

F. No.J-11011/180/2016-IA-II(I)
Government of India
Ministry of Environment, Forest and Climate Change
IA Division

Indira Paryavaran Bhawan
Jor Bagh Road, N Delhi - 3
Dated: 21st August, 2019

To,

M/s RL Fine Chem Private Ltd
Plot No-165-182, APIIC
IDA, Village Thumukunta, Mandal Hindupur
District **Anantapur** (Andhra Pradesh)

Sub: Expansion of Active Pharmaceutical Ingredients and drug intermediates manufacturing unit by M/s RL Fine Chem Private Limited at Plot. No.165-182, APIIC, IDA, Village Thumukunta, Mandal Hindupur, District Anantapur (Andhra Pradesh) - Environmental Clearance - reg.

Ref: Online proposal No.IA/AP/IND2/88190/2017 dated 2nd March, 2019.

Sir,

This has reference to your online proposal No.IA/AP/IND2/88190/2017 dated 2nd March, 2019 for environmental clearance to the above project.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for grant of environmental clearance to the project for expansion of Active Pharmaceutical Ingredients (APIs) and drug intermediates manufacturing unit from 7.2 TPM to 48.6 TPM (26 nos of APIs & drug intermediates-21) by M/s RL Fine Chem Private Limited in an area of 4.32 acres located at Plot. No.165-182, Andhra Pradesh Industrial Infrastructure Corporation Limited (APIIC), IDA, Village Thumukunta, Mandal Hindupur, District Anantapur (Andhra Pradesh).

3. The details of existing and proposed products are as under:-

(a) Existing Products

S. No	Product	Capacity (Kgs/day)
Group A		
1	Chloro acetyl benzo phenone	8.00
2	P-t- Butyl chloride	30.00
3	Piperidine propiophenone	28.00
4	Dotheipinone	94.00
5	Chloro ethyl piperidine HCl	30.00
6	Doxipinone	50.00
Total Group A		240.00
Group B		
1	Hydroxyl dimethyl thiophene	15.00
2	Di benzo suberone	40.00
Total Group B		55.00
Group C		
1	Benzophenone methyl ester	2.50
2	Dotheipinone	200.00
3	Chloro ethyl piperidine HCl	37.50

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	Total Group C	240.00
	Group D	
1	Hydroxyl dimethyl di benzyl	4.50
	Total Group D	4.50
	Worst case Scenario (Any One Group of products will be manufactured at any given point of time)	240.00

(b) Proposed products

S. No	Product	Capacity (Kgs/day)	Capacity (TPM)
	API's		
1	Nortrytyline HCl	37.33	1.12
2	Desipramine HCl	4.33	0.13
3	Cyproheptadine HCl	3.00	0.09
4	Pitofenone HCl	3.04	0.09
5	Pyrimethamine	2.22	0.07
6	Cyclobenzaprine HCl	3.96	0.12
7	Clomipramine HCl	2.67	0.08
8	Chlorpromazine HCl	5.25	0.16
9	Doxlamine Succinate	4.79	0.14
10	Trimipramine Maleate	2.06	0.06
11	Flupentixol HCl	1.11	0.03
12	Melitracen HCl	1.64	0.05
13	Carbinoxamine Maleate	2.92	0.09
14	Opipramol HCL	1.50	0.05
15	Sulfadoxine	8.33	0.25
16	Doxiepin HCl	1.56	0.05
17	Dothiepin HCl	4.097	0.12
18	Flunarazine HCl	2.39	0.07
19	Duloxetine HCl	3.33	0.10
20	Dapoxetine HCl	1.67	0.05
21	Desvenlafaxine HCl	2.11	0.06
22	Trihexyphenaldyl HCl	3.33	0.10
23	Tramadol HCl	9.00	0.27
24	Sulfamethoxy Pyrazine HCl	2.08	0.06
25	Buclazine HCl	2.50	0.08
26	Meclazine HCl	2.28	0.07
	Total (APIs)	118.50	3.55
	Drug Intermediates		
1	Orphenadrine base	266.67	8.00
2	Carbamezapine	66.67	2.00
3	Hydroxy dimethyl dibenzyl Intermediate	20.00	0.60
4	Piperidine propiophenone	33.33	1.00
5	Cinnarizine crude	66.67	2.00
6	Doxiepinone	20.00	0.60
7	Ditheipinone	33.33	1.00
8	Methoxy Dichloro Pyrimidine	66.67	2.00
9	P- t- Butyl benzyl chloride	33.33	1.00
10	Chloro Acetyl benzo phenone	50.00	1.50
11	Chloro ethyl piperidino Hydrochloride	33.33	1.00

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12	Dibenzo suberone	266.67	8.00
13	Hydroxy dimethyl amino thiophene	16.67	0.50
14	Chlorolmino di benzyl	100.00	3.00
15	Benzophenone methyl ester	33.33	1.00
16	2-Amino Nitro Benzo Phenone	26.67	0.80
17	Dimethylaminocyclohexanone	83.33	2.50
18	Bromo anisole	83.33	2.50
19	ChloroPheno thiazine	66.67	2.00
20	Iso propyl propionate (Ester)	33.33	1.00
21	Di Methyl amino propyl chloride	100.00	3.00
	Total Intermediates	1500.00	45.00
	Total APIs + Intermediates	1618.50	48.6
	By Products		
1	Sodium chloride	9.59	0.3
2	Ammonium chloride	22.9	0.7
3	Spent Acid	270.41	8.1
4	Ammonium Phosphate	67.65	2.0
5	Sodium Acetate	35.27	1.1

4. Existing land area is 4.32 acres, and no additional land shall be required for the proposed expansion. Green belt will be developed in 33% i.e.1.42 acres of the total project area. The estimated project cost is Rs.3.0 crores. Total capital cost earmarked towards environmental pollution control measures is Rs.1.5 crores and the recurring cost (O&M) will be about Rs.30 lakhs per annum.Total Employment will be 70 persons as direct & 30 persons indirect for the proposed project.

