (EC)	EC vide order No. F.No. J-11011/375/2013-IA II (I) dated 30-12-2015 Permitted Capacity : 2400 TPA (200 TPM) along with 3 MW coal based CPP (Any 20 products at a time out of 65 products)
CFE	CFE from TSPCB No. vide order No. 01/TSPCB/CFE/RO-SR-I/HO/2016-1596 dated 29-09-2016
CFO	CFO from TSPCB vide order No. TSPCB/SRD/HO/CFO/2017-2861 dated 28-01-2017 valid upto 30-09-2021
Land Area	Total land 11.85 Ha
Amendment in Utilities and Production	**Permitted** : 3MW Captive Power Plant using 30TPH coal fired boiler with 150 TPD coal consumption. Electrostatic Precipitator (ESP) is installed to control the particulate (PM) emissions within statutory limit of 115 mg/Nm^3 & 55 m height stack installed for 30 TPH Boiler to facilitate wider dispersion of pollutants Existing 10 TPH, 4 TPH coal fired boilers and 15 lac K.cal/hr coal fired thermic fluid heater are standby. **For amendment:** Proposes an additional 20 TPH coal fired boiler for 2 MW Captive Power Generation with additional 100 TPD coal (Total coal: 250 TPD) ➢ After the unit was put into operation in January 2017, it has come to the knowledge that the overall Steam and power requirement was under estimated during the proposal submitted in 2015 for expansion by about 12 TPH. ➢ With thorough understanding of the requirement, industry proposed for the installation of an additional boiler of 20 TPH coal fired boiler with 2 MW Captive Power generation. ➢ Also proposes changes in the list of products i.e. dropping 20 products out of total 65 products and revise individual production capacity of about 3 products. ➢ Industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant
Water Requirement	Permitted : 457 KLD (Fresh Water); After amendment : 543 KLD (Fresh water) Additional fresh water requirement after amendment will be 86 KLD (Source : Private Tankers)
Wastewater generation	Permitted : 298 KLD; After Amendment: 315 KLD Amendment for additional 17 KLD. (Total 315 KLD will be segregated and sent to proposed ETP-ZLD with in the premises)
Investment	Gross investment increases from Rs.212.94 crores to Rs.225 Crores. Capital cost for Environmental Protection Measures for Air Pollution Control (ESP with Stack) would increase by Rs.100 lakhs

Reasons for EC Amendment

ANNEXURE - III

S. No	Description	Permitted	After Amendment	Reasons For Amendment	Pollution mitigation measures
1	Products	20 products out of total 65 products with total production capacity of 2400 TPA (200 TPM)	20 Products to be dropped out of the permitted 65 products and retain 45 products. Total production capacity would be 2420 TPA (202 TPM)	• Industry proposes to drop 20 products which does not have good market from total 65 products. • Industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant	--
2	Boilers Coal fired	30 TPH with 3MW Captive Power generation	Additional 20 TPH capacity with 2 MW Captive Power generation Total 5 MW Captive Power Plant from 30 & 20 TPH Boilers	▪ To meet the steam & power requirements which were underestimated during the EC approval. ▪ Steam is required for purification of by-products which are to be re-used in the plant, solvent recovery, ETP, etc.	Electrostatic Precipitators followed with a stack of 45m height will be provided to control particulate emissions within permissible limits.

Project Site Location Map

ANNEXURE - III

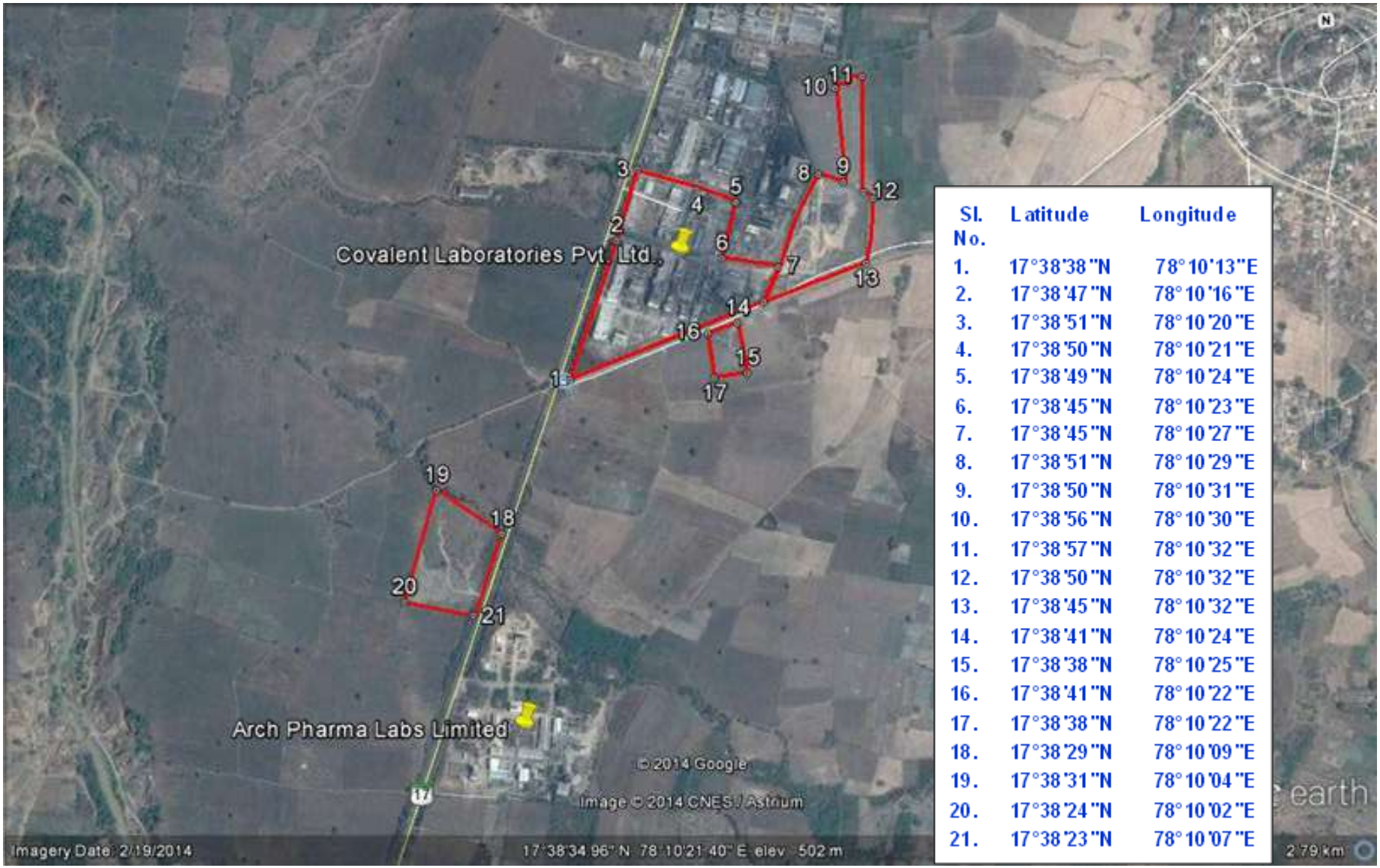
Telangana State

Hatnoor Mandal, Sangareddy District

Project Site

Google Map showing Project Boundaries

ANNEXURE - III



Sl. No.	Latitude	Longitude
1.	17°38'38"N	78°10'13"E
2.	17°38'47"N	78°10'16"E
3.	17°38'51"N	78°10'20"E
4.	17°38'50"N	78°10'21"E
5.	17°38'49"N	78°10'24"E
6.	17°38'45"N	78°10'23"E
7.	17°38'45"N	78°10'27"E
8.	17°38'51"N	78°10'29"E
9.	17°38'50"N	78°10'31"E
10.	17°38'56"N	78°10'30"E
11.	17°38'57"N	78°10'32"E
12.	17°38'50"N	78°10'32"E
13.	17°38'45"N	78°10'32"E
14.	17°38'41"N	78°10'24"E
15.	17°38'38"N	78°10'25"E
16.	17°38'41"N	78°10'22"E
17.	17°38'38"N	78°10'22"E
18.	17°38'29"N	78°10'09"E
19.	17°38'31"N	78°10'04"E
20.	17°38'24"N	78°10'02"E
21.	17°38'23"N	78°10'07"E

Plant Layout

ANNEXURE - III

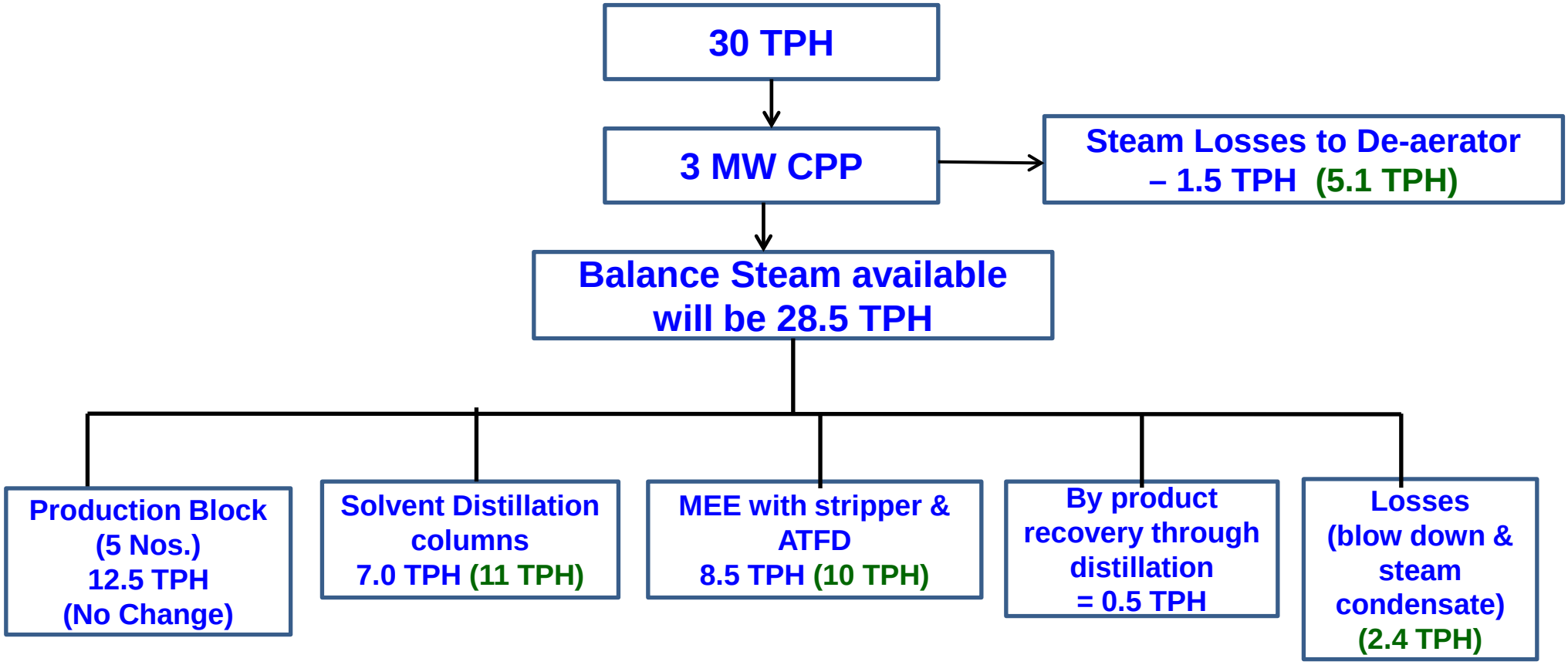
Steam Requirement

ANNEXURE - III

- Steam is required for captive power generation, process, solvent recovery and ETP (MEE with stripper & ATFD)
- Permitted 30 TPH coal fired boiler steam distribution is as follows:
  - For generating 3 MW captive power
  - 12.5 TPH steam is distributed to the 5 production blocks.
  - Steam loss through de-aerator of about 1.5 TPH
  - Other than process, steam is required for solvent recovery (7 TPH), ETP (MEE with stripper & ATFD) (8.5 TPH) and for recovery of by-products (0.5 TPH).
- Due to underestimation of steam requirement and also as the power requirement is on higher side, industry identified an additional 12 TPH of steam is required for better operations
- Industry also proposes to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.
- Hence Industry requests for additional 20 TPH coal fired boiler with 2 MW Captive power generation.

Estimation of Steam Requirement during EC Application

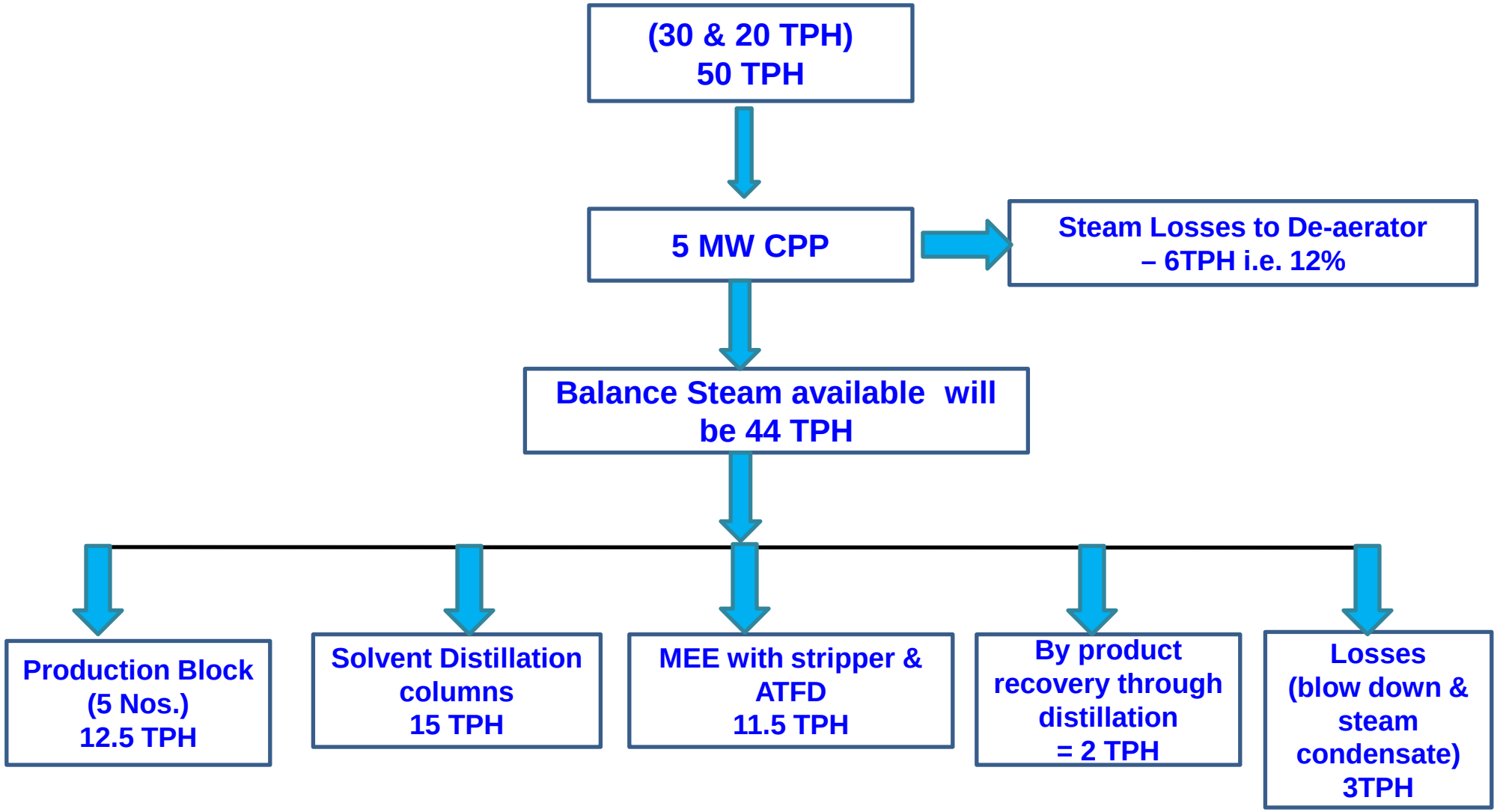
ANNEXURE - III



- Estimation of steam requirement was based on above distribution.
- But actual requirement was steam losses to De-Aerator (5.1 TPH), Process (No change), Solvent Distillation (11 TPH), Stripper, MEE & ATFD (10 TPH), By-product recovery (0.5 TPH) and additional losses for steam ejector & steam condensate (2.4 TPH).
- Hence the actual under estimation was 12 TPH considering the actual losses of about 12% for De-aerator and 5-6% for blow down & condensate losses. Thereby totaling to Boiler requirement of 42 TPH

