

**F. No. J-11011/327/2019-I-II(I)**

Government of India  
Ministry of Environment, Forest & Climate Change  
Impact Assessment Division

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Indira Paryavaran Bhavan,  
Vayu Wing, 3<sup>rd</sup> Floor, Aliganj,  
Jor Bagh Road, New Delhi-110 003

Dated: 11<sup>th</sup> May, 2020

To,

**M/s Graddy Pharmachem,**  
Plot No. 205, 206, 207/18, GIDC Estate-Panoli,  
Taluka Ankleshwar,  
District **Bharuch** (Gujarat)

**Sub: Setting up Bulk Drug and Drug Intermediates manufacturing unit by M/s Graddy Pharmachem at Plot No. 205, 206, 207/18, GIDC Estate-Panoli, Taluka Ankleshwar, District Bharuch (Gujarat) - Environmental Clearance - reg.**

Sir,

This has reference to your online proposal No.IA/GJ/IND2/123966/2019 dated 1<sup>st</sup> February, 2020 for environmental clearance to the above mentioned project.

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 Drug Intermediates manufacturing unit of capacity 100 TPM by M/s Graddy Pharmachem in an area of 2592 sqm at Plot No. 205, 206, 207/18, GIDC Estate-Panoli, Taluka Ankleshwar, District Bharuch (Gujarat).

3. The details of products and capacity as under:

S. No.	Name of Product	CAS. No.	Capacity (TPM)	END Use
1.	Pregabalin	148553-50-8	50	Anti-Epileptic
2.	Atorvastatin Calcium	134523-00-5		Anti-Lipemic
3.	Metoprolol Tartrate	56392 -17-7		Anti-Hypertensive
4.	Metoprolol succinate	98418-47-41		Anti-Hypertensive
5.	Rosuvastatin	287714-41-4		Anti-Lipemic
6.	Amlodipine Besylate	88150-42-9		Used to treat high blood pressure and coronary artery disease
7.	Pantoprazole	102625-70-7		Used for the treatment of stomach ulcers, short-term treatment of erosive esophagitis due to gastroesophageal reflux disease
8.	Piroxicam	36322-90-4		Anti-inflammatory drug
9.	Lidocaine	137-58-6		Used to treat ventricular tachycardia and to perform nerve blocks
10.	Veratic Acid	93-07-2		Used in API as a Raw Material

EC for M/s Graddy Pharmachem

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11.	Lornoxicam	70374-39-9	<b>50</b>	Anti-inflammatory
12.	Mefenamic Acid	61-68-7		Anti-pain
13.	N,N'-Carbonyldiimidazole	530-62-1		Used in to couple amino acids during artificial peptide synthesis. Reagent in organic synthesis. To convert amines to amides, carbamates, ureas, alcohol to ester etc.
14.	Chloromethyl methyl ether	107-30-2		Used as an alkylating agent, industrial solvent, water repellent, synthesis of ion-exchange resin. Synthesis of MOM (methoxymethyl) protecting group, industrial polymer.
15.	tert-Butyl carbazate	870-46-2		Used as intermediate in the synthesis of HIV-1 protease inhibitors, palladium catalyzed cross coupling with vinyl halide to prepare N-Boc-N-alkenylhydrazines, peptide synthesis, purity determination of alpha amino aldehyde. Starting material for preparation of Boc-azide, sulfonic acid, carboxylic hydrazides.
16.	2,4,5 Trichloropyrimide	5750-76-5		It is used as chemical intermediate for the synthesis of antibacterial and anti-inflammatory drugs, synthesis of anaplastic lymphoma kinase inhibitor used as anti-tumor treatment, synthesis of EGFR inhibitors.
17.	Iodobenzene diacetate	3240-34-4		It is used in organic synthesis as reagents in many chemical reactions. It is used for preparation of glycol diacetates, selective catalyst for amination of hydrocarbons, preparation of heterocyclic compounds, synthesis of sulfonyloxyketones used as strong oxidizing agents.
18.	4-Methoxybenzyl chloride	824-94-2		Used as a protecting group for alcohols, phenol & various nitrogen moieties in organic synthesis. It is known as efficient protection of imide nitrogen in ribosyl nucleobase, glutarimide etc.
19.	N-Boc-piperazine	57260-71-6		It is used in the synthesis of



				varieties of pharmaceutical drugs, Preparation of series of m-phenoxy phenyl substituted derivatives, termination step during synthesis of poly(2-oxazoline) lipopolymers via living cationic ring opening polymerization.
20.	10-Methoxy-5H-dibenz[b,f]azepine-5-carbonylchloride, 10-Methoxyiminostilbene-5-carbonylchloride	28721-08-6		Use as a raw material to manufacture of Oxcarbapazine
<b>Total</b>			<b>100</b>	

4. Total land area is estimated to be 2592 sqm. Green belt will be developed in 40% i.e., 1036 sqm out of total project area. The estimated project cost is Rs. 4.5 Crores. Total capital cost earmarked towards environmental pollution control measures is Rs. 1.3 Crores and the Recurring cost (operation and maintenance) will be about Rs. 2.8 Crores per annum. Total Employment will be 30 persons as direct & indirect for project.