5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves and Wildlife Corridors etc within 10 km from the project site. River Pennar flows at a distance of 2.2 km in West direction from the site.

6. Total water requirement is estimated to be 67.9 cum/day, which includes fresh water requirement of 39.9 cum/day, proposed to be met from APIIC water supply.

Effluent of 30.9 cum/day quantity will be treated through Stripper, Multiple Effect Evaporator and Agitated Thin Film Dryer for high TDS Stream. Low TDS effluent will be treated in ETP followed by RO system. Treated effluent of 28 cum/day shall be reused in the process. There will be no discharge of treated/untreated waste water from the unit, and thus ensuring Zero Liquid Discharge.

Power requirement after expansion will be 500 kVA, proposed to be met from Andhra Pradesh State Power Distribution Corporation limited (APSPDCL). Existing unit has one DG set of 200 kVA capacity. Additionally, 1 X 250 kVA DG Set will be used as standby during power failure. Stack (height 3.2 m) will be provided as per CPCB norms to the proposed DG set

Existing unit has one briquette fired boiler of capacity 2 TPH. To cater the proposed expansion, one more boiler of capacity 2 TPH will be installed along with multi cyclone separator and stack of height of 30 m to control the particulate emissions (within statutory limit of 115 mg/Nm³).

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7. The project/activity is covered under category B of item 5(f) 'Synthetic Organic Chemicals' of schedule to the Environment Impact Assessment (EIA) Notification, 2006. However, due to applicability of general condition (interstate boundary within 5 km), the proposal requires appraisal/approval at central level in the Ministry.

8. The standard terms of reference for the project was granted on 31st January, 2018. Public hearing is exempted as the project site is located inside the notified industrial area.

9. The proposal for environmental clearance was considered by the EAC (Industry-2) in its meetings held on 6-8 May, 2019, wherein the project proponent and their accredited consultant presented the EIA/EMP report. The Committee found the EIA/EMP report complying with the ToR and recommended the project for grant of environmental clearance.

10. Based on the proposal submitted by the project proponent and recommendations of the EAC, Ministry of Environment, Forest and Climate Change hereby accords environmental clearance to the project for **expansion of Active Pharmaceutical Ingredients (APIs) and drug intermediates manufacturing unit from 7.2 TPM to 48.6 TPM by M/s RL Fine Chem Private Limited** at Plot. No.165-182, APIIC, IDA, Village Thumukunta, Mandal Hindupur, District Anantapur (Andhra Pradesh), under the provisions of the EIA Notification, 2006, read with subsequent amendments therein, subject to compliance of the terms and conditions as environmental safeguards, as under:-

(a) Necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, shall be obtained from the State Pollution Control Board.

(b) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.

(c) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.

(d) National Emission Standards for Bulk drugs Manufacturing Industry issued by the Ministry vide G.S.R.149(E) dated 4th March, 2009 and amended from time to time shall be followed. Fugitive emissions shall be controlled at 99.98% with effective chillers.

(e) No raw material/solvent prohibited by the concerned regulatory authorities from time to time, shall be used.

(f) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.

(g) 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.
- (h) Total fresh water requirement shall not exceed 39.9 cum/day, proposed to be met from APIIC Water Supply. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (i) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- (j) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (k) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- (l) 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.
- (m) Fly ash should be stored separately as per CPCB guidelines so that it may not adversely affect the air quality. Direct exposure of workers to fly ash and dust should be avoided.
- (n) The company shall undertake waste minimization measures as below:-
 - (i) Metering and control of quantities of active ingredients to minimize waste.
 - (ii) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - (iii) Use of automated filling to minimize spillage.
 - (iv) Use of Close Feed system into batch reactors.
 - (v) Venting equipment through vapour recovery system.
 - (vi) Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- (o) The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (p) At least 1% of the total project cost shall be allocated for Corporate Environment Responsibility (CER) and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (q) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- (r) 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.



(s) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

(t) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

10.1 The grant of Environmental Clearance is further subject to compliance of other generic conditions as under:-

(i) The project authorities must strictly adhere to the stipulations made by the state Pollution Control Board (SPCB), State Government and/ or any other statutory authority.

(ii) No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

(iii) The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.

(iv) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with.

(v) The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).

(vi) The Company shall harvest rainwater from the roof tops of the buildings to recharge ground water, and to utilize the same for different industrial operations within the plant.

(vii) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis.

(viii) The company shall 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 shall be implemented.


(ix) The company shall undertake all measures for improving socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villagers, administration and other stake holders. Also eco-developmental measures shall be undertaken for overall improvement of the environment.



- (x) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- (xi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.
- (xii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parishad/ Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.
- (xiii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
- (xiv) 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&CC by e-mail.
- (xv) The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at <http://moef.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional office of the Ministry.

11. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.

12. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991, read with subsequent amendments therein.


21/8/2019
(S. K. Srivastava)
Scientist E

Copy to:-

1. The Addl. PCCF, Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1st&2nd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, **Chennai** - 34

2. The Principal Secretary, Department of Environment, Forest, Science & Technology, Government of Andhra Pradesh, **Hyderabad** (Andhra Pradesh)
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, **Delhi** - 32
4. The Member Secretary, Andhra Pradesh Pollution Control Board, Paryavaran Bhawan, A-III, Industrial Estate, Sanath Nagar, **Hyderabad** (Andhra Pradesh)
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor bagh Road, **New Delhi**
6. Guard File/Monitoring File/Record File.

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21/8/2019

(S. K. Srivastava)
Scientist E