Re-estimation of Steam after considering all Parameters

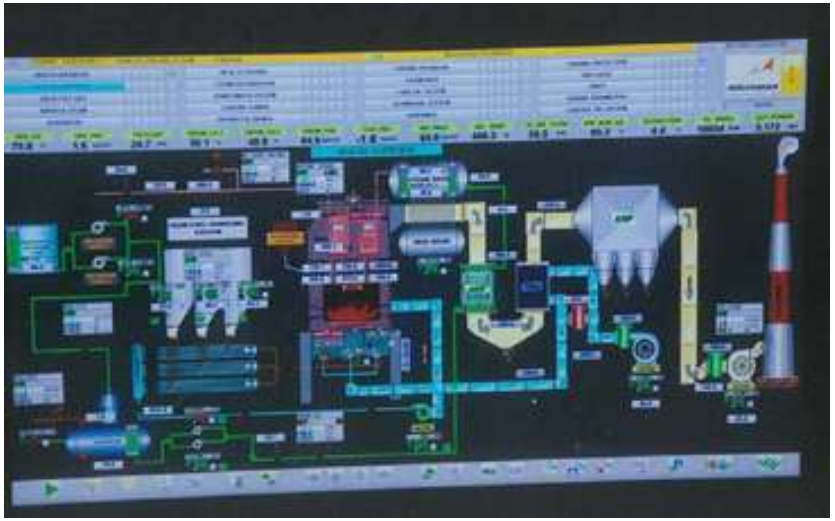
ANNEXURE - III



Underestimated Steam of 12 TPH + additional steam of 8 TPH incl. losses = 20TPH of addl. Boiler and 30TPH existing boiler.

Photographs of Installed 30 TPH Boiler for 3 MW CPP

ANNEXURE - III



List and Quantities of the Proposed and retained permitted Products and its status

ANNEXURE - III

Sl. No.	Products	Permitted Quantity (TPA)	Proposed Quantity (TPA)	CAS No.	Status	Therapeutic Category / API Intermediate
1	**Cefixime Trihydrate**	**780**	**1100**	125110-14-7	Increased	Antibiotic
2	**Cefpodoxime Proxetil**	**120**	**300**	87239-81-4	Increased	
3	**Cefuroxime Axetil**	**180**	**300**	64544-07-6	Increased	
4	Cefuroxime Sodium	24	**24**	56238-63-2	Retained	
5	**Ceftriaxone Sodium**	**180**	**180**	104376-79-6	Retained	
6	Cefpirome Sulfate	12	12	98753-19-6	Retained	
7	**Cefdinir Monohydrate**	**72**	**72**	213978-34-8	Retained	
8	**Cefprozil Monohydrate**	**60**	**60**	121123-17-9	Retained	
9	Cefepime Dihydrochloride Monohydrate	12	12	123171-59-5	Retained	
10	**Cefuroxime Acid**	**36**	**36**	55268-75-2	Retained	Anti-Infective
11	Cefditoren Pivoxil	12	12	117467-28-4	Retained	Antibiotic
12	Ceftibuten Monohydrate	24	**24**	97519-39-6	Retained	Anti-Infective
13	Cefazoline Sodium	12	12	27164-46-1	Retained	Anti-Infective
14	Cefoperazone Sodium	12	12	62893-20-3	Retained	Antibiotic
15	Cefoxitin Sodium	6	6	33564-30-6	Retained	
16	Ceftazidime Pentahydrate	6	6	78439-06-2	Retained	
17	**Cefotaxime Sodium**	**36**	**36**	64485-93-4	Retained	
18	Ceftizoxime Sodium	12	12	68401-82-1	Retained	
19	Cephalothin Sodium	12	12	58-71-9	Retained	
20	Cefpodoxime Acid	12	12	80210-62-4	Retained	Antibacterial

List and Quantities of the Proposed and retained permitted Products and its status

ANNEXURE - III

Sl. No.	Products	Permitted Quantity (TPA)	Proposed Quantity (TPA)	CAS No.	Status	Therapeutic Category / API Intermediate
21	Cefcapene Pivoxil	9.6	10	105889-45-0	Retained	Antibiotic
22	Cefmetazole Sodium	12	12	56796-39-5	Retained	
23	Cefmetazole	12	12	56796-20-4	Retained	
24	**Meropenem**	**60**	-	96036-03-2	Dropped	Antibiotic
25	Imipenem	24	-	74431-23-5	Dropped	
26	Cilastatin Sodium	24	-	81129-83-1	Dropped	
27	Ertapenem Sodium	12	-	153773-82-1	Dropped	
28	**Doripenem Monohydrate**	**60**	-	364622-82-2	Dropped	
29	Biapenem	12	-	153851-71-9	Dropped	
30	**Faropenem Sodium**	**36**	-	122547-49-3	Dropped	
31	Panipenem	12	-	87726-17-8	Dropped	
32	Tebipenem Pivoxil	1.2	-	161715-24-8	Dropped	
33	Darifenacin Hydrobromide	6	-	133099-07-7	Dropped	Anticholinergic
34	Solifenacin Succinate	6	-	242478-38-2	Dropped	Antimuscarinic
35	Tolterodine Tartrate	6	-	124937-52-6	Dropped	Antispasmodic
36	**7-AVNA**	**60**	**60**	79349-82-9	Retained	Cefixime Intermediate
37	**MEAT (Thio Ester)**	**60**	**60**	143183-03-3	Retained	Cefdinir Intermediate
38	**7-APCA**	**36**	**36**	120709-09-3	Retained	Cefprozil Intermediate

List and Quantities of the Proposed and retained permitted Products and its status

ANNEXURE - III

Sl. No.	Products	Permitted Quantity (TPA)	Proposed Quantity (TPA)	CAS No.	Status	Therapeutic Category / API Intermediate
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	12	12	24701-69-7	Retained	Cefpodoxime Proxetil Intermediate
40	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**24**	**24**	155723-02-7	Retained	Cefditoren Pivoxil Intermediate
41	**Lacosamide**	**120**	-	175481-36-4	Dropped	Anticonvulsant
42	Silodosin	24	-	160970-64-9	Dropped	Antagonist
43	Fingolimod Hydrochloride	24	-	162359-56-0	Dropped	Multiple Sclerosis
44	**Cinacalcet Hydrochloride**	**120**	-	364782-34-3	Dropped	Treatment of Hyperparathyroidism
45	**Fexofenadine Hydrochloride**	**120**	-	153439-40-8	Dropped	Antihistamine
46	Sitagliptin Phosphate	24	**18**	654671-78-0	Decreased	Antidiabetic
47	Prasugrel Hydrochloride	24	**18**	389574-19-0	Decreased	Anti-Hypertensive
48	Venlafaxine Hydrochloride	24	-	99300-78-4	Dropped	Anti-depressant
49	Pregabalin	24	**18**	148553-50-8	Decreased	Anti-Convulsant
50	Diacerein	24	**18**	13739-02-1	Decreased	Anti-inflammatory
51	**Dronedarone Hydrochloride**	**120**	-	141625-93-6	Dropped	Anti-arrhythmic
52	Linezolid	24	**18**	165800-03-3	Decreased	Antibiotic
53	Ropinirole Hydrochloride	24	**18**	91374-20-8	Decreased	Antidyskinetic

List and Quantities of the Proposed and retained permitted Products and its status

ANNEXURE - III

Sl. No.	Products	Permitted Quantity (Kg/Day)	Proposed Quantity (TPA)	CAS No.	Status	Therapeutic Category / API Intermediate
54	D-Cycloserine	24	18	68-41-7	Decreased	Antituberculosis
55	Clopidogrel Hydrogen Sulfate	24	18	135046-48-9	Decreased	Anti-thrombotic
56	Bosentan	24	18	147536-97-8	Decreased	Anti-Hypertensive
57	Candesartan Cilexitil	24	18	145040-37-5	Decreased	Anti-Hypertensive
58	**Deferasirox**	**120**	-	201530-41-8	Dropped	Antidote
59	Febuxostat	24	18	144060-53-7	Decreased	Antigout
60	Azilsartan medoxomil	24	18	863031-21-4	Decreased	Anti-Hypertensive
61	Solifenacin Succinate	24	18	242478-38-2	Decreased	Antimuscarinic Agent
62	Darifenacin Hydrobromide	24	18	133099-07-7	Decreased	Anticholinergic
63	Trospium Chloride	24	18	10405-02-4	Decreased	Antispasmodic
64	Tolterodine Tartrate	24	18	124937-52-6	Decreased	Antimuscarinic Agent
65	Valsartan	24	18	137862-53-4	Decreased	Anti-Hypertensive
Maximum Production on various combinations (any 20 products at a time on campaign basis)		**2400**	**2420**			
Captive Power Generation		**3 MW**	**3 & 2 MW**			

Proposed Products and Therapeutic Category

ANNEXURE - III

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	CAS No.	Therapeutic Category / API Intermediate
1	**Cefixime Trihydrate**	**3055**	**1100**	125110-14-7	Antibiotic
2	**Cefpodoxime Proxetil**	**833**	**300**	87239-81-4	
3	**Cefuroxime Axetil**	**833**	**300**	64544-07-6	
4	Cefuroxime Sodium	**66.7**	**24**	56238-63-2	
5	**Ceftriaxone Sodium**	**500**	**180**	104376-79-6	
6	Cefpirome Sulfate	33.3	12	98753-19-6	
7	**Cefdinir Monohydrate**	**200**	**72**	213978-34-8	
8	**Cefprozil Monohydrate**	**166.7**	**60**	121123-17-9	
9	Cefepime Dihydrochloride Monohydrate	33.3	12	123171-59-5	
10	**Cefuroxime Acid**	**100**	**36**	55268-75-2	Anti-Infective
11	Cefditoren Pivoxil	33.3	12	117467-28-4	Antibiotic
12	Ceftibuten Monohydrate	**66.7**	**24**	97519-39-6	Anti-Infective
13	Cefazoline Sodium	33.3	12	27164-46-1	Anti-Infective
14	Cefoperazone Sodium	33.3	12	62893-20-3	Antibiotic
15	Cefoxitin Sodium	16.7	6	33564-30-6	
16	Ceftazidime Pentahydrate	16.7	6	78439-06-2	
17	**Cefotaxime Sodium**	**100**	**36**	64485-93-4	
18	Ceftizoxime Sodium	33.3	12	68401-82-1	
19	Cephalothin Sodium	33.3	12	58-71-9	
20	Cefpodoxime Acid	33.3	12	80210-62-4	Antibacterial
21	Cefcapene Pivoxil	26.7	10	105889-45-0	Antibiotic
22	Cefmetazole Sodium	33.3	12	56796-39-5	
23	Cefmetazole	33.3	12	56796-20-4	

Proposed Products and Therapeutic Category

ANNEXURE - III

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	CAS No.	Therapeutic Category of API Intermediate
24	**7-AVNA**	**166.7**	**60**	79349-82-9	Cefixime Intermediate
25	**MEAT (Thio Ester)**	**166.7**	**60**	143183-03-3	Cefdinir Intermediate
26	**7-APCA**	**100**	**36**	120709-09-3	Cefprozil Intermediate
27	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	12	24701-69-7	Cefpodoxime Proxetil Intermediate Cefditoren Pivoxil Intermediate
28	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**66.7**	**24**	155723-02-7	
29	Sitagliptin Phosphate	**50**	**18**	654671-78-0	Antidiabetic
30	Prasugrel Hydrochloride	**50**	**18**	389574-19-0	Anti-Hypertensive
31	Pregabalin	**50**	**18**	148553-50-8	Anti-Convulsant
32	Diacerein	**50**	**18**	13739-02-1	Anti-inflammatory
33	Linezolid	**50**	**18**	165800-03-3	Antibiotic
34	Ropinirole Hydrochloride	**50**	**18**	91374-20-8	Antidyskinetic
35	D-Cycloserine	50	18	68-41-7	Antituberculosis
36	Clopidogrel Hydrogen Sulfate	50	18	135046-48-9	Anti-thrombotic
37	Bosentan	50	18	147536-97-8	Anti-Hypertensive
38	Candesartan Cilexitil	50	18	145040-37-5	Anti-Hypertensive
39	Febuxostat	50	18	144060-53-7	Antigout
40	Azilsartan medoxomil	50	18	863031-21-4	Anti-Hypertensive
41	Solifenacin Succinate	50	18	242478-38-2	Antimuscarinic Agent
42	Darifenacin Hydrobromide	50	18	133099-07-7	Anticholinergic
43	Trospium Chloride	50	18	10405-02-4	Antispasmodic
44	Tolterodine Tartrate	50	18	124937-52-6	Antimuscarinic Agent
45	Valsartan	50	18	137862-53-4	Anti-Hypertensive
	Total (Any 20 products at a time)	**6721**	**2420**		
	Captive Power Generation	**3 & 2 MW**			

Recovered & Purified By-Products for Reuse

ANNEXURE - III

- R&D is a continuous process. Covalent, with a specific focus on waste minimization has identified some by-products for recovery & reuse in the plant and some by-products for recovery & sale. In this line the following table shows the quantities of by-products recovered & reused/sold.

