

State Environment Impact Assessment Authority, M.P.
(Government of India, Ministry of Environment & Forests)

Research and Development Wing
Madhya Pradesh Pollution Control Board
Paryavaran Parisar, E-5, Arera Colony
Bhopal-4620 16
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No: 438 / EPCO-SEIAA /12

Date: 28/6/2012

To,
Amit Sareen (Sr. G. Manager)
M/s Lupin Limited
Plot No. 2, (Special Economic Zone) SEZ
Phase-II, Misc. Zone Apperal Park
Pithampur, Dist. Dhar (M.P) - 454775
Phone no. 07292-417311
Email – amitsareen@Lupinpharma.com

Sub: Case No. 546/2010, Prior Environmental Clearance for manufacturing facility for formulation products and active pharmaceutical ingredients (API) at plot no. 2, SEZ, Phase-II, Miscellaneous Zone, Apparel Park, Pithampur, District Dhar, M.P. by M/s Lupin Ltd.

This has reference to your letter No. Nil dtd. 03.04.2010 received in SEIAA office on 08.04.2010, ToR issued by SEAC on 24.06.2010 and subsequent letters seeking Prior Environmental Clearance for the above project under the EIA Notification, 2006. The proposal has been appraised as per prescribed procedure in the light of provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the Form - I, Pre-Feasibility Report, ToR and subsequently submission of EIA and the additional clarifications furnished in response to the observations of the State Expert Appraisal Committee (SEAC) and State Environment Impact Assessment Authority (SEIAA) constituted by the competent Authority.

2. It has been noted that the proposal is for manufacture of for Manufacturing of Active Pharmaceuticals Ingredients (API) at Plot No. No. 2, SEZ Phase-II, Misc. Zone Apperal Park, Pithampur, Dist. Dhar (M.P) by M/s Lupin Limited. The total land acquired by the plant is 107965 M2. It lies 75° 38' 8"E longitude and 22° 37' 17" N latitude and an altitude 558 m above MSL. The project site is 28 km from Indore Municipal Corporation. The nearest town village Pithampur is 4.0 km ESE.
3. The total production capacity enhancement of two products (Norethindrone and Levonorgestrel), while remaining four products will continue to be manufactured at existing production capacity. The proposed expansion capacity is as follows:

S. No.	Product	Production (kg/year)	Remark
1.	Norethindrone	64.9	Out of the ten products, only three products shall be manufactured at a time
2.	Levonorgestrel	184.1	
3.	Drosperinone	509	

4.	Dinogest	169.8	Out of the four products, only one products shall be manufactured at a time
5.	Gestodene	10	
6.	Estradiol Valerate	16.5	
7.	Ethinyl Estradiol Betadex	2	
8.	Balara (Chlormadinone)	121.3	
9.	Northindrone Acetate	2	
10.	Qlaira	2	
11.	Travoprostone	0.96	
12.	Bimatoprost	0.96	
13.	Latnoprost	0.96	
14.	Lubiprostone	1.92	

The by products will be as follows:

S. No.	By Product	Capacity (TPA)
1	Recovered Solvents	4005

4. The additional water required i.e. 274 KLD will be supplied by MPAKVN. (325.5 m3/day for process 379 m3/day for cooling / boiler and 81 m3/day for domestic purpose). The waste water 147 KLD generated from various activities due to proposed expansion will be treated in the effluent treatment. ETP capacity is 150 KLD. Power backup supply 2 no. DG sets (1500 KVA and 1250 KVA) will be installed. An area of 35721.24 sqmt shall be covered under plantation.
5. The project has been considered in accordance with the provisions of the EIA notification issued by the Ministry of Environment & Forests vide S.O. 1533 (E), dated September 14, 2006.
6. The project is located in notified industrial area, as per notification issued by Commerce Industries and Employment Deptt. GoMP (Letter no. 154/165/2012/B-11 dtd 08.01.12) the proposed activity is not prohibited in industrial area. Hence public hearing was not required.
7. Based on the information submitted at Para 2 and 3 above, the State Level Environment Impact Assessment Authority (SEIAA) considered the case in its 96th meeting held on 11.06.12 and decided to accept the recommendations 80th SEAC meeting held on 03.09.2011.
8. Hence Prior Environmental Clearance is accorded for manufacturing facility for formulation products and active pharmaceutical ingredients (API) at plot no. 2, SEZ, Phase-II, Miscellaneous Zone, Apparel Park, Pithampur, District Dhar, M.P. by M/s Lupin Ltd. under the provisions of EIA notification dtd. September 14, 2006, subject to the compliance of the Standard Conditions enclosed at Annex-I (except conditions no.31) and the following additional Specific Conditions as recommended by SEIAA & SEAC:
 - a. Effluent treatment plant proposed to be installed should be designed for the worst scenario as the key parameters observed in the raw waste water vary from batch to batch.
 - b. Facility to analyze total and dissolved organic carbon on regular basis should be developed prior to production.
 - c. CSR activities proposed for Dist. Dhar should be taken up immediately as per plan.

