

J-11011/232/2014-IA II (I)  
Government of India  
Ministry of Environment, Forest & Climate Change  
(IA Division)

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Dated: 31<sup>st</sup> January, 2017

To,

The Vice President  
M/s Alembic Pharmaceuticals Limited (API Unit-II)  
Survey No. 119, 120 & 121, Village - Panelav,  
Halol, District - Panchmahal  
Gujarat - 389350

**Subject: Expansion of Active Pharmaceutical Ingredient (APIs) in Existing Unit at Survey No. 119, 120 & 121, At & Post village Panelav, Tehsil Halol, District Panchmahal, Gujarat by M/s Alembic Pharmaceuticals Limited (API Unit - I) - Environmental Clearance - reg.**

**Ref.: Your online proposal no. IA/GJ/IND2/30972/2014 dated 16<sup>th</sup> September, 2015.**

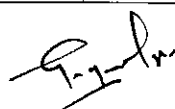
Sir,

This has reference to your online proposal no IA/GJ/IND2/30972/2014 dated 16<sup>th</sup> September, 2015 along with project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report along with Public Hearing Report regarding above mentioned project.

2.0 The Ministry of Environment, Forests and Climate Change has examined the application. It is noted that proposal is for expansion of Active Pharmaceutical Ingredient (APIs) in Existing Unit at Survey No. 119, 120 & 121, At & Post village Panelav, Tehsil Halol, district Panchmahal, Gujarat by M/s Alembic Pharmaceuticals Limited (API Unit - I). Total plot area is 68530.26 m<sup>2</sup>, of which greenbelt will be developed on 24000 m<sup>2</sup> (i.e. 35% of total area). Total cost of the expansion project is ` 36.81 crore. Out of this, ` 4.32 crore is earmarked for environment management system. A river Vishwamitri is flowing at a distance 3.2 km. Following products will be manufactured:

S. No.	Product	Existing (MT/M)	Proposed (After Expansion) (MT/M)
1	Clarithromycin	25	75
2	Azithromycin		
3	Roxythromycin		
4	Venlafaxine		
5	Fenofibrate		

6	Irbesartan		
7	Valsartan		
8	Telmisartan		
9	Clonidine Hydrochloride		
10	Modafinil		
11	Leflunomide		
12	Alendronate Sodium		
13	O Desmethyl Venlafaxine		
14	Meprobamate		
15	Vildagliptin		
16	Rivastigmine Tartrate		
17	Topiramate		
18	Lacosamide		
19	Pramipexole Dihydrochloride Monohydrate		
20	Olmesartan Medoxomil		
21	Linezolid		
22	Lercanidipine Hydrochloride		
23	Fluxetine Hydrochloride		
24	Deferasirox		
25	Ropinorole Hydrochloride		
26	Hydrochlorothiazide		
27	Lamotrigine		
28	Metoprolol Tartrate		
29	Metoprolol Succinate		
30	Quetiapine Fumarte		
31	Pentosan Polysulphate Sodium		
32	Levetiracetam		
33	Famotidine		
34	Memantine HCL	0	
35	Pregabalin		
36	Ivabradine		
37	Azilsartan		
38	Etoricoxib		
39	Derifenacin		
40	Celecoxib		
41	Rabeprazole Sodium		
42	Clopidogrel Bisulfate		
43	Felodipine		
44	Prasugrel Hydrochloride		
45	Mexiletine Hydrochloride		
46	Warfarin		
47	Bazedoxifene		
48	Bosentan		
49	Febuxostate		
50	Dronedarone		
51	Dabigatran		
52	Rivaroxaban		
53	Asenapine		



54	Silosodine		
55	Zolmitritan		
56	Iloperidone		
57	Agomelatine		
58	Ticagrelor		
59	Metaxalon		
60	Vilazodone Hydrochloride		
61	Teriflunomide		
62	Nisoldipine		
63	Fesoterodine Furmarate		
64	Minodronic acid		
65	Erlotinib		
66	Gefitinib		