S. No.	By-Product	Permitted Crude (TPA)	Proposed Crude (TPA)	By product from the product	Reuse/ Sale
1.	**Triphenylphosphine oxide**	565.3	797.6	**Cefixime Trihydrate**	Reuse
2.	**2-Mercaptobenzothiazole**	280.7	396.05	**Cefixime Trihydrate**	Reuse
		57.5	143.94	**Cefpodoxime Proxetil**	Reuse
		36.36	36.36	**MEAT (Thio Ester)**	Reuse
3.	**Recovered Sodium Salts** (Sodium Bromide & Sodium Chloride)	-	623.5	**Cefixime Trihydrate** **Cefuroxime Axetil** **7-AVNA**	Sale
4.	**Phenyl acetic acid**		330.05	**Cefixime Trihydrate**	Reuse
		-	36.72	**7-AVNA**	Reuse

- Sodium Bromide is 426.8 TPA (68.5 %) in the total recovered Sodium Salts of 623.5 TPA.

Maximum Pollution Load For The Permitted Products On Various Combinations

ANNEXURE - III

Product	PRODUCTION		EFFLUENT DETAILS				SOLID WASTE				Emissions	
	Tons / Month	Per day (Kg)	Water Input Per Day (Lit)	Total Effluent Per Day (Lit)	TDS (Kg/day)	COD (Kg/ day)	Org.res./ Semi solid (Kg/day)	Inorganics + EVA.Salts (Kg/day)	Spent Carbon (Kg/ day)	Total S.W. (Kg/ day)	Process (Kg/ day)	Solvent Loss (Kg/ day)
Proposed Products (Maximum 20 Products at a time)												
Combination-1	***200***	***6667***	138238	150642	12380	5786	7784	12380	847	21011	1176	15469
Combination-2	164	5467	***160959***	***175001***	15201	7069	8593	15201	916	24711	1451	15006
Combination-3	177	5900	160626	174341	14973	7151	8750	14973	956	24680	1411	15344
Combination-4	172	5727	154493	168381	***15518***	6716	8398	***15519***	885	24802	1507	15161
Combination-5	169	5633	159916	173560	14894	***7153***	8690	14894	956	24540	1529	15319
Combination-6	179	5967	149211	162880	14633	6631	***9357***	14633	938	24928	1334	15071
Combination-7	190	6333	139022	151718	14039	5837	8118	14051	***974***	23143	1290	14326
Combination-8	178	5933	154443	168416	15110	6776	9093	15110	935	***25138***	1393	15469
Combination-9	155	5177	143368	157037	14151	6331	7409	14152	797	22358	***1712***	13418
Combination-10	189	6300	154201	167821	15000	6809	8558	15000	925	24483	1548	***15691***

Maximum Pollution Load For The Permitted Products On Various Combinations

ANNEXURE - III

Combination-1: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefuroxime Acid + Cefotaxime Sodium + Meropenem + Doripenem Monohydrate + Faropenem Sodium + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Lacosamide + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Dronedarone Hydrochloride + Deferasirox

Combination-2: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Meropenem + Imipenem + Doripenem Monohydrate + Biapenem + Faropenem Sodium + 7-AVNA + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Fingolimod Hydrochloride + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Pregabalin + Dronedarone Hydrochloride

Combination-3: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Meropenem + Imipenem + Doripenem Monohydrate + Biapenem + Faropenem Sodium + 7-AVNA + 7-APCA + Fingolimod Hydrochloride + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Pregabalin + Dronedarone Hydrochloride

Combination-4: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefcapene Pivoxil + Meropenem + Imipenem + Doripenem Monohydrate + Faropenem Sodium + 7-AVNA + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Lacosamide + Silodosin + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Dronedarone Hydrochloride

Combination-5: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Meropenem + Imipenem + Doripenem Monohydrate + Biapenem + Faropenem Sodium + 7-AVNA + 7-APCA + Fingolimod Hydrochloride + Cinacalcet Hydrochloride + Pregabalin + Dronedarone Hydrochloride + D-Cycloserine

Combination-6: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Ceftibuten Monohydrate + Meropenem + Imipenem + Cilastatin Sodium + Doripenem Monohydrate + Faropenem Sodium + 7-AVNA + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Lacosamide + Venlafaxine Hydrochloride + Pregabalin + Dronedarone Hydrochloride + Deferasirox

Combination-7: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Cefuroxime Sodium + Ceftriaxone Sodium + Cefpirome Sulfate + Cefdinir Monohydrate + Ceftibuten Monohydrate + Cefotaxime Sodium + Meropenem + Imipenem + Doripenem Monohydrate + Biapenem + Faropenem Sodium + 7-AVNA + Lacosamide + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Dronedarone Hydrochloride + Deferasirox

Combination-8: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Meropenem + Imipenem + Doripenem Monohydrate + Faropenem Sodium + 7-AVNA + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Lacosamide + Fexofenadine Hydrochloride + Venlafaxine Hydrochloride + Pregabalin + Dronedarone Hydrochloride

Combination-9: Cefixime Trihydrate + Cefuroxime Axetil + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefuroxime Acid + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefoxitin Sodium + Cefcapene Pivoxil + Meropenem + Doripenem Monohydrate + Faropenem Sodium + 7-AVNA + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Silodosin + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Dronedarone Hydrochloride + D-Cycloserine

Combination-10: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Meropenem + Imipenem + Doripenem Monohydrate + Faropenem Sodium + 7-AVNA + MEAT (Thio Ester) + 7-APCA + Lacosamide + Cinacalcet Hydrochloride + Fexofenadine Hydrochloride + Dronedarone Hydrochloride + D-Cycloserine

Maximum Pollution Load For The Proposed Products On Various Combinations

ANNEXURE - III

Product	PRODUCTION		EFFLUENT DETAILS (per day)				SOLID WASTE (per day)				Emissions (per day)	
	Tons / Month	Per day (Kg)	Water Input Per Day (Lit)	Total Effluent Per Day (Lit)	TDS (Kg)	COD (Kg)	Org.res./ Semi solid (Kg)	Inorganics + EVA.Salts (Kg)	Spent Carbon (Kg)	Total S.W. (Kg)	Process (Kg)	Solvent Loss (Kg)
Proposed Products (Maximum 20 Products at a time)												
Combination-1	***202***	***6721***	156007	164015	12996	6750	9294	13009	1062	23374	1020	13862
Combination-2	*193*	*6431*	***165757***	*174646*	*13851*	*7018*	*9424*	*13842*	*1088*	*24364*	*1071*	*14395*
Combination-3	*193*	*6431*	*165757*	***174646***	*13851*	*7018*	*9424*	*13842*	*1088*	*24364*	*1071*	*14395*
Combination-4	*181*	*6048*	*163122*	*171794*	***13987***	*6935*	*9058*	***13978***	*1027*	*24072*	*1108*	*13958*
Combination-5	*193*	*6431*	*163900*	*172371*	*13598*	***7082***	*9347*	*13589*	*1078*	*24024*	*1148*	*14406*
Combination-6	*197*	*6564*	*162362*	*170743*	*13562*	*6921*	***9758***	*13589*	*1080*	*24436*	*1060*	*14372*
Combination-7	*194*	*6471*	*157708*	*166283*	*13069*	*6574*	*9001*	*13070*	***1142***	*23223*	*974*	*13709*
Combination-8	*197*	*6581*	*163738*	*172496*	*13819*	*6988*	*9662*	*13810*	*1080*	***24562***	*1094*	*14479*
Combination-9	156	5198	135833	143804	10393	6123	7746	10395	858	18999	***1265***	11265
Combination-10	*198*	*6604*	*162031*	*170765*	*13434*	*6895*	*9332*	*13435*	*1112*	*23889*	*1144*	***14668***

Maximum Pollution Load For The Proposed Products On Various Combinations (Contd…)

ANNEXURE - III

Combination-1: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Cefuroxime Sodium + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefuroxime Acid + Ceftibuten Monohydrate + Cefotaxime Sodium + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Sitagliptin Phosphate + Prasugrel Hydrochloride + Pregabalin + Diacerein + Linezolid + Ropinirole Hydrochloride

Combination-2: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefepime Dihydrochloride Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefazoline Sodium + Cefoperazone Sodium + Cefoxitin Sodium + Ceftazidime Pentahydrate + Cefcapene Pivoxil + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA) + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Pregabalin

Combination-3: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefepime Dihydrochloride Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefazoline Sodium + Cefoperazone Sodium + Cefoxitin Sodium + Ceftazidime Pentahydrate + 7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA) + Cefcapene Pivoxil + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Pregabalin

Combination-4: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefuroxime Acid + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefazoline Sodium + Cefoperazone Sodium + Cefoxitin Sodium + Ceftazidime Pentahydrate + Cefotaxime Sodium + Cefpodoxime Acid + Cefcapene Pivoxil + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Sitagliptin Phosphate + Pregabalin

Combination-5: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefepime Dihydrochloride Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefazoline Sodium + Cefoperazone Sodium + Cefoxitin Sodium + Ceftazidime Pentahydrate + Cefcapene Pivoxil + 7-AVNA + MEAT (Thio Ester) + 7-APCA + Pregabalin + D-Cycloserine + Febuxostat

Combination-6: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefpirome Sulfate + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefoxitin Sodium + Cefotaxime Sodium + Cefcapene Pivoxil + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Prasugrel Hydrochloride + Pregabalin + Diacerein + Febuxostat

Combination-7: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Cefuroxime Sodium + Ceftriaxone Sodium + Cefpirome Sulfate + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefepime Dihydrochloride Monohydrate + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefazoline Sodium + Cefoperazone Sodium + Ceftazidime Pentahydrate + Ceftizoxime Sodium + Cephalothin Sodium + Cefotaxime Sodium + 7-AVNA + MEAT (Thio Ester) + 7-Amino3-thiazole cephalosporanic acid (7-ATCA)

Combination-8: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefuroxime Acid + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefoperazone Sodium + Cefoxitin Sodium + Ceftazidime Pentahydrate + Cefotaxime Sodium + Cefcapene Pivoxil + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Pregabalin + Febuxostat

Combination-9: Cefixime Trihydrate + Cefuroxime Axetil + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefuroxime Acid + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefazoline Sodium + Cefoperazone Sodium + Cefoxitin Sodium + Cefcapene Pivoxil + 7-AVNA + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + Sitagliptin Phosphate + Prasugrel Hydrochloride + Ropinirole Hydrochloride + D-Cycloserine + Clopidogrel Hydrogen Sulfate + Tolterodine Tartrate

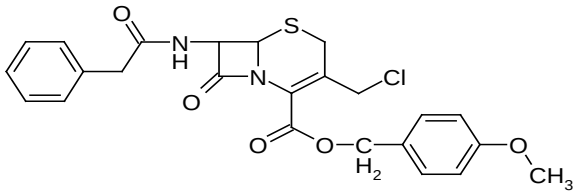
Combination-10: Cefixime Trihydrate + Cefpodoxime Proxetil + Cefuroxime Axetil + Ceftriaxone Sodium + Cefpirome Sulfate + Cefdinir Monohydrate + Cefprozil Monohydrate + Cefepime Dihydrochloride Monohydrate + Cefuroxime Acid + Cefditoren Pivoxil + Ceftibuten Monohydrate + Cefoperazone Sodium + Ceftazidime Pentahydrate + Cefotaxime Sodium + 7-AVNA + MEAT (Thio Ester) + 7-APCA + 7-Amino3-thiazole cephalosporanic acid (7-ATCA) + D-Cycloserine + Febuxostat

Manufacturing Details of the 3 Products

ANNEXURE - III

Cefixime Trihydrate - Route of Synthesis

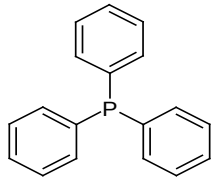
Stage-I :



(4-Methoxyphenyl)methyl-3-(chloromethyl)-8-methyl-7-[(2-phenylacetyl)amino]-5-thia-1-aza-bicyclo[4.2.0]octa-2-ene-2-carboxylate

(M.Wt : 486.5)

+



Triphenylphosphine

(262)

+ HCHO

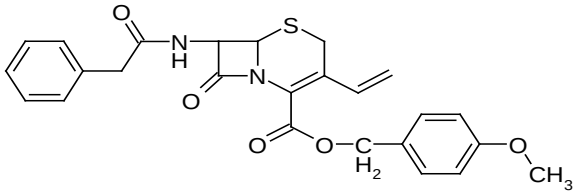
Formaldehyde

(30)

+ NaOH

Sodium Hydroxide

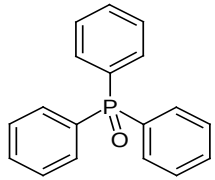
(40)



Stage-1 Compound

(M.Wt : 464)

+



Triphenylphosphine Oxide

(278)

+ NaCl

Sodium Chloride

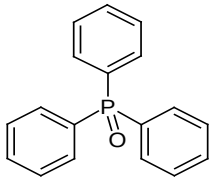
(58.5)

+ H_2O

Water

(18)

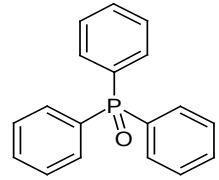
RECOVERY OF WASTE AND CONVERSION INTO BY-PRODUCT



Triphenylphosphine oxide (Crude)

(M.Wt : 278)

Toluene

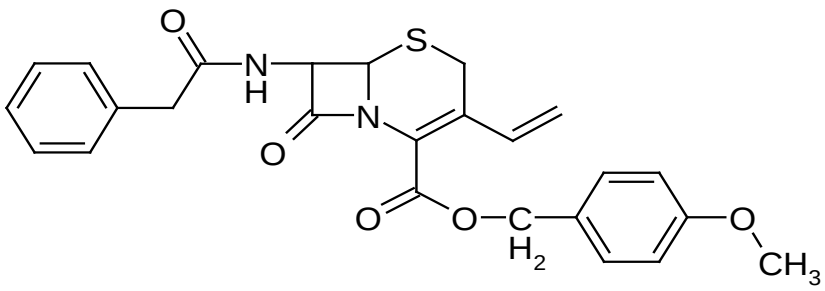


Triphenylphosphine oxide (Pure)

