



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

Environmental Planning Coordination Organization (EPCO)  
Paryavaran Parisar, E-5. Arera Colony  
Bhopal-4620 16

visit us <http://www.mpseiaa.nic.in>

Tel: 0755-2466970, 2466859

Fax : 0755-2462136

REGISTERED - POST.

No: 2953

/SEIAA/2015

Date: 3.7.15


To,  
Mr. V.S. Satpute (Sr. Vice President & Site Head)  
M/s Lupin Ltd Plot No.198-202,  
New Industrial Area No. 2, Mandideep,  
Distt.-Raisen (MP) 462046.

**Sub:- Case No. 970/2012** Prior Environmental Clearance for Capacity Enhancement of the existing products (22 nos.), production of 08 new products and solvent recovery; at existing Plot Nos. 198-202; area 230447 sq.m, New Industrial Area No. 2, Mandideep, Distt. Raisen (MP) by M/s Lupin Ltd. through Mr. V.S. Satpute (Sr. Vice President & Site Head) Plot No 198-202, New Industrial Area No. 2, Mandideep, Distt.-Raisen (MP) 462046.

**Ref:** Your application dtd. 05.11.12 received in SEIAA office on 07.11.2012

With reference to above, the proposal has been appraised as per prescribed procedure & provisions under the EIA notification issued by the Ministry of Environment & Forests vide S.O. 1533 (E), dated 14<sup>th</sup> September 2006 and its amendments, on the basis of the mandatory documents enclosed with the application viz., Form I, pre-feasibility report, ToR and EIA Report and additional clarifications furnished in response observations by the State Expert Appraisal Committee (SEAC) and State Environment Impact Assessment Authority (SEIAA) constituted by the competent Authority.

- (i) This is a case of expansion of existing Pharmaceutical Bulk Drugs plant and no construction of building is required for proposed expansion. The project is proposed in the existing premises of Lupin at Plot No. 198-202, New Industrial Area No. - 2, Mandideep, Distt. - Raisen (MP).
- (ii) The project is covered under 5 (f) category B of the Schedule of EIA Notification issued by the Ministry of Environment & Forests vide S.O.1533(E), dtd. September 14, 2006 and its amendments.

  
(Ajatshatru Shrivastava)  
Member Secretary

Case No. 970/2012

Issued vide letter no. 2953-54 dated 3.7.15

Case No.: To be quoted in registered cases for correspondence


- (iii) The proposed unit is an existing unit. PP has obtained prior EC from MoEF, Gol vide letters dtd 29.04.1997 & 10.05.2006. MP-SEIAA has issued prior EC vide letter no. 145 dtd 28.05.2010 (case no. 148/2008) for 10 products. Presently PP has applied for enhancement of production capacity of existing products (22 nos.) and production of 8 new products and solvent recovery as follows :-

S. No.	Product Name	Existing Capacity (MTA)	Additional Proposed (MTA)	Total (MTA)
1	Cephalexin	1000	--	1000
2	Cefadroxil	120	--	120
3	Cefaclor	120	180	300
4	Cefazoline Sodium	20	--	20
5	Cephadrine	10	--	10
6	Cefuroxime Axetil	20	30	50
7	Ceftriaxone Disodium	25	--	25
8	Cefotaxime Sodium	25	--	25
9	CeftazidimePentahydrate	25	--	25
10	Lisinopril	100	50	150
11	Benazepril	10	--	10
12	Cefdinir	24	26	50
13	CefiximeTrihydrate	15	--	15
14	CefpodoximeProxetil	12	8	20
15	Cefprozil Monohydrate	10	15	25
16	Cefipime	10	--	10
17	Ceftiofur Sodium	10	--	10
18	Perindopril	10	--	10
19	Trandolapril	5	--	5
20	Quinapril	20	--	20
21	Ramipril	15	--	15
22	Brimonidine Tartrate	--	1	1
23	Candesartan Cilexetil	--	1	1
24	Amlodipine Besylate	--	10	10
25	Donepezil Hcl	--	1	1
26	Tolterodine Tartrate	--	1	1
27	Rosuvastatin Calcium	--	8	8
28	Pitavastatin	--	1	1
29	CeftarolineFosamilMonoacetate	--	5	5
30	Pilot Plant (R&D and Trial Run Products)	1	9	10
By-product Generation				
31.	Recovered Solvent	7000	--	7000