5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc. within 10 km distance of the project site.

6. Total water requirement is 61 cum/day of which fresh water requirement of 29 cum/day and will be met from GIDC Water Supply. Total wastewater generation will be 36.0 cum/day (Industrial: 34.7 KL/day + Domestic: 1.3 KL/day). 36 cum/day effluent will be treated in primary treatment in ETP and then sent to In-House MEE plant Followed by Solvent Stripper & ATFD. 32 cum/day MEE Condensate Will be Reuse in Plant Premises & MEE Salt will be sent to TSDF Site. 1.3 KLD Domestic wastewater will be disposed through Septic Tank/Soak Pit.

Power requirement for proposed project will be 250 KVA and will be met from DGVCL. 2 Nos. DG set of 125 KVA capacity shall be used as standby during power failure. Stack (height 18 m) will be provided as per CPCB norms to the proposed DG sets of 125 KVA which will be used as standby during power failure.

Unit shall have 1 Nos. of 1 TPH Natural Gas = 500 Nm<sup>3</sup>/Day, 1 Nos. of 2 LakhKcal/Hr Natural Gas = 200 Nm<sup>3</sup>/Day, 2 Nos. of D.G Set HSD - 100 Liter/Day will be installed. Adequate Stack height will be provided. Stack of height of 18 m will be installed for controlling the Particulate emissions (within statutory limit of 150 mg/Nm<sup>3</sup>) respectively.

7. All Synthetic Organic Chemicals Industry (Dyes & Dye Intermediates; Bulk Drugs and Intermediates Excluding Drug Formulations; Synthetic Rubbers; Basic Organic Chemicals, Other Synthetic Organic Chemicals And Chemical Intermediates) are listed in S.N. 5(f) of Schedule of Environment Impact Assessment (EIA) Notification under category 'B' to be appraised at State level. However being the project is located inside the critically polluted area, the project appraised at Central level in the Ministry.

8. The Standard terms of reference (ToR) for the project was granted on 12<sup>th</sup> December, 2019. Public hearing is exempted as per para 7(i), III. Stage (3), (i)(b) of the EIA Notification, 2006, and in accordance with the Ministry's OM dated 27<sup>th</sup> April 2018, as the project site is located in the notified industrial area.



9. The proposal for environmental clearance was considered by the EAC (Industry-2) in its meeting held on 13-15 April, 2020. The project proponent and their consultant M/s Aqua-Air Environmental Engineers Pvt. Ltd. (Hon'ble High Court of Gujarat stay order), made a detailed presentation through Video Conferencing (VC) and have presented the EIA/EMP report. The Committee found the EIA/EMP report to be satisfactory, complying with the ToR, and recommended the project for grant of environmental clearance.

10. The EAC, constituted under the provision of the EIA Notification, 2006 and comprising of Experts Members/domain experts in various fields, have examined the proposal submitted by the Project Proponent in desired form along with EIA/EMP report prepared and submitted by the Consultant on behalf of the Project Proponent. The EAC noted that the project proponent has given undertaking that the data and information given in the application and enclosures are true to the best of his knowledge and belief and no information has been suppressed in the EIA/EMP report. If any part of data/information submitted is found to be false/ misleading at any stage, the project will be rejected and Environmental Clearance given, if any, will be revoked at the risk and cost of the project proponent.

11. The Committee noted that the EIA/EMP report is in compliance of the ToR issued for the project, reflecting the present environmental concerns and the projected scenario for all the environmental components. The Committee has found the baseline data and incremental GLC due to the proposed project within NAAQ standards. The EAC has deliberated the proposal and has made due diligence in the process as notified under the provisions of the EIA Notification, 2006, as amended from time to time and accordingly made the recommendations to the proposal. The Experts Members of the EAC have found the proposal in order and have recommended for grant of Environmental Clearance (EC). The Committee also deliberated the compliances of the Ministry's OM dated 31.10.2019 (Critically Polluted Areas)

12. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), Ministry of Environment, Forest and Climate Change hereby accords environmental clearance to the project for **setting up Bulk Drug and Drug Intermediates manufacturing unit of capacity 100 TPM by M/s Graddy Pharmachem** at Plot No. 205, 206, 207/18, GIDC Estate-Panoli, Taluka Ankleshwar, District Bharuch (Gujarat), under the provisions of the EIA Notification, 2006, and the amendments therein, subject to compliance of the terms and conditions as under:-