(M.Wt : 278)

Cefixime Trihydrate - Route of Synthesis

Stage-II :



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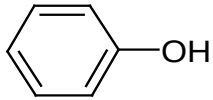


\+ H_2O

Stage-1 Compound

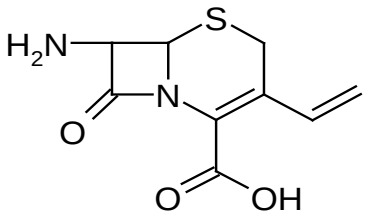
(M.Wt : 464)

Phenol

(94)

Water

(18)



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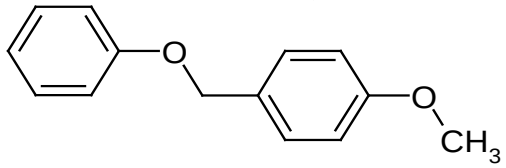

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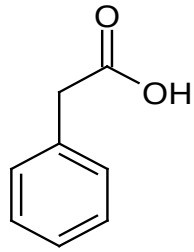


Stage-2 Compound

(M.Wt : 226)

1-Methoxy-4-[phenoxymethyl]benzene

(214)

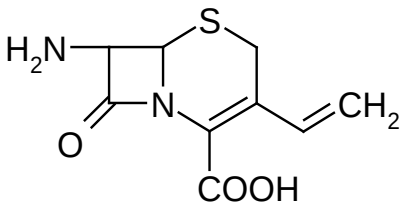
Phenyl aceticacid

(136)

Cefixime Trihydrate - Route of Synthesis

ANNEXURE - III

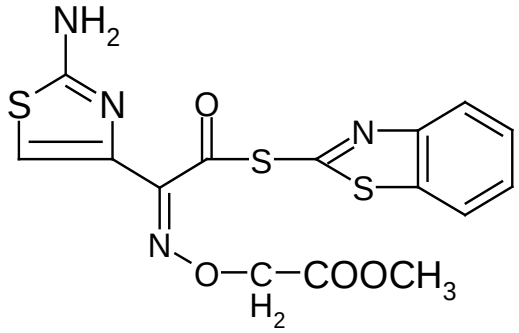
Stage-III



Stage-2 Compound

(M.Wt : 226)

+



MICA ester

(M.Wt : 408)

+ 3 H2O

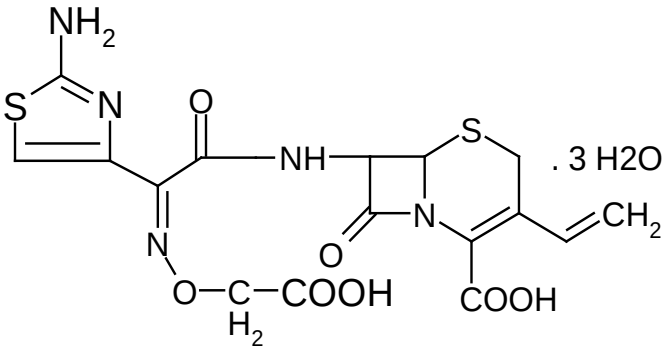
Water

(18)

+ NaOH

Sodium Hydroxide

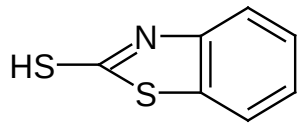
(40)



Cefixime Trihydrate

(M.Wt : 507)

+



MBT

(167)

+ CH_3ONa

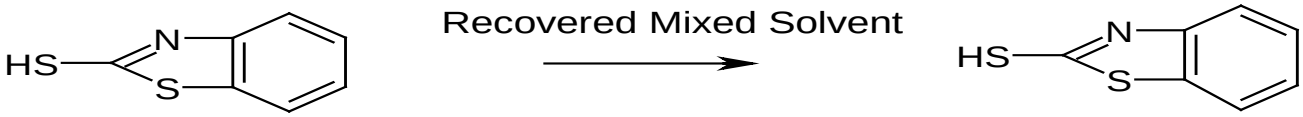
SMO

(54)

Cefixime Trihydrate - Route of Synthesis

ANNEXURE - III

By-product 2-Mercaptobenzothiazole Purification



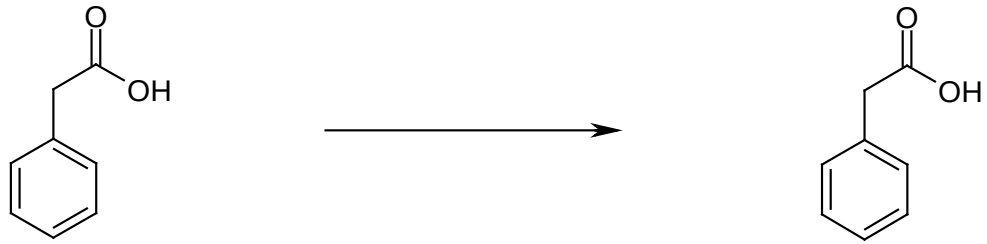
MBT (Crude)

(M.Wt : 167)

MBT(Pure)

(M.Wt : 167)

By-product Phenyl Acetic Acid Purification



Phenylacetic acid (Crude)

(M.Wt : 136.5)

Phenylacetic acid (Pure)

(M.Wt : 136.5)

Material Balance : Cefixime Trihydrate

ANNEXURE - III

Stage : 1 : **Material Balance:**

INPUT		Kg
(4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	=	255
Triphenylphosphine	=	140
Formaldehyde (40%)	=	50
Methanol	=	2040
Methylene Dichloride	=	750
Sodium Bromide	=	59
Sodium Hydroxide	=	22
Hydrochloric Acid (35%)	=	3
Dimethylformamide	=	365
Water	=	1535
		65
Total Input	=	5219

OUTPUT		Kg
Product		
Stage-1	=	210
By-Product		
Triphenylphosphine oxide	=	145
Sodium Salts as Recovered By-product		
Sodium Bromide+ Sodium Chloride	=	91.17
Recovery		
Methylene Dichloride	=	713
Methylene Dichloride Loss	=	22
Methanol	=	1938
Methanol Loss	=	61
Dimethylformamide	=	343
Dimethylformamide Loss	=	14
Effluent	**=**	**1630.24**
Hydrochloric acid	0.11	
Formaldehyde	4.28	
Methanol	41	
Dimethylformamide	8	
gen.water	9.9	
Water from Hydrochloric acid	1.95	
Water from Formaldehyde	30	
Water	1535	
Organic Residue	**=**	**51.59**
Organic Impurities	33.21	
Triphenylphosphine Oxide	0.71	
Triphenylphosphine	2.67	
Methylene Dichloride	15	
Total Output	=	5219

Material Balance : Cefixime Trihydrate

Recovery of Waste and Conversion into By-Product

Material Balance:

INPUT		Kg
Triphenylphosphine oxide (Crude)	=	145
Toluene	=	725
Water	=	100
Total Input	=	970

OUTPUT		Kg
Product		
Triphenylphosphine oxide (Pure)	=	120
Recovery		
Toluene	=	695
Toluene Loss	=	15
Effluent	**=**	**110.4**
Organic Compound	10	
Toluene	0.4	
Water	100	
Organic Residue	**=**	**29.6**
Organic Impurities	15	
Toluene	14.6	
Total Output	=	970

Material Balance : Cefixime Trihydrate

Stage : 2 Material Balance:

ANNEXURE - III

INPUT		Kg
Stage-1	=	210
Phenol	=	365
Butyl Acetate	=	1000
Sodium Bicarbonate	=	28
Sodium Chloride	=	5
Sodium Carbonate	=	12
Carbon	=	23
Ethylenediaminetetraacetic acid	=	2
Sulfuric acid	=	28
Acetone	=	630
Water	=	800
Total Input	=	3103

OUTPUT		Kg
Product		
Stage-2	=	98
By-Product		
Phenylacetic acid	=	60
Recovery		
Acetone	=	586
Acetone Loss	=	31
Butyl Acetate	=	960
Butyl Acetate Loss	=	20
Phenol	=	297
Phenol Loss	=	18
Effluent	**=**	**869.24**
Phenylacetic acid	1.56	
Phenol	7.46	
Sodium Sulfate	39.75	
Sodium Chloride	5	
Sulfuric acid	0.58	
Ethylenediaminetetraacetic acid	2	
Acetone	13	
gen.water	8.04	
Water	791.85	
Organic Residue	**=**	**121.13**
Organic Impurities	4.28	
1-Methoxy-4-[phenoxymethyl] benzene	96.85	
Butyl Acetate	20	
Spent Carbon	**=**	**23**
Carbon	23	
Process Emissions	**=**	**19.63**
Carbon Dioxide	19.63	
Total Output	=	3103

Material Balance : Cefixime Trihydrate

Stage : 3

Material Balance:

INPUT		Kg
Stage-2	=	98
MICA Ester	=	178
Triethylamine	=	52
Methanol	=	290
Hydrochloric acid (35%)	=	53
Sodium Hydroxide	=	20
Water	=	280
Total Input	=	971

OUTPUT		Kg
Product		
Cefixime Trihydrate	=	200
By-Product		
2-Mercaptobenzothiazole	=	72
Recovery		
Methanol	=	283
Methanol Loss	=	15
Triethylamine	=	48
Triethylamine Loss	=	3
Effluent	**=**	**326.65**
Sodium Chloride	29.25	
Hydrochloric acid	0.3	
Triethylamine	1	
Methanol	3.88	
gen.water	1.19	
Water from Hydrochloric acid	34.45	
Water	256.58	
Organic Residue	**=**	**23.35**
Organic Impurities	20.93	
2-Mercaptobenzothiazole	0.42	
Methanol	2	
Total Output	=	971

Material Balance : Cefixime Trihydrate

Recovery & Purification of By-Product

Material Balance:

INPUT		Kg
2-Mercaptobenzothiazole (Crude)	=	72
Recovered Mixed Solvent	=	650
Hydrose	=	1
Activated Carbon	=	2
Water	=	70
Total Input	=	795

OUTPUT		Kg
Product		
2-Mercaptobenzothiazole (Pure)	=	55
Recovery		
Recovered Mixed Solvent	=	624
Recovered Mixed Solvent Loss	=	13
Effluent	**=**	**71.5**
Hydrose	1	
Organic Compound	0.5	
Water	70	
Organic Residue	**=**	**29.5**
Organic Impurities	16.5	
Recovered Mixed Solvent	13	
Spent Carbon	**=**	**2**
Carbon	7	
Total Output	=	795

Material Balance : Cefixime Trihydrate

ANNEXURE - III

Recovery & Purification of By-Product

Material Balance:

INPUT		Kg
Phenylacetic acid (Crude)	=	60
Sodium Hydroxide	=	18
Hydrogen Chloride	=	14
Carbon	=	9
Hydrose	=	0.3
EDTA	=	0.3
Water	=	590
Total Input	=	691.6

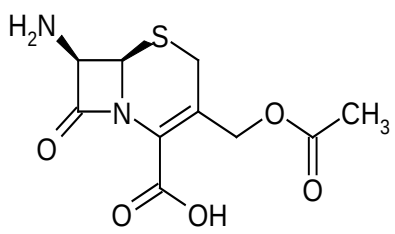
OUTPUT		Kg
Product		
Phenylacetic acid (Pure)	=	45
Effluent	**=**	**637.6**
Sodium Chloride	22.44	
Sodium Hydroxide	2.66	
Hydrose	0.3	
EDTA	0.3	
Organic Compound	15	
gen.water	6.9	
Water	590	
Spent Carbon	**=**	**9**
Carbon	9	
Total Output	=	691.6

Cefpodoxime Proxetil

ANNEXURE - III

Route of Synthesis:

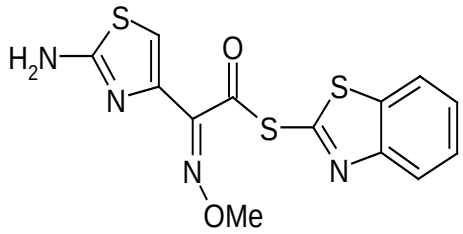
Stage-I:



7-Aminocephalosporanic acid

(M.Wt : 272)

+



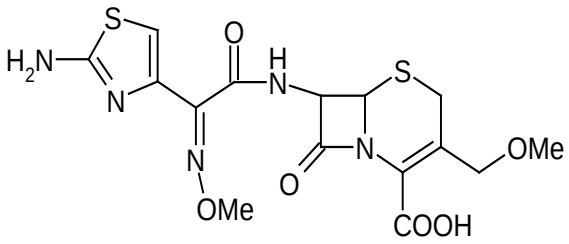
Benzothiazol-2-yl-2-(2-aminothiazol-4-yl) -(Z)-2-methoxyiminothioacetate

(350)

+ BF_3 Boron Trifluoride (68)

+ CH_3OH Methanol (32)

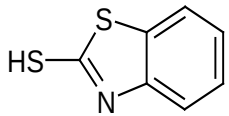
+ 4 NaOH Sodium Hydroxide (40)



Stage-1compound

(M.Wt. : 427)

+



2-Mercaptobenzothiozole

(167)

+ CH_3COONa Sodium Acetate (82)

+ H_2O Water (18)

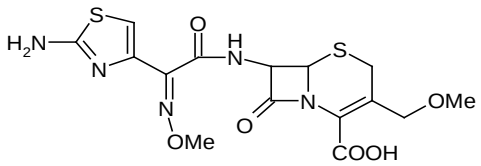
+ NaF Sodium Fluoride (42)

+ H_3BO_3 Boric acid (62)

Cefpodoxime Proxetil: Route of Synthesis

ANNEXURE - III

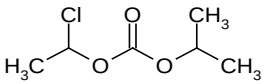
Stage-II:



Stage-1Compound

(M.Wt. : 427)

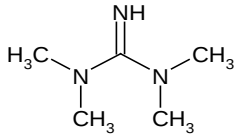
+



Chloroethylisopropyl carbonate

(166.5)

+ NaI +

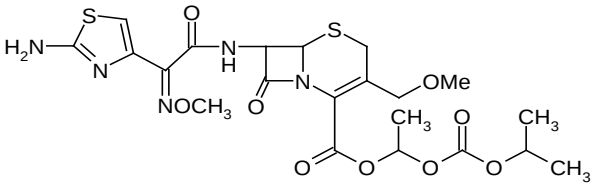


Sodium Hydroxide

(150)

1,1,3,3-Tetramethyl gunadine

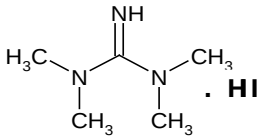
(115)



Cefpodoxime Proxetil

(M.Wt. : 557)