(Ajatshatru Shrivastava)  
Member Secretary



- (iv) There is no National park / Sanctuaries, Eco-sensitive areas, critically polluted areas and inter-State boundaries within 05 km around the proposed site.
- (v) The total land area of the project is 230447 sq.m for which allotment letters issued from MP Audyogik Kendra Vikas Nigam (Bhopal) Ltd. for plot nos. 198 to 202 (vide dtd 28.10.1986, 09.03.1987, 09.03.1987, 30.05.1988 & 28.10.1986).
- (vi) The proposed unit is located in notified Industrial area Mandideep, Distt. Raisen (M.P) hence as per GoI, MoEF OM dtd 10.12.14 Public hearing is exempted.
- (vii) The source of water supply is MPAKVN (letter dtd 13.03.2014 for supply of 600 KLD water) & Ground water (CGWA letter dtd 03.11.2008 for withdrawal of 300 m3 per day). The total water requirement is 1400 KLD (Existing 1161 KLD + additional 239 KLD) & shall be used for process, utilities (boiler & cooling tower) and domestic purpose.
- (viii) After expansion the waste water generation shall be 630 KLD (Process - 450 KLD Utilities boiler & cooling tower-68 KLD Domestic-112 KLD. For the treatment of waste water PP has proposed two ETPs, 1<sup>st</sup> ETP (100 KLD) with two stage aeration system for low pollution effluent and 2<sup>nd</sup> ETP (600 KLD) with anaerobic system & two stage aeration system for high pollution effluent. PP has proposed to recycle 100% effluent through RO, MEE & ATFD for recovery of water and reuse in cooling towers boiler feed water and domestic purposes.
- (ix) Hazardous Waste will be generated from used/spent oil, spent solvent, Process residues and waste, spent catalyst, spent carbon etc and will be disposed by selling to registered recyclers or common TSDF (letter from MPPCB dtd 11.07.11 regarding authorization under Hazardous Waste (Management, Handling and Transboundary Movement Rules 2008). PP has also obtained membership of Ramky for disposal of hazardous waste at TSDF-Pithampur.
- (x) The air emission shall include NOx, SO2, PM10, PM2.5. & CO. For air pollution control PP has proposed to provide Emission control systems (scrubbers, high efficient dust collector, cycle separator, solvent in close loop system, leak detection and repair system).
- (xi) Regarding firefighting measure PP has proposed that the plant will be well equipped with suitable numbers of fire fighting and personnel protective equipment.
- (xii) The rain water harvesting is proposed from the selected clean roof top of the plant area.
- (xiii) PP has developed greenbelt in 7.65 ha (33% of total area) in the plant premises and has planted 22293 no. of plants species in and around the plant site and also along the road side.

  
(Ajatshatru Shrivastava)  
Member Secretary

Case No. 970/2012

Issued vide letter no. 2953-54 dated 3.7.15

Case No.: To be quoted in registered cases for correspondence




Based on the information submitted at Para i to xiii above and others, the State Level Environment Impact Assessment Authority (SEIAA) considered the case in its 202<sup>nd</sup> meeting held on 25.05.2015 and decided to accept the recommendations of 183<sup>rd</sup> SEAC meeting held on dtd 27.04.15.

Hence, Prior Environmental Clearance is accorded under the provisions of EIA notification dtd. 14<sup>th</sup> September 2006 to the proposed Capacity Enhancement of existing products (22 nos), production of 08 new products and solvent recovery; at existing Plot Nos. 198-202; area 230447 sq.m, New Industrial Area No. 2, Mandideep, Distt. Raisen (MP) by M/s Lupin Ltd. through Mr. V.S. Satpute (Sr. Vice President & Site Head) Plot No.198-202, New Industrial Area No. 2, Mandideep, Distt.-Raisen (MP) subject to the compliance of the Standard Conditions enclosed at Annex-I and the following additional Specific Conditions as recommended by SEIAA & SEAC in its meetings.

**A. Specific Conditions as recommended by SEIAA**

1. PP should ensure that the demand of fresh water should not exceed 801KLD.
2. PP should ensure:
  - (a) Recycling of effluent through RO, MEE and ATFD for recovery of water and reuse for boiler and cooling tower. The Part of the treated effluent of ETP-I should be used for chemical preparation in ETP-II.
  - (b) The waste water generated should be treated in the Effluent Treatment Plant and recycled in the Zero Liquid Discharge facility to recover water and there should be no discharge from the unit.
  - (c) Proper piezometric holes for ground water sampling.
  - (d) Maximum solvent recovery during process.
3. PP should ensure :
  - (a) Solid waste disposal and Hazardous Waste disposal as per the conditions of Authorization issued by MPPCB.
  - (b) Disposal of hazardous waste is linked with TSDF Ramky on regular practice.
  - (c) Installation of decanters & spin flash dryer at site for ETP sludge and non-hazardous waste.
  - (d) The storage area has a proper and adequate secondary containment system, drain all along its periphery. The shed has provision of adequate storage capacity for the waste generated in the premises.
  - (e) No open storage is done and the designated hazardous waste storage area has proper enclosures, including safety requirements.
4. The performance of air pollution control system should be regularly monitored and maintained. Regular stack monitoring & ambient air quality monitoring should be carried out as per the guidelines/norms of MPPCB/CPCB.

