

F.No. IA-J-11011/557/2017- IA II(I)
Government of India
Ministry of Environment, Forest and Climate Change
(IA-II Section)

Indira Paryavaran Bhawan
Jorbagh Road, New Delhi - 3

Dated: 18th September, 2019

To

M/s Emmennar Pharma Pvt Ltd
Plot No. A-4, Industrial Estate
Opposite Sanath Nagar Police Station
Sanath Nagar
Hyderabad – 500 018 (Telangana)

Sub: Setting up Bulk Drug and Intermediates manufacturing unit at Village Peddapally, Mandal Jadcherla, District Mahabubnagar (Telangana) by M/s Emmennar Pharma Pvt Ltd (Unit V)- Environmental Clearance - reg.

Sir,

This has reference to your proposal No. IA/TG/IND2/71286/2017 dated 10th April 2019, on the subject matter.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for environmental clearance to the project for Setting up Bulk Drug and Intermediates manufacturing unit of capacity 960 TPM by M/s Emmennar Pharma Pvt Ltd (Unit V) in an area of 45 acres located at Sy. Nos. 632 (Part), 633 (Part), 635, 636 (Part), 637 (Part), 638 (Part) & 642 (Part) Village Peddapally, Mandal Jadcherla, District Mahabubnagar (Telangana). The proposal also involves manufacture of R&D products of capacity 50 kg/day and installation of co-generation power plant of 5 MW capacity.

3. The details products and by-products are as under:

S.No	Product	Capacity	
		TPM	TPD
1	(2-Nitro-1-(Methylamino)-1-(Methylthio) ethane (NMSM)	90	3
2	Cyclopropylamine	60	2
3	Methyl Ester	210	7
4	Levetiracetam	120	4
5	Omeprazole	60	2
6	Meta Chloroanisole	210	7
7	Meta Chloro Nitrobenzene	210	7
	Total	960	32
8	R&D and Validation Products	50 Kg/day	
9	Co-Generation Power Plant	5 MW	

By-Products

S.No	Product	Stage	By Product	Quantity (Kg/day)
1	Methyl Ester	I	Sulfur	3068.5
2	Levetiracetam	I	Tartaric acid	4041.5
		I	Hydrochloric acid (35%)	89.3

3	Omeprazole	II	Hydrochloric Acid (30%)	952
		II	Ammonium Sulfate	2144
4	Meta Chloroanisole	I	Sodium hydroxide (48%)	4091
5	Meta Chloro Nitrobenzene	I	Hydrochloric Acid (35%)	5587
			P - Chloro Nitrobenzene	873.3
			O - Chloro Nitrobenzene	873.3

4. The land available for the project is 45 acres. Industry will develop greenbelt in an area 15 acres covering 33.33% of total project area. The estimated project cost is Rs.45 crores. Total capital cost earmarked towards environmental pollution control measures is Rs.10.7 crores and the recurring cost (O&M) will be about Rs.19.43 crores per annum. Employment opportunity will be for 450 persons directly and 250 persons indirectly.

5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves and Wildlife Corridors etc within 10 km from the project site. Dindi stream is flowing from northwest to northeast direction at a distance of 9 km in northeast direction.

6. The total water requirement is estimated to be 1017.5 cum/day, which includes fresh water requirement of 549.5 cum/day, proposed to be met from ground water.

Effluent of 496.6 cum/day will be treated through effluent treatment system. High COD/TDS stream of 286.6 cum/day is segregated and sent to stripper followed by multiple effect evaporators (MEE), and agitated thin film dryer (ATFD). Condensate from stripper is sent to cement plants for co-incineration, while condensate from MEE and ATFD is mixed with low TDS/COD from utility blow downs and domestic wastewater of 210 cum/day in biological treatment plant followed by Reverse Osmosis. The treated wastewater of 468 cum/day is reused for cooling towers make-up/process. There will be no discharge of treated/untreated waste water from the unit, and thus ensuring Zero Liquid Discharge.

Power requirement will be met by AP Transco and co-generation power plant. DG sets of capacity 2 x 1010 kVA, 3 x 720 kVA and 2 x 320 kVA is proposed to cater to the energy requirement during load shut down. Stack height will be provided as per CPCB norms to the proposed DG sets.