+ NaCl +



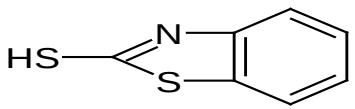
Sodium Chloride

(58.5)

1,1,3,3-Tetramethyl gunadine Hydrogen Iodide

(243)

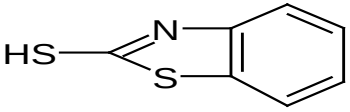
PURIFICATION OF BY-PRODUCT



MBT (Crude)

(M.Wt : 167)

Recovered Mixed Solvent



MBT(Pure)

(M.Wt : 167)

Material Balance: Cefpodoxime Proxetil

ANNEXURE - III

Stage : 1 :Material Balance:

INPUT		Kg
7-Amino cephalosphoranic acid	=	138
Benzothiazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyiminothioacetate	=	178
Triethylamine	=	830
Borantrifluoride	=	104
Sulfolane	=	1380
Methylene Dichloride	=	2100
Sodium Hydroxide	=	220
Sodium Chloride	=	180
Tetrahydrofuran	=	620
Ethyl Acetate	=	1050
Methanol	=	320
Sulfuric Acid	=	18
Carbon	=	14
Water	=	3800
Total Input	=	10952

OUTPUT		Kg
Product		
Stage-1	=	152
By-Product		
2-Mercaptobenzothiazole	=	84
Recovery		
Sulfolane	=	1330
Sulfolane Loss	=	42
Methylene Dichloride	=	1995
Methylene Dichloride Loss	=	63
Methanol	=	282
Methanol Loss	=	16
Triethylamine	=	788
Triethylamine Loss	=	25
Ethyl Acetate	=	1008
Ethyl Acetate Loss	=	31
Tetrahydrofuran	=	577
Tetrahydrofuran Loss	=	31
Effluent	**=**	**4397.2**
Sodium Fluoride	192.71	
Boric acid	94.83	
Sodium Sulfate	26.08	
Sodium Chloride	180	
Sodium Acetate	41.6	
Sodium Hydroxide	1.48	
Sulfolane	8	
Methanol	5.76	
Triethylamine	17	
Tetrahydrofuran	12	
Ethyl Acetate	2	
gen.water	15.74	
Water	3800	
Organic Residue	**=**	**116.8**
Organic Impurities	65.07	
2-Mercaptobenzothiazole	0.73	
Methylene Dichloride	42	
Ethyl Acetate	9	
Spent Carbon	**=**	**14**
Carbon	14	
Total Output	=	10952

73

Material Balance: Cefpodoxime Proxetil

ANNEXURE - III

Stage : 2

Material Balance:

INPUT		Kg
Stage-1	=	152
1-Chloroethyl isopropyl carbonate	=	60
Sodium Iodide	=	55
18-Crown-6	=	5
1,1,3,3-Tetramethyl gunadine	=	41
Toluene	=	470
Ethyl Acetate	=	2190
Methanol	=	810
Dimethylacetamide	=	700
Hydrochloric acid (35%)	=	8
Ammonia (10%)	=	13
Sodium Chloride	=	45
Sodium Thiosulfate	=	8
Carbon	=	12
TBAB	=	1
Water	=	940
Cyclohexane	=	3500
Total Input	=	9010

OUTPUT		Kg
Product		
Cefpodoxime Proxetil	=	175
Recovery		
Ethyl Acetate	=	2087
Ethyl Acetate Loss	=	88
Methanol	=	753
Methanol Loss	=	41
Toluene	=	445
Toluene Loss	=	18
Dimethylacetamide	=	665
Dimethylacetamide Loss	=	28
Cyclohexane	=	3345
Cyclohexane Loss	=	140
Effluent	**=**	**1156.93**
1,1,3,3-Tetramethyl gunadine Hydrogen Iodide	86.51	
Sodium Chloride	65.82	
Sodium Iodide	1.6	
Sodium Thiosulfate	8	
Ammonium Chloride	4.1	
TBAB	1	
18-Crown-6	5	
Methanol	16	
Ethyl Acetate	5	
Dimethylacetamide	7	
Water from Hydrochloric acid	5.2	
Water from Ammonia	11.7	
Water	940	
Organic Residue	**=**	**56.07**
Organic Impurities	24.07	
Toluene	7	
Cyclohexane	15	
Ethyl Acetate	10	
Spent Carbon	**=**	**12**
Carbon	12	
Total Output	=	9010

Material Balance: Cefpodoxime Proxetil

Recovery & Purification of By-Product

Material Balance:

INPUT		Kg
2-Mercaptobenzothiazole (Crude)	=	84
Recovered Mixed Solvent	=	760
Hydrose	=	2
Activated Carbon	=	5
Water	=	430
Total Input	=	1281

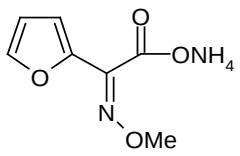
OUTPUT		Kg
Product		
2-Mercaptobenzothiazole (Pure)	=	65
Recovery		
Recovered Mixed Solvent	=	730
Recovered Mixed Solvent Loss	=	15
Effluent	**=**	**432.5**
Hydrose	2	
Organic Compound	0.5	
Water	430	
Organic Residue	**=**	**33.5**
Organic Impurities	18.5	
Recovered Mixed Solvent	15	
Spent Carbon	**=**	**5**
Carbon	5	
Total Output	=	1281

Cefuroxime Axetil

ANNEXURE - III

Route of Synthesis:

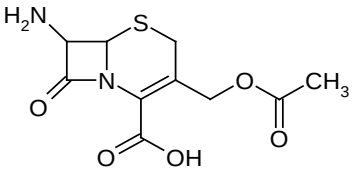
Stage-I:



Synammonium salt of methoxy imino-2-furyl-2-acetate

(M.Wt : 186)

+



7-Aminocephalosporanic acid

(272)

+ PCl_5

Phosphorous pentachloride

(208.5)

+ 2 NaOH

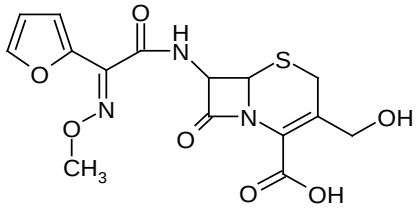
Sodium Hydroxide

(40)

+ HCl

Hydrochloric acid

(36.5)



Stage-1 Compound

(M.Wt : 381)

+ $POCl_3$

Phosphorous Oxychloride

(153.5)

+ 2 NaCl

Sodium Chloirde

(58.5)

+ NH_4Cl

Ammonium Chloride

(53.5)

+ CH_3COONa

Sodium Acetate

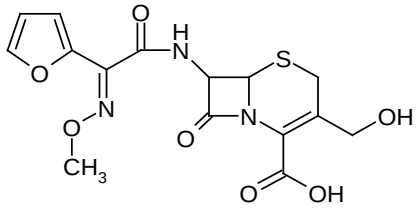
(82)

+ $^1/_2\ H_2O$

Water

(18)

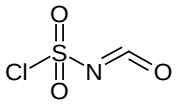
Stage-II:



Stage-1 Compound

(M.Wt : 381)

+



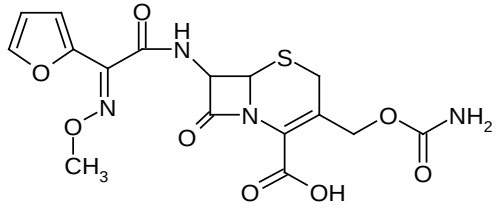
Chlorosulfonyl isocyante

(141.5)

+ 3 NaOH

Sodium Hydroxide

(40)



Stage-2 Compound

(M.Wt : 424)

+ NaCl

Sodium Chloirde

(58.5)

+ Na_2SO_4

Sodium Sulfate

(142)

+ H_2O

Water

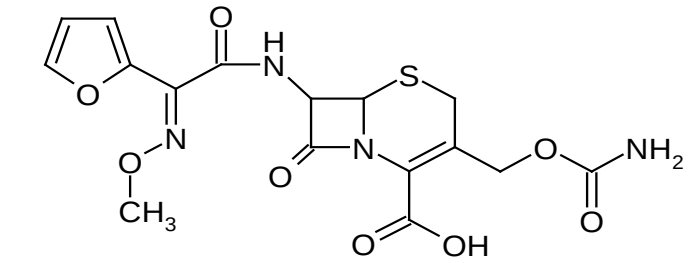
(18)

Cefuroxime Axetil : Route of Synthesis

ANNEXURE - III

CEFUROXIME AXETIL

Stage-III:



Stage-2 Compound

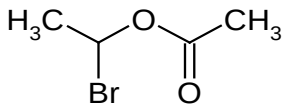
(M.Wt. : 424)

+ $^1/_2$ Na_2CO_3

Sodium Carbonate

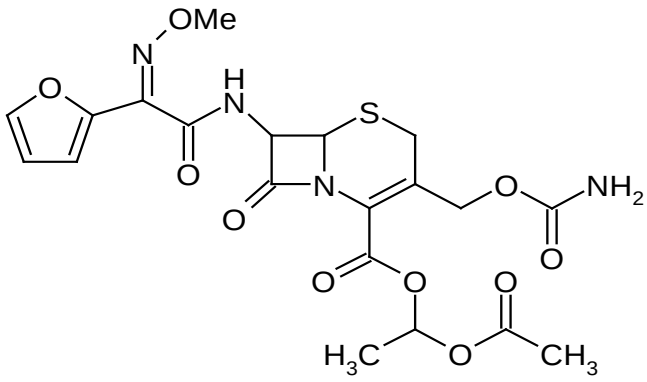
(106)

+



1-Acetoxy Ethylbromide

(167)



Cefuroxime Axetil

(M.Wt. : 510)

+ NaBr

Sodium Bromide

(103)

+ $^1/_2$ CO_2

Carbon Dioxide

(44)

+ $^1/_2$ H_2O

Water

(18)

Material Balance: Cefuroxime Axetil

ANNEXURE - III

Stage : 1: Material Balance:

INPUT		Kg
7-Amino cephalosphoranic acid	=	188
(Z)-2-Methoxyimino-2-(furyl-2-yl) acetic acid ammonium salt	=	135
Phosphorus Pentachloride	=	150
Sodium Hydroxide	=	210
Sodium Metabisulfite	=	2
Sodium Carbonate	=	20
Hydrochloric acid (35%)	=	40
Acetic Acid	=	17
Methylene Dichloride	=	2870
Methanol	=	550
Dimethylacetamide	=	265
Water	=	2730
Total Input	=	7177

OUTPUT		Kg
Product		
Stage-1	=	250
Recovery		
Methylene Dichloride	=	2670
Methylene Dichloride Loss	=	172
Methanol	=	512
Methanol Loss	=	28
Dimethylacetamide	=	254
Dimethylacetamide Loss	=	8
Effluent	**=**	**3226.94**
Sodium Chloride	192.08	
Sodium Acetate	74.23	
Ammonium Chloride	36.98	
Sodium Metabisulfite	2	
Sodium Dihydrogen Phosphate	102.16	
Hydrochloric acid	0.23	
Acetic acid	4.16	
Methanol	10	
Dimethylacetamide	3	
gen.water	46.1	
Water from Hydrochloric Acid	26	
Water	2730	
Organic Residue	**=**	**47.76**
Organic Impurities	19.76	
Methylene Dichloride	28	
Process Emissions	**=**	**8.3**
Carbon Dioxide	8.3	
Total Output	=	7177

Material Balance: Cefuroxime Axetil

Stage : 2

Material Balance:

INPUT		Kg
Stage-1	=	250
Chlorosulfonyl Isocyanate	=	100
Sodium Hydroxide	=	90
Hydrose	=	8
Acetone	=	1075
Methylene Dichloride	=	2120
Water	=	1170
Total Input	=	4813

OUTPUT		Kg
Product		
Cefuroxime Acid	=	250
Recovery		
Acetone	=	1000
Acetone Loss	=	54
Methylene Dichloride	=	1972
Methylene Dichloride Loss	=	127
Effluent	**=**	**2358.57**
Sodium Chloride	38.39	
Sodium Hydroxide	7.22	
Sodium Sulfate	100.36	
Ammonium Chloride	2.7	
Hydrose	8	
Acetone	21	
gen.water	11.81	
Water	1169.09	
Organic Residue	**=**	**49.22**
Organic Impurities	28.22	
Methylene Dichloride	21	
Process Emissions	**=**	**2.21**
Carbon Dioxide	2.21	
Total Output	=	5813

Material Balance: Cefuroxime Axetil

ANNEXURE - III

Stage : 3 Material Balance:

INPUT		Kg
Cefuroxime Acid	=	250
1-Acetoxy Ethyl Bromide	=	100
Sodium Carbonate	=	38
Sodium Hydrosulfite	=	5
Sodium Thiosulfate	=	10
Sodium Chloride	=	15
Ammonia Solution (10%)	=	138
Diethylacetamide	=	750
Ethyl Acetate	=	1200
Methanol	=	400
Cyclohexane	=	700
Sodium Hydroxide	=	45
Water	=	1000
Carbon	=	50
Total Input	=	4701

OUTPUT		Kg
Product		
Cefuroxime Axetil	=	275
By-Product		
Recovered Sodium Bromide	=	**60.73**
Recovery		
Dimethylacetamide	=	713
Dimethylacetamide Loss	=	22
Ethyl Acetate	=	1041
Ethyl Acetate Loss	=	36
Methanol	=	372
Methanol Loss	=	20
Cyclohexane	=	665
Cyclohexane Loss	=	21
Ethanol	=	49
Ethanol Loss	=	1.5
Effluent	**=**	**1306.57**
Sodium Acetate	92.26	
Sodium Hydrosulfite	5	
Sodium Chloride	15	
Sodium Carbonate	6.75	
Sodium Thiosulfate	10	
Ammonia	13.8	
Methanol	8	
Dimethylacetamide	15	
Ethyl Acetate	10	
Ethanol	1.25	
gen.water	5.31	
Water from Ammonia Solution	124.2	
Water	1000	
Organic Residue	**=**	**55.23**
Organic Impurities	27.24	
Ethyl Acetate	13.99	
Cyclohexane	14	
Spent Carbon	**=**	**50**
Carbon	5	
Process Emissions	**=**	**12.97**
Carbon Dioxide	12.97	
Total Output	=	4701