**A. Specific Condition**

- (i) Consent to Establish/Operate (CTE/CTO) for the project shall be obtained from the State Pollution Control Board (SPCB) as required under the Air (Prevention and Control of Pollution) Act, 1981 and the Water (Prevention and Control of Pollution) Act, 1974, and the SPCB shall follow the mechanism/protocol issued by the Ministry vide letter no. Q-16017/38/2018-CPA dated 24<sup>th</sup> October, 2019 and forwarded by Central Pollution Control Board vide letter dated 25<sup>th</sup> October, 2019 to the SPCB's, while issuing the CTE/CTO for the project, for improvement of environmental quality in the area.
- (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. All the waste water to be collected and to be reused after treatment.
- (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 4<sup>th</sup> March, 2009 and amended from time to time shall be followed.
- (v) Fugitive emissions shall be controlled at 99.98% with effective chillers.
- (vi) Volatile organic compounds (VOCs)/Fugitive emissions shall be controlled at 99.997% with effective chillers/modern technology.
- (vii) No raw material/solvent prohibited by the concerned regulatory authorities from time to time, shall be used.
- (viii) 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.
- (ix) 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) Solvents shall be stored in a separate space specified with all safety measures.
  - (d) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - (e) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
  - (f) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (x) Total fresh water requirement shall not exceed 29 cum/day, proposed to be met from GIDC water supply. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (xi) 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. All the vent pipes should be above the roof level.
- (xii) 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. Raw material and products should be stored in leak proof containers. Spent acid to be stored over the ground tank and to be sent to TSDF.
- (xiii) 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.
- (xiv) 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.
- (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 cleaning to reduce wastewater generation.
- (xvii) The green belt of at least 5-10 m width shall be developed in not less than 40% 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) As proposed 4% of the total project cost shall be allocated towards Corporate Environment Responsibility (CER). As proposed, and the CER allocation shall be spent mainly for addressing the issues (social, health, employment, infrastructure, Drinking water facility, skill development, plantation etc).
- (xix) Preference shall be given to local villagers for employment in the unit. 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.
- (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 including dental check up of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (xxii) 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 ZLD, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

## **B. General Conditions:**

- (i) The Project Proponent shall obtain all other statutory/necessary permissions/recommendations/NOCs prior to start of construction/operation of the project, which inter alia include, permission/approvals under the Forest (Conservation) Act, 1980; the Wildlife (Protection) Act, 1972; the Coastal Regulation Zone Notification, 2019, as amended from time to time, and other Office Memoranda/Circular issued by the Ministry of Environment, Forest and Climate Change from time to time, as applicable to the project.
- (ii) The project proponent shall ensure compliance of 'National Emission Standards', as applicable to the project, issued by the Ministry from time to time. The project proponent shall also abide by the rules/regulations issued by the CPCB/SPCB for control/abatement of pollution.
- (iii) The project authorities shall adhere to the stipulations made by the State Pollution Control Board/Committee, Central Pollution Control Board, State Government and any other statutory authority.



- (iv) The project proponent shall prepare a site specific conservation plan and wildlife management plan in case of the presence of Schedule-1 species in the study area, as applicable to the project, and submit to Chief Wildlife Warden for approval. The recommendations shall be implemented in consultation with the State Forest/Wildlife Department in a time bound manner.
- (v) No further expansion or modifications in the plant, other than mentioned in the EIA Notification, 2006 and its amendments, 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.
- (vi) The energy source for lighting purpose shall be preferably LED based, or advance having preference in energy conservation and environment betterment.
- (vii) 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 station each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (viii) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> November, 2009 shall be followed.
- (ix) 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).
- (x) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and to utilize the same for process requirements.
- (xi) 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.
- (xii) 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, and risk mitigation measures relating to the project shall be implemented.
- (xiii) The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CER activities shall be undertaken by involving local villages and administration and shall be implemented.
- (xiv) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- (xv) A separate Environmental Management Cell (having qualified person with Environmental Science/Environmental Engineering/specialization in the project area) equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- (xvi) 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.
- (xvii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad/Municipal Corporation, Urban local Body and the local



- NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.
- (xviii) 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.
  - (xix) The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF&CC by e-mail.
  - (xx) 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 and at <https://parivesh.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.
  - (xxi) 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.
  - (xxii) This Environmental clearance is granted subject to final outcome of Hon'ble Supreme Court of India, Hon'ble High Court, Hon'ble NGT and any other Court of Law, if any, as may be applicable to this project.

**13.** 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.

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

**15.** Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

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

**17.** This issues with the approval of the competent authority.

  
(Dr. R. B. Lal)  
Scientist 'E'/Additional Director



**Copy to: -**

1. The Principal Secretary, Forests & Environment Department, Government of Gujarat, Sachivalaya, 8<sup>th</sup> Floor, **Gandhi Nagar** - 382 010 (Gujarat)
2. The Dy. Director General of Forest (Western Zone), MoEF&CC, Regional Office, E-5, Arera Colony, Link Road -3, Ravishankar Nagar, **Bhopal** - 462 016 (MP)
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, **Delhi** -32
4. The Member Secretary, Gujarat Pollution Control Board, Paryavaran Bhawan, Sector 10 A, **Gandhi Nagar**-382 043 (Gujarat)
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, **New Delhi** - 3
6. District Collector, **Bharuch, (Gujarat)**
7. Guard File/Record File/Monitoring File/Website of MoEF&CC

  
(Dr. R. B. Lal)  
**Scientist 'E'/Additional Director**