- d. Dedicated & well designed solvent recovery plant has to be installed to ensure more than 95 % recovery of solvents.
- e. A thick green belt shall be developed around the periphery of the unit using selected trees with rich canopy.
- f. Characterizations of all solid wastes have to be carried out immediately after production is commenced and the report with collection, storage & disposal plan has to be submitted to MPPCB and MoEF.
- g. Use of Poly-electrolytes in effluent treatment shall be evaluated and monitored as a part of project monitoring and reported to MPPCB & MoEF.
- h. Organic Carbon has to be analyzed in ground water periodically and reported to MPPCB.
- i. Detailed mitigation plan for any adverse findings has to be prepared and submitted to MPPCB prior to commencement of production.
- j. CREP Charter has to be followed stringently.

Encl: Annex-I


4/c **Member Secretary**

Endt No. 439 / EPCO - SEIAA/12 Dated: 25/6/2012

Copy to:-

1. Principal Secretary, Department of Environment, Government of Madhya Pradesh, Mantralaya, Bhopal.
2. Member Secretary, SEAC, Research and Development Wing Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5. Arera Colony Bhopal-4620 16
3. Member Secretary, Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5, Arera Colony, Bhopal-462016
4. Collector, District Dhar, M.P.
5. Division, Monitoring Cell, MoEF, GoI, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi- 110 003
6. General Manager, MP Audyogik Kendra Vikas Nigam (Indore) Ltd., Free Press House, First Floor, 3/54, Press Complex, Agra-Mumbai Road, Indore-452 018 ()
7. Director (S), Regional Office, Western Region, Kendriya Paryawarn Bhawan, Link Road No. 3 Ravi Shankar Nagar, Regional office of the MOEF, Bhopal-462016
8. Guard file

Encl: Annex-I


4/c (Dr. U. M. Shukla)
Officer-in-Charge

State Environment Impact Assessment Authority, M.P.


(Government of India, Ministry of Environment & Forests)
Research and Development Wing, Madhya Pradesh Pollution Control Board,
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Annex-I

Standard Conditions related to item 5 (f) of the schedule of EIA notification, 2006

(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)

1. The company shall install an effluent treatment plant to treat the effluent generated due to proposed activity. The treated water shall be utilized within the premises to achieve zero discharge.
2. The hazardous wastes and Incineration from the process and treatment should be disposed off as per Hazardous Wastes ^{waste} (Management & Handling) Rules, 1989 and subsequent amendments.
3. The project authority shall obtain the membership of CTSDf (Common Treatment Storage & Disposal Facility) for disposal of solid and hazardous waste (if applicable) and copy of the same shall be submitted to the Regional Office of MoEF, Gol at Bhopal. The company shall maintain the valid membership of CTSDf.
4. The process emissions, VOCs and particulate matter from various units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission level shall go beyond the stipulated standards.
5. 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 MPPCB.
6. The company shall carry out the HAZOP study and the report shall be submitted to Regional Office of MoEF, Gol at Bhopal.
7. The company shall comply with the CREP guidelines prepared by MPPCB for Bulk Drug Plants.
8. The company shall develop greenbelt in the project area as per the guidelines of CPCB to mitigate the effect of fugitive emission.
9. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixings of accidental spillages with domestic waste and storm drains.