Permitted Water Balance

ANNEXURE - III

Sl. No.	Description	Input (KLD)		Output (KLD)		Segregation type of Wastewater
		Fresh Water	Reused Water	Generation / Evaporation/ Handling Losses	Total Waste water	
1.	Process & washings	161	--	(-)14	175	(HTDS/HCOD)
2.	Washings (reactor, containers, floor moping, etc.)	25	--	--	25	(LTDS/LCOD)
3.	Boiler (30 TPH for 3 MW power plant)	145 (20% Make up)	---	120	25 (Blow down)	(HTDS)
4.	Cooling Towers 5000 TR	23 (Make up)	277	275	25 (Bleed)	(HTDS)
5.	DM Regeneration	10	--	--	10	(HTDS)
6.	Scrubber	8	--	--	8	(HTDS)
7.	Q.C & R&D	5	--	--	5	(LTDS/LCOD)
8.	Domestic	30	--	5	25	(LTDS/LCOD)
9.	Gardening 10 Acres- 5 KL/acre	50	--	50	--	Reuse:277KLD
Total		**457**	**277**	**436**	**298**	
		734		**734**		

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Revised Water Balance

ANNEXURE - III

Sl. No.	Description	Input (KLD)		Output (KLD)		Segregation type of Wastewater	Treatment and Reuse Method
		Fresh Water	Recycled water	Evaporation / Handling Loss	Total Wastewater		
1	Process	**166**	**-**	**-9**	**175**	HCOD/HTDS	Segregation, Collection and Treatment separately in ETP with ZLD System for reusing the treated effluent in cooling towers
2	Washings (reactors, centrifuges, nutch filters, containers, floor moping, etc.)	25	-	-	25	LTDS/LCOD	
3	Boiler (30 & 20 TPH)	240	-	200	**40**	HTDS	
4	Cooling Towers (5000 TR)	7	293	275	25	HTDS	
5	DM Regeneration	12	-	-	12	HTDS/LCOD	
6	Scrubber	8	-	-	8	HTDS/LCOD	
7	Q.C and R&D	5	-	-	5	LTDS/LCOD	
8	Domestic	30	-	5	25		
9	Gardening	50	-	50	-		
Total		**543**	**293**	**521**	**315**	**Reuse:**	Total reuse is 293 KLD
		836		**836**			

- Fresh water consumption increased by 86 KLD and Total effluent increased by 17 KLD

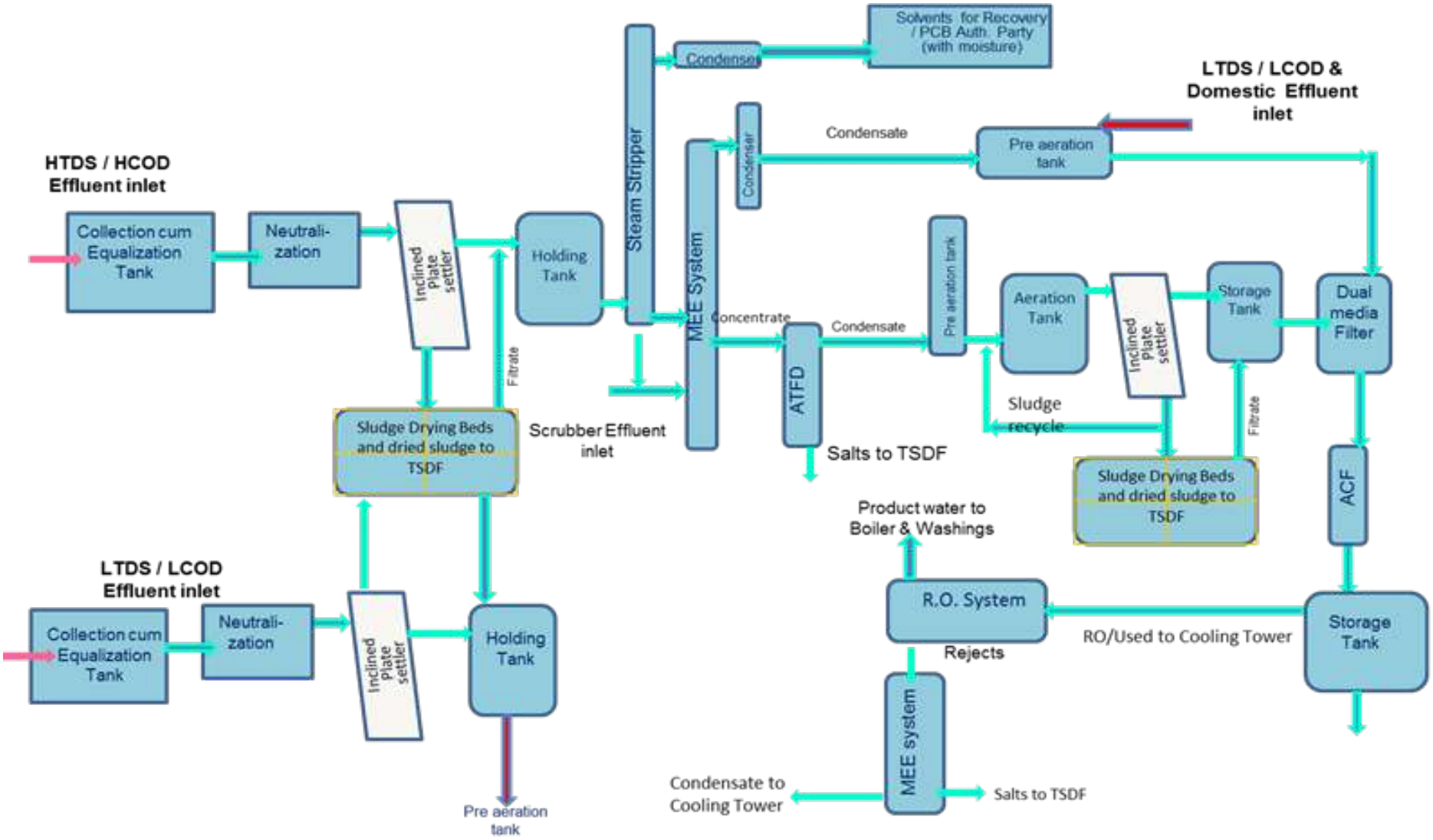
Effluent Treatment Flow as per Segregation for Permitted & Proposed

ANNEXURE - III

Effluent	Proposed Qty. (KLD)	pH	TDS (mg/l)	COD (mg/l)	Treatment Flow
HTDS/ HCOD & HTDS	260	2 to 12	<100000	<30000	Collection →Equalization → Neutralization → Settling → Holding → Steam stripper → MEE along with HTDS effluent → Condensate to ETP(biological treatment) → Concentrate to ATFD ATFD Condensate to ETP (Biological Treatment) along with domestic wastewater (septic tank overflow) → Pressure Sand Filter → Activated Carbon Filter → R.O → R.O rejects to MEE. R.O Permeate & Condensate to Boiler ATFD Salts to TSDF and stripped solvents to SPCB authorized cement industries
LTDS / LCOD	30	6-10	< 5000	< 3000	Collection → Equalization → Neutralization →ETP (Biological Treatment) along with MEE condensate.
Domestic	25	6-9	< 2000	< 1000	Septic tank→Overflow to Biological treatment of ETP

Schematic Effluent Treatment Scheme – HTDS/HCOD & LTDS/LCOD

ANNEXURE - III



Hazardous / Solid Waste Generation from the Permitted & Proposed Products

ANNEXURE - III

Sl. No.	Description	Existing Quantity (TPD)	Proposed Quantity (TPD)	Handling Method	Disposal
1.	Process Organic	9.4	9.8	HDPE Bags / Drums	Sent to SPCB Authorized Cement industries / TSDF
2.	Spent carbon	0.98	1.1		
3.	Distillation residue	Lumpsum	Lumpsum		
4.	Inorganic & Evaporation salt (Process)	16.1	14	HDPE Bags	
5.	Evaporation salt (Non-Process)	2.5	2.5		
6.	ETP Sludge	1	1		
7.	Boiler Ash	45	75	Stored in covered area	Sold to Cement Brick Manufacturers
Other Hazardous Waste generation from the Plant					
8.	Detoxified Container / Liners drums, HDPE Carboys, Fiber Drums, PP Bags	200 Nos./ month 1000 Nos/month 500 nos/month 500 kg/month	200 Nos./ month 1000 Nos/month 500 nos/month 500 kg/month	Designated covered area	Disposed to SPCB Authorized agencies after complete detoxification
9.	Spent Mixed solvents	6 KLD	6 KLD	Stored Tanks/ Drums	Sent to SPCB Authorized Recyclers / Cement industries
10.	Waste oils & Grease	2 KL/annum	2 KL/annum	MS Drums	Sent to SPCB Authorized agencies for reprocessing / recycling.
11.	Used Lead acid Batteries	100 nos/month	100 nos/month	Designated covered area	Sent to suppliers on buy-back basis.
12.	E- waste	-	1 kg/day	Designated covered area	Send to authorized e-waste Collection centers/ registered dismantlers/ authorized recyclers/ return back to manufacturers
13.	Canteen food waste	-	Lumpsum	HDPE Bags	Disposed to Village authorized agencies
14.	Paper waste & Misc.	-	Lumpsum	HDPE Bags	Scrap Venders
15.	Misc. Waste (spill control waste)	-	Lumpsum	Stored in Drums	TSDF

- Boiler ash storage will be continued to be sent to silos with dust control systems and will be sent to cement brick manufacturing units.

ANNEXURE - III

Maximum Quantity of Process Emissions from Permitted & Proposed Products

Name of the Gas	Permitted Quantity (kg/day)	Proposed Quantity (kg/day)	Treatment
CO_2	1553.34	**1073.71**	Dispersed into atmosphere
HCl	71.33	**61.07**	Scrubber with water / caustic solution
HF	29.38	**29.38**	Scrubber with caustic sol.
H_2	19.46	**1.87**	Diffused with flame arrestor
SO_2	53.78	**40.34**	Scrubber with caustic solution
HBr	0.03	**0.02**	Scrubber with caustic sol.

Solvent Balance

	Solvent Input	Solvent Loss in Effluent	Solvent Loss in Org. residue	Solvent Loss (Handling)	Solvent Recovery	Solvent Recovery
	(KLD)	**(KLD)**	**(KLD)**	**(KLD)**	**(KLD)**	**(%)**
Permitted	340	3.2	2.7	15.3	317.7	93
Proposed	**326**	**3.1**	**2.7**	**13.6**	**306.5**	**94**

Stack Emission Details

Boiler specifications	20 TPH Boiler (Additional)	30 TPH Boiler	Proposed Stand by	
			10 TPH Boiler	4 TPH Boiler & 15 lac K cal TFH
No. of flues	1	1	1	2
Stack Type	Circular	Circular	Circular	Circular
Stack Height from ground level (m)	45	55	30	30
Stack Dia. (m)	1.1	1.3	0.9	0.9
Exhaust Gas Temperature (^{0}C)	150	150	150	150
Exit Gas Velocity (m/s)	16.2	17.3	9.61	6.24
Volumetric flow rate (m^3/s)	15.4	22.89	6.11	3.97
Fuel	Coal	Coal	Coal	Coal
Fuel quantity	100 TPD	150 TPD	40 TPD	26 TPD
Emission Rate of PM (g/sec) (<115 mg/Nm^3)	0.813	1.2	0.44	0.29
Emission Rate of SO_2 (g/sec)	9.84	15.62	4.16	2.71
Emission Rate of NO_x (g/sec)	7.29	10.94	2.92	1.89

Comparison of Pollution Loads for the Permitted and Proposed Products

ANNEXURE - III

Sl. No.	Description	Permitted	Revised Pollution load
1.	Total Production Capacity (TPM)	200	**201.63**
2.	Water Input for Process (KLD)	161	**166**
3.	Total Process Effluent (KLD)	171	**175**
4.	TDS (kg/day)	15518	**13987**
5.	COD (kg/day)	7153	**7082**
6.	Fresh Water requirement	457	**543**
7.	Total Effluent (KLD)	298	**315**
8.	Organic Residue (kg/day)	9357	**9758**
9.	Inorganic & Eva. Salts (kg/day)	15519	**13978**
10.	Spent Carbon (kg/day)	989	**1142**
11.	Total Solid Waste (kg/day)	25138	**24562**
12.	Process Emissions (kg/day)	1712	**1265**

- Total production capacity marginally increased from 200 TPM to 201.63 TPM.
- Overall process effluent marginally increased from 171 KLD to 175 KLD.
- Overall solid waste has decreased from 25138 kg/day to 24562 kg/day.
- Overall solvent recovery improved from 93% to 94%.
- Overall reduction in gaseous emissions from 1712 kg/day to 1265 kg/day.
- Spent Mixed solvents are used for purification and recovery of by-products that was previously included in Hazardous waste is now recovered

Brief Summary

ANNEXURE - III

Description	Units	Permitted / Present	Additional	Total after amendment
Products	Nos.	20 products at a time from total 65 products	**20 Products out of 45 products (20 products dropped from total 65 products)**	20 Products out of 45 products (20 products dropped from total 65 products)
Capacity	TPA	2400	**20**	2420
Land	Hectares	11.85 Ha	**No Change**	11.85 Ha
Water requirement (Fresh)	KLD	457	**86**	543
Waste water generation	KLD	298	**17**	315
Coal fired Boilers	TPH	30 TPH for 3 MW CPP, Existing 10 TPH, 4 TPH are standby	**20 TPH for 2 MW CPP**	30 TPH for 3 MW & 20 TPH for 2 MW CPP, Existing 10 TPH, 4 TPH are standby
Thermic Fluid Heater (TFH)	Kcal/hr	15 lac K.cal/hr coal fired TFH (stand by)	**No Change**	15 lac K.cal/hr coal fired TFH (stand by)
DG Sets	KVA	320 KVA and 5x1010 KVA	**No Change**	320 KVA and 5x1010 KVA

Maximum Incremental and Resultant GLCs

Pollutant	Maximum Incremental Level with 30 TPH boiler ($\mu g/m^3$)	Maximum Incremental Level with 20 TPH boiler ($\mu g/m^3$)	Maximum Incremental Level with 30 & 20 TPH boilers ($\mu g/m^3$)	Maximum Baseline ($\mu g/m^3$)	Maximum Resultant ($\mu g/m^3$)	NAAQ Standard ($\mu g/m^3$)
PM_{10}	0.63	**0.56**	**1.19**	69	**70.19** (69.63)	100
SO_2	8.2	**6.84**	**15.04**	14	**29.04** (22.2)	80
NOx	5.7	**5.11**	**10.81**	17	**27.81** (22.7)	80

Stack Analysis Report of 30 TPH Boiler

ANNEXURE - III

TELANGANA STATE POLLUTION CONTROL BOARD

ZONAL LABORATORY

25-39/11, Tulasi Reddy Complex, R.C.Puram, Sangareddy Dist.