  
(Ajatshatru Shrivastava)  
Member Secretary

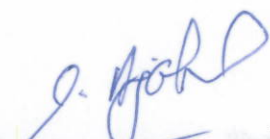


5. PP should obtain fire NOC from the competent authority.
6. PP should ensure rain water harvesting.
7. PP should ensure plantation as proposed in 7.65 ha and it should be as per the CPCB guidelines.
8. PP should obtained approval from competent authority for health & safety measure, Onsite & offsite disaster management, and risk management plan.

**B. Specific Conditions as recommended by SEAC**

9. All vents from the exhausts of the processes shall be connected to a scrubbing system and the scrubbing media shall be treated through the effluent treatment plant.
10. Zero liquid discharge shall be observed.
11. Log-books shall be maintained for disposal of all types of hazardous wastes and shall be submitted with the compliance report.
12. Dedicated power supply shall be ensured for uninterrupted operations of treatment systems.


**Standard Conditions - Encl: Annex-I**

  
(Ajatshatru Shrivastava)  
Member Secretary.

Endt No. / SEIAA/ 15      Dated  
Copy to:-

- (1). Principal Secretary, Urban Development & Environment Deptt. 3<sup>rd</sup> Floor, Mantralaya Vallabh Bhawan, Bhopal.
- (2). Secretary, SEAC, Research and Development Wing Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5, Arera Colony Bhopal-462016.
- (3). Member Secretary, Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5, Arera Colony, Bhopal-462016.
- (4). The Collector, Distt- Raisen -M.P.
- (5). M.D.MPAKVN (B), 1<sup>st</sup> Floor, Tawa Complex, Bittan Market, E-5, Arera Colony, Bhopal - 462 016, M.P.
- (6). Director, I.A. Division, Monitoring Cell, MoEF, GoI, Ministry of Environment & Forest Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110 003
- (7). Director (S), Regional office of the MOEF, (Western Region), Kendriya Paryavaran Bhawan, Link Road No. 3, Ravi Shankar Nagar, Bhopal-462016.
- (8). Guard file.

**Encl: Standard Conditions (Annex-I)**

  
(Ajatshatru Shrivastava)  
Member Secretary

Case No. 970/2012

Issued vide letter no. 2953-54... dated 3.9.15

Case No.: To be quoted in registered cases for correspondence



**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

27

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 (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

1 of 4

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)

24/04/2012  
23/5/2012

Issued Vide No. 2953-54  
Dated 3.7.15



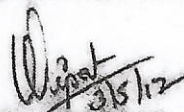
28

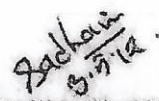
**State Environment Impact Assessment Authority, M.P.**

(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

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.

  
(Dr R P Singh)  
Officer-in-Charge

  
(Dr Vinita Vipat)  
Officer-in-Charge

  
(Dr Sadhna Tiwari)  
Officer-in-Charge

2 of 4

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)

Issued Vide No. 243-114/AA/EPCO  
Dated 23/5/2012

Issued Vide No. 2953-54/AA/EPCO  
Dated 3-7-18



# 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

29

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, GoI, 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, GoI, 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 1<sup>st</sup> June and 1<sup>st</sup> 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, GoI, 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](http://www.mpseiaa.nic.in) and a copy of the same shall be forwarded to the Regional Office, MoEF, GoI, 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.

(Dr R P Singh)  
Officer-in-Charge

(Dr Vinita Vipat)  
Officer-in-Charge

(Dr Sadhna Tiwari)  
Officer-in-Charge

3 of 4

5 (i) 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)

Issued Vide No. 29.53-54/AA/EPCO  
Dated 23.11.2022

Issued Vide No. 29.53-54/AA/EPCO  
Dated 3.7.15





(30)


**State Environment Impact Assessment Authority, M.P.**

(Government of India, Ministry of Environment & Forests)  
Research and Development Wing, Madhya Pradesh Pollution Control Board,  
Paryavarān Parisar, E-5, Arera Colony, Bhopal-4620 16

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, Gol, 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, SO<sub>2</sub>, NO<sub>x</sub> (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 31<sup>st</sup> 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.

  
(Dr R P Singh)  
Officer-in-Charge

  
(Dr Vinita Vipat)  
Officer-in-Charge

  
(Dr Sadhna Tiwari)  
Officer-in-Charge

4 of 4

5 (i) 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)

Issued Vide No. 243-14/SAIA/VEPCO  
Dated.....23/5/2012

Issued Vide No. 2953-54/SAIA/VEPCO  
Dated.....3-7-15