(Dr R P Singh)
Officer-in-Charge


(Dr Vinita Vipat)
Officer-in-Charge


(Dr Sadhna Tiwari)
Officer-in-Charge

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5 (f) 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

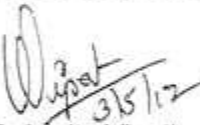
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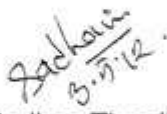
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10. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
11. The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.
12. The DG set will be provided with acoustic arrangements to attenuate the noise pollution. The emission from DG set shall be dispersed as per the CPCB/MPPCB standards.
13. Industry should get the Emergency Disaster Management Plan approved by DTHS and should also comply with the provisions made in Public Liability Insurance Act, 1991.
14. Any enhancement of capacity, change in technology, modernization and scope of working shall again require prior environmental clearance as per EIA notification, 2006.
15. All activities / mitigative measures proposed by PP in Environmental Impact Assessment must be ensured.
16. All activities / mitigative measures proposed by PP in Environmental Management Plan and approved by SEAC must be ensured.
17. All parameters listed in Environmental Monitoring Plan approved by SEAC must be monitored at approved locations and frequencies.
18. Vehicular emissions shall be kept under control and regularly monitored. Vehicles used for transportation of raw material and others shall have valid permissions as prescribed under Central Motor Vehicle Rules, 1989 and its amendments. No overloading of raw material for transportation shall be committed.
19. The company shall develop rain water harvesting structures to harvest the run off water for recharge of ground water.
20. A separate Environmental Management Cell with suitable qualified personnel shall be set-up under the control of a Senior Executive, who will report directly to the Head of the Organization.
21. The funds earmarked for environmental protection measures shall be kept in separate account and shall not be diverted for other purpose. Year wise expenditure shall be reported to the Regional office of the Ministry of Environment and Forest, Bhopal and MP PCB.
22. Commitment towards CSR have to be followed strictly.


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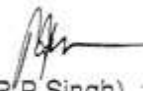
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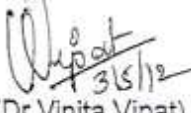
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23. All other statutory clearances such as the approvals for storage of diesel from Chief Controller of Explosives, Fire Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wildlife (Protection) Act, 1972 etc. shall be obtained (as and when applicable), by the project proponent from the respective competent authorities.
24. The Regional Office, MoEF, Gol, Bhopal and MP PCB shall monitor compliance of the stipulated conditions. A complete set of documents including Environment Impact Assessment Report, Environmental Management Plan, should be given to Regional Office, MoEF, Gol, Bhopal and MP PCB.
25. The Project Proponent has to submit half yearly compliance report of the stipulated prior environmental clearance terms and conditions in hard and soft copy to the Regulatory Authority on 1st June and 1st December of each calendar year.
26. A copy of the environmental clearance shall be submitted by the Project Proponent to the Heads of the Local Bodies, Panchayat and Municipal Bodies as applicable in addition to the concerned Government Departments / organization responsible for controlling the proposed projects who in turn has to display the same for 30 days from the date of receipt.
27. The project proponent has to strictly follow directions/guideline issued by the MoEF, Gol, CPCB and other Govt. agencies from time to time.
28. The Project Proponent shall advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the clearance letter informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with the State Pollution Control Board and also at web site of the State Level Environment Impact Assessment Authority (SEIAA) website at www.mpseiaa.nic.in and a copy of the same shall be forwarded to the Regional Office, MoEF, Gol, Bhopal and MP PCB.
29. The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.
30. The SEIAA of M.P. reserves the right to add additional safeguard measures subsequently, if found necessary, and to take action including revoking of the environment clearance under the provisions of the Environmental (Protection) Act, 1986, to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.


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5 (f) 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)

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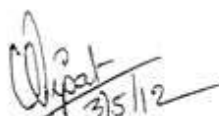
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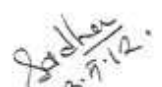
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31. Action plan with respect to suggestion/improvement and recommendations made and agreed during public hearing consultation shall be submitted to the Regional Office, MoEF, GoI, Bhopal, MP PCB within six months.
32. These stipulations would be enforced among others under the provisions of Water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and control of Pollution) Act 1981, the Environment (Protection) Act, 1986, the Public Liability (Insurance) Act, 1991 and EIA Notification, 2006.
33. The Ministry or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.
34. 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.
35. Any appeal against this prior environmental clearance shall lie with the Green Tribunal, if necessary, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
36. The prior Environmental Clearance granted for the project is valid for a period of five years as per EIA notification dtd. 14.09.2006.
37. The proponent shall upload the status of compliance of the stipulated EC conditions, including results of monitored data on their 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 SPCB. The criteria pollutant levels namely; SPM, RSPM, SO₂, NO_x (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the project shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.
38. The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent 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 EC conditions and shall also be sent to the Regional Office of MoEF.


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