FORM IV

(See Rule – 34 and sub-section (3) of Section 16 of the Act)

Report No. 2017 -3-184 Dated: 14/2/2017

I hereby certify that I, Md.Sadiq Ali, Board Analyst duly appointed under sub-section (2) of Section 29 of the Air (as Prevention and Control of Pollution) Act 1981, received a stack monitoring sample on 13/2/2017, (collected on 10/2/2017) from Env.Engineer, RO-Sangareddy-I, a sample of M/s. Covalent Laboratories Pvt.Ltd, Sy.No.374, Gaddamaadhanoor (V), Hatnoor (M), Sangareddy District.

The sample was in a condition fit for analysis report below:

I further certify that I have analyzed the aforementioned sample on 14/2/2017 and declare the results of the analysis to be as follows:

Sl. No.	Parameter	Stack Identity	Result mg/Nm³	Standard mg/Nm³
	SPM	Stack attached to 30 TPH Coal fired Boiler	52	115

The condition of the seals, fastening, and container on receipt was "Intact"

Observations of Sampling In charge:

1) At the time of monitoring, the Industry was operating with capacity of 22 TPH capacity against installed capacity of 30 TPH capacity

2) Industry provided ESPs to control dust emissions and is in operation.

3) The height of the stack attached to coal fired boiler is 56 mtrs.

Signed this: 14/2/2017

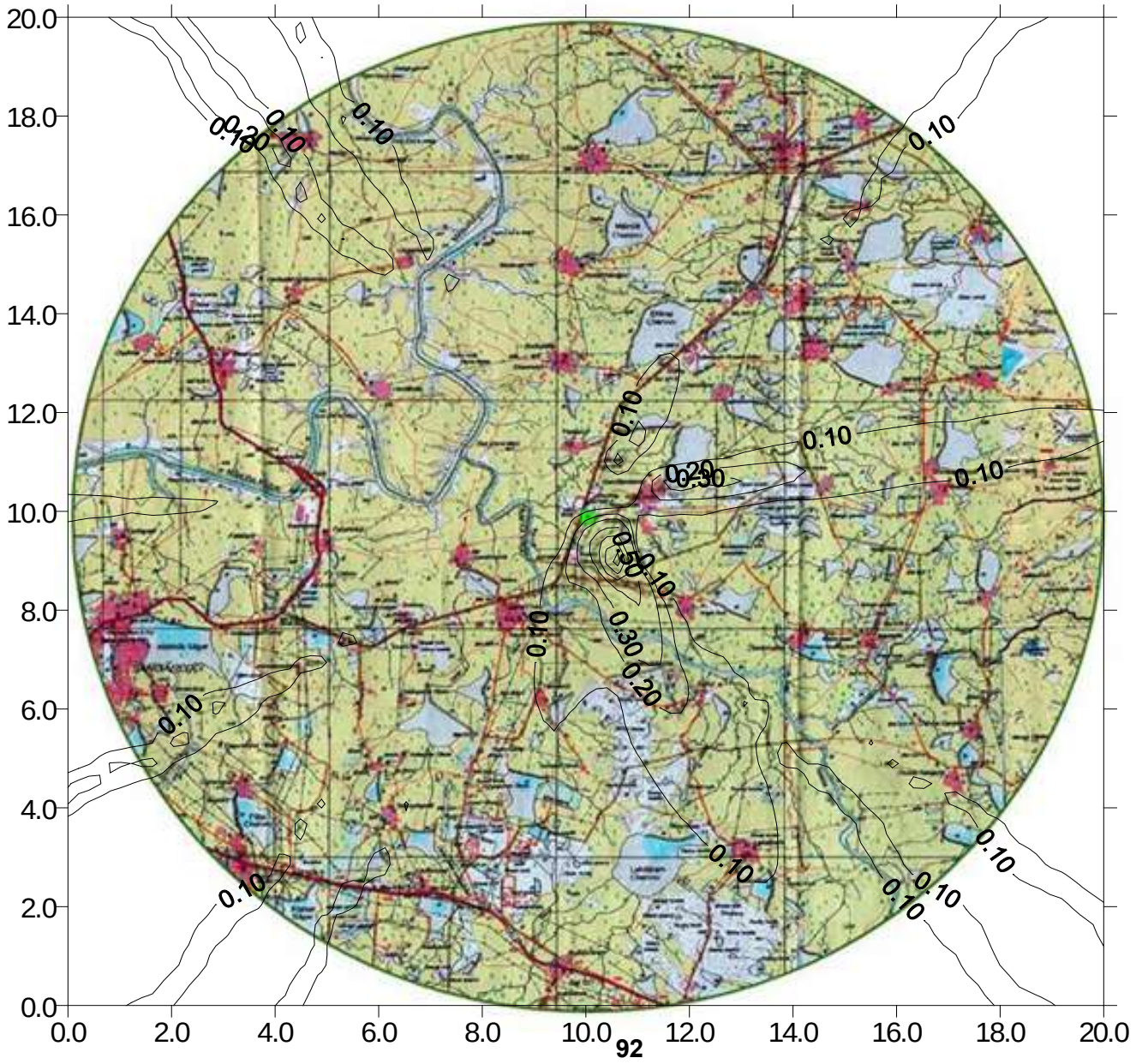
Md. Sadiq Ali
BOARD ANALYST

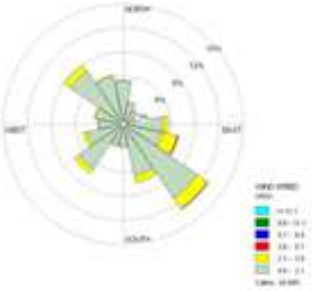
To

The Environmental Engineer,
T.S.Pollution Control Board,
RO-Sangareddy-I.

Predicted GLC of PM_{10} in $\mu g/m^3$ – 24 hourly basis

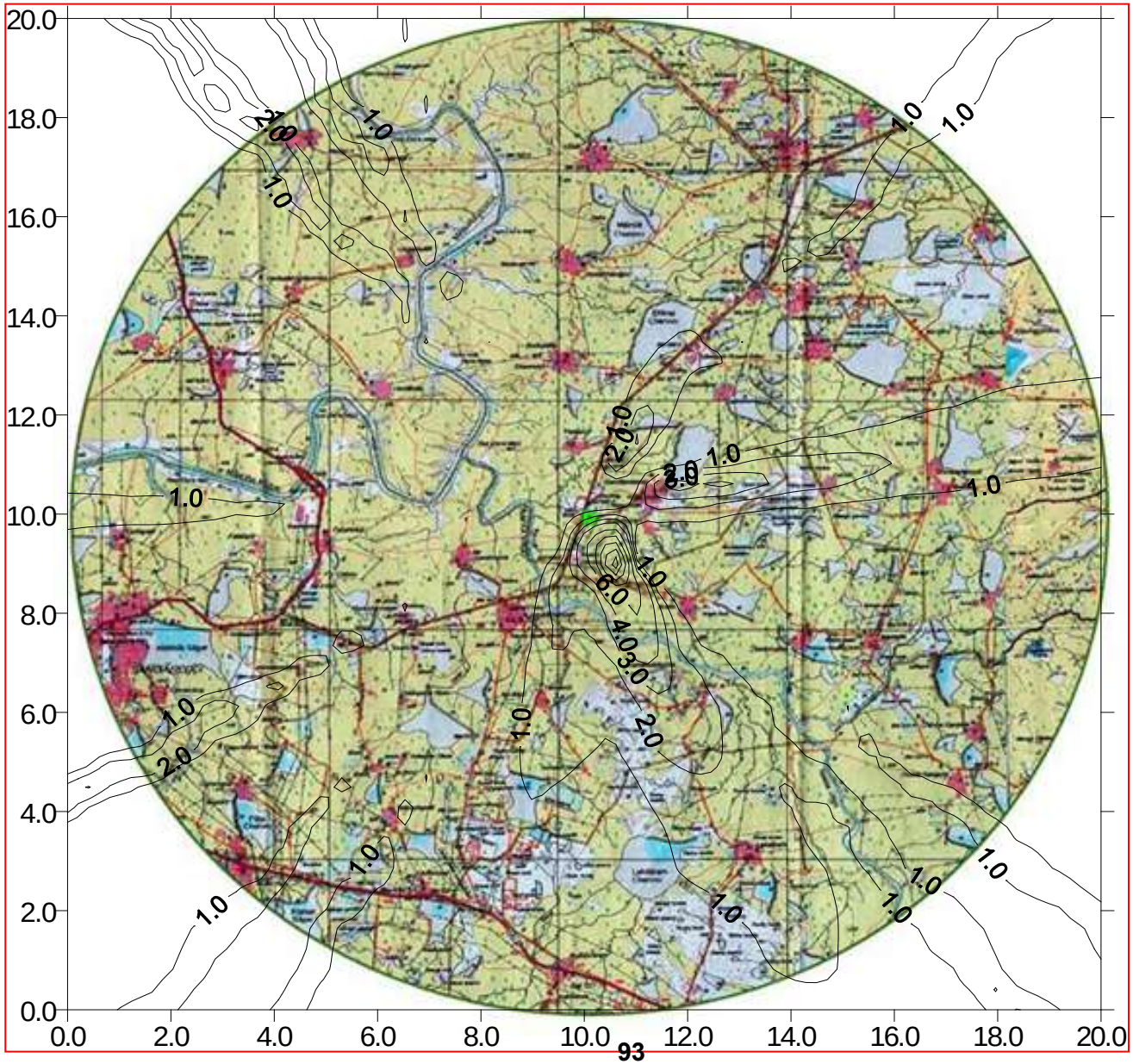
ANNEXURE - III

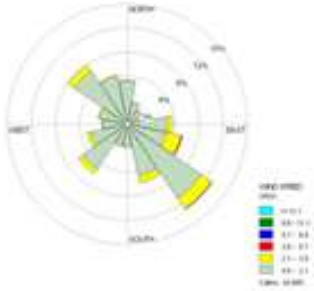




Predicted GLC of SO_2 in $\mu g/m^3$ – 24 hourly basis

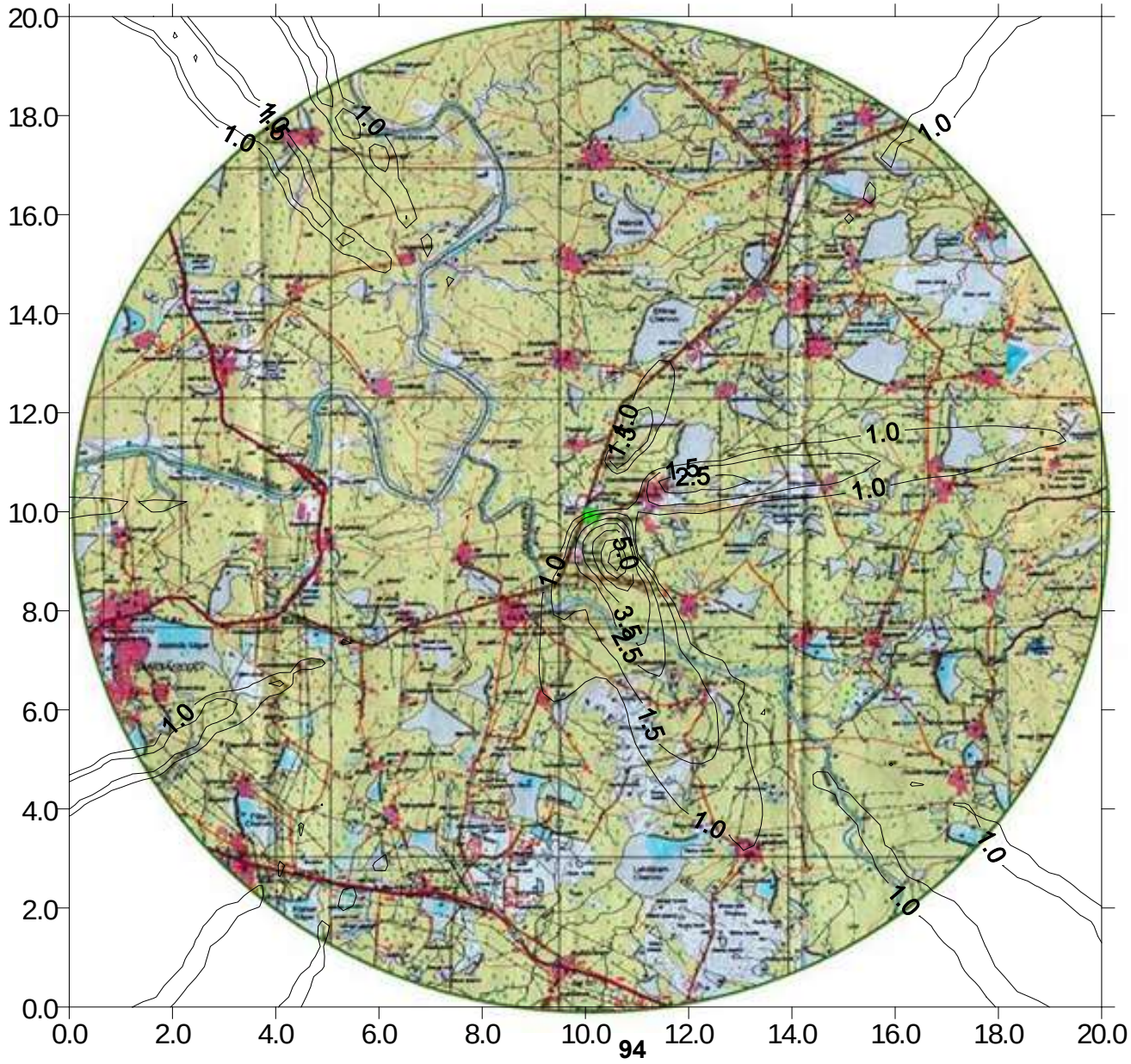
ANNEXURE - III

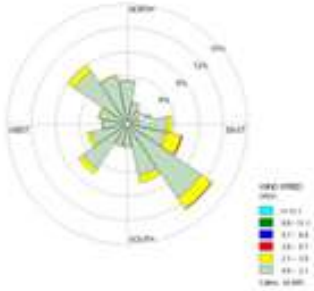




Predicted GLC of NO_x in µg/m^3 – 24 hourly basis

ANNEXURE - III





Conclusion

We humbly request the Honorable EAC Committee (Industry -2) to kindly consider our request for EC Amendment and issue the amended EC.

Thank You

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 :yogendra78@nic.in
Telefax : 011: 24695365
Dated: 23rd June, 2017

To,

M. Narayan Reddy, Managing Director
M/s Covalent Lab. Pvt. Ltd
8-3,677/18, SKD Nagar
Yellareddyguda, Hyderabad-500073
Telangana.