3.0 Bag filter will be provided to agro-waste/briquettes fired boiler to control particulate emissions. ESP will be provided to imported coal fired boiler. Quencher and alkali scrubber will be provided to incinerator. Scrubber will be provided to control process emissions viz. HCl, Cl<sub>2</sub> and NH<sub>3</sub>. Total Water requirement will be increased from 195 m<sup>3</sup>/day to 397.5 m<sup>3</sup>/day after expansion. Out of which fresh water requirement from ground water source will be 160 m<sup>3</sup>/day. Industrial effluent generation will be 245 m<sup>3</sup>/day, which is proposed to be segregated into high COD/TDS and low COD/TDS effluent stream. High COD effluent will be neutralized, treated through solvent stripper and multi effect evaporator and ATFD. Low COD/TDS effluent stream will be treated in the ETP followed by RO and treated effluent from RO will be recycled/reused for cooling tower make up. No effluent will be discharged outside the plant premises. ETP sludge and sludge from scrubber will be sent to TSDF. Distillation residue and process waste will be sent to Authorized recyclers/re-processors.

4.0 Public Hearing / Public Consultation meeting was conducted by the Gujarat Pollution Control Board on 12th June 2015.

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-2) in its 7<sup>th</sup> and 12<sup>th</sup> meetings held during 28<sup>th</sup>-29<sup>th</sup> April, 2016 and 23<sup>rd</sup>-24<sup>th</sup> August, 2016. Project Proponent and the EIA Consultant namely Aqua-Air Environmental Engineers Pvt. Ltd. Stay order no. SCA/4979/2012 dated 24/1/2013., have presented EIA / EMP report as per the TOR. EAC has found the EIA / EMP Report and additional information to be satisfactory and in full consonance with the presented TORs. The Committee recommended the proposal for environmental clearance.

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 14<sup>th</sup> September 2006, subject to the compliance of the following Specific and General Conditions:

**A. SPECIFIC CONDITIONS:**



- i. Bagfilter and the stack of adequate height shall be provided to additional coal fired boiler. Online monitoring system to be installed to stack and emission level to be uploaded to company's website and displayed to the main gate for public.
- ii. Scrubber shall be provided to control process emissions viz. NH<sub>3</sub>, HCl and Cl<sub>2</sub>. 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.
- iii. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits imposed by SPCB. Odour management plan shall be implemented.
- iv. Total fresh water requirement from ground water source shall not exceed 160 m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA.
- v. 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.
- vi. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- vii. 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.
- viii. 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 SPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire-fighting facilities in case of emergency.
- ix. Fly ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
- x. Solvent management shall be as follows :
  - Reactor shall be connected to chilled brine condenser system
  - Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
  - The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery



- Solvents shall be stored in a separate space specified with all safety measures.
- Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
- Entire plant where solvents are used shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- xi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xii. All the issues raised during the Public Hearing/consultation meeting held on 12th June 2015 shall be satisfactorily implemented and adequate budget provision shall be made accordingly.
- xiii. As proposed, an amount of Rs. 5.42 core should be earmarked towards the Enterprise Social Commitment on the activities proposed by PP for local and social development and based on Public Hearing issues. Annual physical and financial progress achieved to be submitted to the Ministry's Regional Office at Bhopal. Implementation of such program shall be ensured accordingly in a time bound manner.
- xiv. As proposed, green belt of 24000 m<sup>2</sup> 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.

#### **B. GENERAL CONDITIONS:**

- i. The project authorities must strictly adhere to the stipulations made by the Gujarat State Pollution Control Board (GPCB), 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 GPCB and it shall be ensured that at least one station 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. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic wastewater and storm water drains.
- vii. Usage of Personnel Protection Equipments by all employees/ workers shall be ensured.
- viii. 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.
- ix. The company shall also comply with all the environmental protection measures and safeguards proposed in the project report 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.
- x. The company shall undertake CSR activities and all relevant measures for improving the socio-economic conditions of the surrounding area.
- xi. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xiii. The company shall earmark sufficient funds for recurring cost per 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.
- xiv. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, ZilaParisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who suggestions/ representations, if any, were received while processing the proposal.
- xv. 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 State Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
- xvi. The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated shall be submitted to the 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 Bhopal Regional Offices of MoEF by e-mail.

xvii. 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.

xviii. 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.

  
(Yogendra Pal Singh)  
Scientist 'D'

**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 Chief Conservator of Forests (Western Zone), Ministry of Environment & Forests, Regional Office, E-5, Arera Colony, Link Road -3, Bhopal -462 016, M.P.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, Gujarat State Pollution Control Board, Paryavaran Bhawan, Sector 10 A, Gandhi Nagar-382 043, Gujarat.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Guard File/Monitoring File/Record File.

  
(Yogendra Pal Singh)  
Scientist 'D'