Coal fired boilers of 30 TPH&10 TPH and 4 x2 Lac K.cal/hr thermic fluid heater will be installed. Electrostatic precipitator (ESP) and Bag filters will be installed for controlling the particulate emissions.

7. The project/activity is covered under category A of item 5(f) 'Synthetic organic chemicals industry' of the Schedule to the Environment Impact Assessment (EIA) Notification, 2006, and requires appraisal at central level by the sectoral EAC in the Ministry.

8. Standard terms of reference (ToR) for the project was granted on 25th January, 2018. Public hearing for the project was conducted by the Telangana State Pollution Control Board on 28th December, 2018.

9. The proposal was considered by the Expert Appraisal Committee (Industry-2) in the Ministry in its meeting held during 30-31 May, 2019, wherein the project proponent and their consultant M/s TEAM Labs and Consultants presented the EIA/EMP report as per the ToR. 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 (Industry-2), the Ministry of Environment, Forest and Climate change hereby accords environmental clearance to the project for **Setting up Bulk Drug and Intermediates manufacturing unit of capacity 960 TPM by M/s Emmennar Pharma Pvt Ltd (Unit V)** at Sy. Nos. 632 (Part), 633 (Part), 635, 636 (Part), 637 (Part), 638 (Part) & 642 (Part) Village Peddapally, Mandal Jadcherla, District Mahabubnagar (Telangana), under the provisions of the EIA Notification, 2006, subject to the compliance of terms and conditions as under:-

- (i) 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.
- (ii) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
- (iii) 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.
- (iv) National Emission Standards for Pharmaceuticals Industry (Bulk Drugs) 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.
- (v) Health & Risk assessment shall be conducted and the mitigating measures shall be implemented.
- (vi) No raw material/solvent prohibited by the concerned regulatory authorities from time to time, shall be used.
- (vii) 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.
- 4 (viii) Solvent management shall be carried out as follows:
 - (a) Reactor shall be connected to chilled brine condenser system.
 - (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - (c) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - (d) Solvents shall be stored in a separate space specified with all safety measures.
 - (e) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - (f) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - (g) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.

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- (ix) Total fresh water requirement shall not exceed 549.5 cum/day, proposed to be met from ground water. Prior permission in this regard shall be obtained from the concerned regulatory authority/CGWA.
 - (x) 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.
 - (xi) 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.
 - (xii) 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.
 - (xiii) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
 - (xiv) Maximum storage of raw materials viz. Dichloromethane, Toluene and Methanol shall be limited to 20 Tons at any point of time.
 - (xv) 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.
 - (xvi) The company shall undertake waste minimization measures as below:-
 - (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.
 - (xvii) 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.
 - (xviii) All the commitments made regarding issues raised during the public hearing/consultation meeting shall be satisfactorily implemented.
 - (xix) At least 3% 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.
 - (xx) 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.

- (xxi) 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.
- (xxii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (xxiii) 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.
- (xxiv) Process safety and risk assessment studies shall be further carried out using advanced models, and the mitigating measures shall be undertaken accordingly.
- (xxv) The company shall employ person having Post graduate in Environmental Sciences/Environmental Engineering for supervision of environmental management measures.

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 the Environment (Protection) Act, 1986 and the Rules made thereunder.
- (vi) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and 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. Training to all employees on handling of chemicals shall be imparted.

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- (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. CER 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 Parisad/ 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, Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and rules.


18/9/19

(Sharath Kumar Pallerla)
Scientist F

Copy to: -

1. The Deputy DGF (C), MoEF&CC Regional Office (SEZ), 1st and 11nd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, Chennai - 34
2. The Secretary, Department of Environment, Forests, Science and Technology, Government of Telangana, Hyderabad (Telangana)
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, Delhi - 32
4. The Member Secretary, Telangana State Pollution Control Board, Plot No A 3, Paryavaran Bhawan, Sanath Nagar, Hyderabad (Telangana) - 18
5. The Member Secretary, Central Ground Water Authority, 18/11, Jamnagar House, Mansingh Road, New Delhi - 11
6. The District Collector, Mahabubnagar (Telangana)
7. Guard File/Monitoring File/Website/Record File


18/9/19

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