Sub: Expansion of bulk drugs & intermediate manufacturing unit-I along with CPP (3MW) at Sy.No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A, Gundlamachanoor(v), Hatnoora(M), Sangareedy District(formerly Medak Dist.) Telangana State by M/s Covalent Lab. Pvt. Ltd.–Amendment in Environmental Clearance-reg.

Ref :-(i) Your online application vide No.IA/TG/IND2/ 63797/2015 dated 7th April 2017.

Sir,

Kindly refer to your online application vide No.IA/TG/IND2/ 63797/2015 dated 7th April 2017 in which you had requested for amendment in existing EC for installation of an additional boiler of 20 TPH capacity to meet the steam requirement. The proposal also involves dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity of Environmental Clearance issued vide J-11011/375/2013-IA II (I) dated 30.12.2015.

2. MoEF&CC vide letter no. J-11011/375/2013-IA II (I) dated 30.12.2015 had granted Environmental Clearance to M/s Covalent Lab. Pvt. Ltd at village Gunlamachanoor, Mandal Halnoor, District Medak, Andhra Pradesh) to manufacture any 20 products at a time on campaign basis out of 65 products with total production capacity of 2400TPA (200TPM) along with 3 MW coal based CPP.

3. The above proposal was considered by the Expert Appraisal Committee (Industry) in its 22nd meeting held during 17th to 18th April 2017. The project proponent and the accredited consultant M/s KKB Envirocare Consultants Pvt. Ltd., Hyderabad made a detailed presentation on the proposal and informed that:

(i) The project involves expansion of bulk drugs & intermediate manufacturing unit-I along with CPP (3MW) at village Gunlamachanoor, Mandal Halnoor, District Medak, Andhra Pradesh by M/s Covalent Lab. Pvt. Ltd.
(ii) Industry obtained its Environmental Clearance F. No. J-11011/375/2013-IA.II (I) dated 30-12-2015 to manufacture any 20 products at a time on campaign basis out of 65 products with total production capacity of 2400 TPA (200 TPM) along with 3 MW coal based CPP.
(iii) The Public Hearing for this project was conducted on 04-12-2014.

(iv) Industry obtained Consent for Establishment (CFE) vide order No. 01/TSPCB/CFE/RO-SR-I/HO/2016-1596 dated 29-09-2016 and Consent for Operation (CFO) vide order no. TSPCB/SRD/HO/CFO/2017-2861 dated 28-01-2017 valid upto 30-09-2021.

(v) After the unit was put into operation in January 2017, it has come to the knowledge that the overall Steam Requirement was underestimated during the proposal submitted in 2014-15 for expansion by about 12 TPH. Hence, Proponent after thorough understanding of the requirement has proposed to request for Amendment to the Environmental Clearance from the MoEF&CC for the installation of an additional boiler of 20 TPH capacity with 2 MW Captive Power generation along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load.

(vi) *Products and capacities* - Application for Environmental Clearance (EC) amendment for additional boiler of 20 TPH with 2MW CPP with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products.

A. List and Quantities of the Proposed and retained permitted Products and its status:-

Sl. No.	Products	Permitted Quantity (TPA)	Proposed Quantity (TPA)	Status
1	**Cefixime Trihydrate**	**780**	**1100**	Increased
2	**Cefpodoxime Proxetil**	**120**	**300**	Increased
3	**Cefuroxime Axetil**	**180**	**300**	Increased
4	Cefuroxime Sodium	24	**24**	Retained
5	**Ceftriaxone Sodium**	**180**	**180**	Retained
6	Cefpirome Sulfate	12	12	Retained
7	**Cefdinir Monohydrate**	**72**	**72**	Retained
8	**Cefprozil Monohydrate**	**60**	**60**	Retained
9	Cefepime Dihydrochloride Monohydrate	12	12	Retained
10	**Cefuroxime Acid**	**36**	**36**	Retained
11	Cefditoren Pivoxil	12	12	Retained
12	Ceftibuten Monohydrate	24	**24**	Retained
13	Cefazoline Sodium	12	12	Retained
14	Cefoperazone Sodium	12	12	Retained
15	Cefoxitin Sodium	6	6	Retained
16	Ceftazidime Pentahydrate	6	6	Retained
17	**Cefotaxime Sodium**	**36**	**36**	Retained
18	Ceftizoxime Sodium	12	12	Retained
19	Cephalothin Sodium	12	12	Retained
20	Cefpodoxime Acid	12	12	Retained
21	Cefcapene Pivoxil	9.6	10	Retained
22	Cefmetazole Sodium	12	12	Retained
23	Cefmetazole	12	12	Retained
24	**Meropenem**	**60**	-	Dropped
25	Imipenem	24	-	Dropped
26	Cilastatin Sodium	24	-	Dropped
27	Ertapenem Sodium	12	-	Dropped
28	**Doripenem Monohydrate**	**60**	-	Dropped
29	Biapenem	12	-	Dropped
30	**Faropenem Sodium**	**36**	-	Dropped
31	Panipenem	12	-	Dropped
32	Tebipenem Pivoxil	1.2	-	Dropped
33	Darifenacin Hydrobromide	6	-	Dropped
34	Solifenacin Succinate	6	-	Dropped

35	Tolterodine Tartrate	6	-	Dropped
36	**7-AVNA**	**60**	**60**	Retained
37	**MEAT (Thio Ester)**	**60**	**60**	Retained
38	**7-APCA**	**36**	**36**	Retained
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	12	12	Retained
40	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**24**	**24**	Retained
41	**Lacosamide**	**120**	-	Dropped
42	Silodosin	24	-	Dropped
43	Fingolimod Hydrochloride	24	-	Dropped
44	**Cinacalcet Hydrochloride**	**120**	-	Dropped
45	**Fexofenadine Hydrochloride**	**120**	-	Dropped
46	Sitagliptin Phosphate	24	**18**	Decreased
47	Prasugrel Hydrochloride	24	**18**	Decreased
48	Venlafaxine Hydrochloride	24	-	Dropped
49	Pregabalin	24	**18**	Decreased
50	Diacerein	24	**18**	Decreased
51	**Dronedarone Hydrochloride**	**120**	-	Dropped
52	Linezolid	24	**18**	Decreased
53	Ropinirole Hydrochloride	24	**18**	Decreased
53	Ropinirole Hydrochloride	24	**18**	Decreased
54	D-Cycloserine	24	18	Decreased
55	Clopidogrel Hydrogen Sulfate	24	18	Decreased
56	Bosentan	24	18	Decreased
57	Candesartan Cilexitil	24	18	Decreased
58	**Deferasirox**	**120**	-	Dropped
59	Febuxostat	24	18	Decreased
60	Azilsartan medoxomil	24	18	Decreased
61	Solifenacin Succinate	24	18	Decreased
62	Darifenacin Hydrobromide	24	18	Decreased
63	Trospium Chloride	24	18	Decreased
64	Tolterodine Tartrate	24	18	Decreased
65	Valsartan	24	18	Decreased
Maximum Production on various combinations (any 20 products at a time on campaign basis)		**2400**	**2420**	
Captive Power Generation		**3 MW**	**3 & 2 MW**	

B. Proposed Products with their capacities and Therapeutic Category:-

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	CAS No.	Therapeutic Category / API Intermediate
1	**Cefixime Trihydrate**	**3055**	**1100**	125110-14-7	Antibiotic
2	**Cefpodoxime Proxetil**	**833**	**300**	87239-81-4	
3	**Cefuroxime Axetil**	**833**	**300**	64544-07-6	
4	Cefuroxime Sodium	**66.7**	**24**	56238-63-2	
5	**Ceftriaxone Sodium**	**500**	**180**	104376-79-6	

6	Cefpirome Sulfate	33.3	12	98753-19-6	
7	**Cefdinir Monohydrate**	**200**	**72**	213978-34-8	
8	**Cefprozil Monohydrate**	**166.7**	**60**	121123-17-9	
9	Cefepime Dihydrochloride Monohydrate	33.3	12	123171-59-5	
10	**Cefuroxime Acid**	**100**	**36**	55268-75-2	Anti-Infective
11	Cefditoren Pivoxil	33.3	12	117467-28-4	Antibiotic
12	Ceftibuten Monohydrate	**66.7**	**24**	97519-39-6	Anti-Infective
13	Cefazoline Sodium	33.3	12	27164-46-1	Anti-Infective
14	Cefoperazone Sodium	33.3	12	62893-20-3	Antibiotic
15	Cefoxitin Sodium	16.7	6	33564-30-6	
16	Ceftazidime Pentahydrate	16.7	6	78439-06-2	
17	**Cefotaxime Sodium**	**100**	**36**	64485-93-4	
18	Ceftizoxime Sodium	33.3	12	68401-82-1	
19	Cephalothin Sodium	33.3	12	58-71-9	
20	Cefpodoxime Acid	33.3	12	80210-62-4	Antibacterial
21	Cefcapene Pivoxil	26.7	10	105889-45-0	Antibiotic
22	Cefmetazole Sodium	33.3	12	56796-39-5	
23	Cefmetazole	33.3	12	56796-20-4	
24	**7-AVNA**	**166.7**	**60**	79349-82-9	Cefixime Intermediate Cefdinir Intermediate Cefprozil Intermediate Cefpodoxime Proxetil Intermediate Cefditoren Pivoxil Intermediate
25	**MEAT (Thio Ester)**	**166.7**	**60**	143183-03-3	
26	**7-APCA**	**100**	**36**	120709-09-3	
27	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	12	24701-69-7	
28	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**66.7**	**24**	155723-02-7	
29	Sitagliptin Phosphate	**50**	**18**	654671-78-0	Antidiabetic
30	Prasugrel Hydrochloride	**50**	**18**	389574-19-0	Anti-Hypertensive
31	Pregabalin	**50**	**18**	148553-50-8	Anti-Convulsant
32	Diacerein	**50**	**18**	13739-02-1	Anti-inflammatory
33	Linezolid	**50**	**18**	165800-03-3	Antibiotic
34	Ropinirole Hydrochloride	**50**	**18**	91374-20-8	Antidyskinetic
35	D-Cycloserine	50	18	*68-41-7*	Antituberculosis
36	Clopidogrel Hydrogen Sulfate	50	18	135046-48-9	Anti-thrombotic
37	Bosentan	50	18	147536-97-8	Anti-Hypertensive
38	Candesartan Cilexitil	50	18	145040-37-5	Anti-Hypertensive
39	Febuxostat	50	18	144060-53-7	Antigout
40	Azilsartan medoxomil	50	18	863031-21-4	Anti-Hypertensive
41	Solifenacin Succinate	50	18	242478-38-2	Antimuscarinic Agent
42	Darifenacin	50	18	133099-07-7	Anticholinergic

	Hydrobromide				
43	Trospium Chloride	50	18	10405-02-4	Antispasmodic
44	Tolterodine Tartrate	50	18	124937-52-6	Antimuscarinic Agent
45	Valsartan	50	18	137862-53-4	Anti-Hypertensive
	Total (Any 20 products at a time)	**6721**	**2420**		

C. Recovered & Purified By-Products for Reuse:

S. No.	By-Product	Permitted Crude (TPA)	Proposed Crude (TPA)	By product from the product	Reuse/ Sale
1.	Triphenylphosphine oxide	565.3	797.6	Cefixime Trihydrate	Reuse
2.	2-Mercaptobenzothiazole	280.7	396.05	Cefixime Trihydrate	Reuse
		57.5	143.94	Cefpodoxime Proxetil	Reuse
		36.36	36.36	MEAT (Thio Ester)	Reuse
	Total		**576.35**		
3.	Recovered Sodium Salts (Sodium Bromide & Sodium Chloride)	-	623.5	Cefixime Trihydrate Cefuroxime Axetil 7-AVNA	Sale
4.	Phenyl acetic acid		330.05	Cefixime Trihydrate	Reuse
		-	36.72	7-AVNA	Reuse
	Total		**366.77**		

(vii) Land: Permitted Land: 11.85

(viii) Raw materials: Raw materials are chemicals/solvents and the fuel etc. Source local (indigenous) markets/imported based on the availability.

(ix) Water Requirement: Permitted: 457 KLD (Fresh Water): Addittional: 86 KLD and Total after amendment 543 KLD (Fresh Water). Source: Ground water through Private Tankers.

(x) Power: Permitted 30 TPH coal fired boiler for 3 MW CPP and proposed additional 20 TPH coal fired boiler for 2 MW CPP.

(xi) Fuel: Permitted Coal consumption: 150 TPD for 30 TPH boiler. Additional 100 TPD for 20 TPH boiler. Source: Imported/Indian coal Existing 10, 4 TPH boilers and 15 lakh Kcal/hr coal fired Thermic fluid heater will remain standby. 1075 lit/hr of diesel will be used for permitted 5x1010 KVA & 320 KVA DG sets. DG sets are used for during power failure.

(xii) The Gross investment for the proposed project would marginally increase from the originally estimated Rs. 212.94 crores to Rs. 225 Crores.

(xiii) This site is at a distance of about 0.7 km from Gundlamachanoor village (nearest habitation), Water bodies: Nakka Vagu (rivulet) - 1 km; Manjeera River - 2.5 km (W). There are no Reserved Forests in 10 km radius.

4. The EAC after detailed deliberations accepted the amendments subject to compliance of following conditions:

i. No increase in total production/year.
ii. The plant will follow Zero Liquid discharge concept.
iii. The plant will use coal with sulphur content less than 0.5% as a fuel source for boilers.
iv. Development of 10m wide green belt of perennial trees like Neem, Seasam, Kadamda etc. around the plant periphery.
v. Planting of 1000 trees/year for Five Years in Five nearby identified villages. The status of plantation and survival rate of plants shall be reported to RO, MoEF&CC in Six Monthly compliance report.

vi. Environment Management Cell with well-equipped laboratories shall be setup in the unit.A regular environment manager having post graduate qualification in environmental sciences/ environmental engineering to be appointed for looking after the environmental management activities of the proposed plant.

5. The Ministry accepts the recommendation of the EAC (Industry-II) subject to above conditions;

6. All other terms and condition mentioned in Environmental Clearance No.J-11011/375/2013-IA II (I) dated 30.12.2015 will remain the same.

7. This issues with the prior approval of the Competent Authority.

23.6.2017

(Yogendra Pal Singh)
Scientist 'D'

Copy to :

1. The Secretary, Department of Environment and Forests, Govt. Of Andhra Pradesh, Hyderabad.
2. The Chief Conservator of Forests (Central), Ministry of Environment, Forests and Climate Change, Regional Office(SZ), Kendriya Sadan, IVth Floor, E&F Wing, 17th Main Road, Koramangala, Bangalore-560034.
3. The Chairman, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi-110032.

23.6.2017

(Yogendra Pal Singh)
Scientist 'D'