



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
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No: **3623** /SEIAA/2015

19.2.15


To,
Mr. Praveen Nalwaya (G.M.-Operations)
IPCA laboratoties Ltd.1,
Pharma Zone, SEZ Phase II,
Pithampur Distt-Dhar-454775.

Case No. 638/2011: Prior Environmental Clearance for Proposed Production of Synthetic Drug Metformin HCL (4800 TPA) (Active Pharmaceutical Ingredients - API) and expansion of formulation of tablets from 60 crores to 360 crores tablets per annum, in the existing plant premises area 19.84 ha at Plot No. 1, Pharma Zone, SEZ Phase II, AKVN Industrial Area Pithampur, Distt. Dhar by IPCA Laboratories Ltd., through G.M.-Operations Mr. Praveen Nalwaya IPCA laboratoties Ltd. 1,Pharma Zone, SEZ Phase II, Pithampur Distt-Dhar-454775.

Ref: Your application dtd. 02.07.11 received in SEIAA office on 25.07.2011

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 14th September 2006 and its amendment, on the basis of the mandatory documents enclosed with the application viz., Form I, pre-feasibility report, ToR, EIA Report and additional clarifications furnished in response to the observations by the State Expert Appraisal Committee (SEAC) and State Environment Impact Assessment Authority (SEIAA) constituted by the competent Authority.

- (i) The proposed project is the expansion of an operating bulk drug manufacturing unit with existing production capacity of 60 crores/annumn tablets. PP has proposed to manufacture Metformin HCL (Active Pharmaceutical Ingredients-API) 4800 TPA and capacity enhancement from 60 crores to 360 crores tablets/ annum. The bulk drug and intermediates manufacturer units are listed at S. No. 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. hence are required to obtain prior EC.
- (ii) The total land area of the project is 19.84 ha for which lease deed is executed (dtd 31.03.05) for 99 years (31.03.05 to 30.04.2104) with MP Adyogik Kendriya Vikas Nigam, Indore.


(Ajatshatra Shrivastava)
Member Secretary

Case No. 638/2011


Issued vide letter no. dated **19.2.15**

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

- (iii) There is no Wildlife Sanctuary, National Park, and Tiger Reserve within 05 km of the boundary, hence, General conditions not attracted.
- (iv) The project is located in notified Industrial Growth Centre – Pithampur, Distt. - Dhar (M.P.) approved by AKVN and no public hearing is required as per MoEF, GoI O.M. dtd. 10.12.14 issued under EIA notification, 2006.
- (v) The present water requirement is 200 KLD. The total water requirement after expansion will be 600 KLD. The source of water supply is MPAKVN for which Executive Engineer, MPAKVN has issued a commitment letter (dtd. 11.06.13).
- (vi) The total waste water generation is 310 KLD (50 KLD from domestic waste+120 KLD from process waste water+140 KLD from raw water RO & purifier). PP has proposed 50 KLD of domestic waste water will be discharged into AKVN sewerage system after treatment in STP (capacity 50 KLD). The process waste water 120 KLD is to be treated in effluent treatment plant (ETP) capacity 140 m³ / day. The treated waste water will be used in plantation and gardening in an area of 7.0 ha (17 acres) and will maintain **zero discharge** by utilizing entire treated water within the plant premises. The waste water from RO purifier (140 KLD) in the form of reject will be used directly in plantation. PP has proposed a guard pond at the site for storing treated waste water for 15 days.
- (vii) Hazardous waste will be generated from different stages of the production. PP has obtained authorization from MPPCB (dtd 10.06.10) under Hazardous Waste (Management, Handling and Transboundary Movement) Rules 2008 for a period of five years with effect from 09.04.2010.
- (viii) PP has proposed to provide on-site emergency plan and obtained approval from Govt. Of India Deptt. Commerce and Industries office of the Development Commissioner, Indore, SEZ, Indore. (letter dtd 18.02.10.)
- (ix) PP has proposed 7.0 ha (35% of the total project area) for green belt development.

Based on the information submitted at Para ii to ix above and others, the State Level Environment Impact Assessment Authority (SEIAA) considered the case in its 175th meeting held on 13.01.2015 and decided to accept the recommendations of 136th SEAC meeting held on dtd 23.07.13.

Hence, Prior Environmental Clearance is accorded under the provisions of EIA notification dtd. 14th September 2006 to the proposed Production of Synthetic Drug Metformin HCL (4800 TPA) (Active Pharmaceutical Ingredients - API) and expansion of formulation of tablets from 60 crores to 360 crores tablets per annum, in the existing plant premises area 19.84 ha at Plot No. 1, Pharma Zone, SEZ Phase II, AKVN Industrial Area Pithampur, Distt. Dhar by IPCA Laboratories Ltd., through G.M.-Operations Mr. Praveen Nalwaya IPCA laboratories Ltd. 1, Pharma Zone, SEZ Phase II, Pithampur Distt-Dhar-454775 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.


(Ajatshatru Shrivastava)
Member Secretary

A. Specific Conditions as recommended by SEIAA

1. PP should ensure zero discharge .
2. PP should provide a guard pond at site for storing treated waste water for 15 days during rainy season.
3. PP should ensure plantation in 7.0 ha (35% of the total project area with plantation two rows all along the periphery of the project area, and along the roads with one tree per 100 sq. m. of the plot area. PP should ensure plantation of the trees of indigenous local varieties like Neem, Peepal, Kadam, Kachnaar etc. Every effort should be made to protect the existing trees on the plot.

B. Specific Conditions as recommended by SEAC

4. Proposed STP of 50 KLD shall be constructed before commencement of enhanced production.
5. The existing ETP shall be up-graded if required and suggested by the MPPCB.
6. Industry shall maintain 'zero' discharge condition with respect to industrial waste-water.
7. CSR activities as proposed shall be taken up in consultation with local administration.

C. Standard Conditions - Encl: Annex-I

Endt No. ³⁶²⁴ /SEIAA/ 15

Dated 19.2.15

(Ajatshatru Shrivastava)
Member Secretary

Copy to:-

- (1). Principal Secretary, Urban Development & Environment Deptt. 3rd 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- Dhar-M.P.
- (5). M.D. AKVN Industrial Area Pithampur, Distt. Dhar MP
- (6). The Jt. Director, Town & Country Planning, Indore, MP
- (7). Director, I.A. Division, Monitoring Cell, MoEF, Gol, Ministry of Environment & Forest Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110 003
- (8). Director (S), Regional office of the MOEF, (Western Region), Kendriya Paryavaran Bhawan, Link Road No. 3, Ravi Shankar Nagar, Bhopal-462016.
- (9). Guard file.

Standard Conditions Encl: Annex-I

(Ajatshatru Shrivastava)
Member Secretary

Case No. 638/2011

Issued vide letter no. ³⁶²³²⁴ dated ...19.2.15

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(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

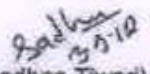
**Standard Conditions related to item 5 (f) of the schedule of EIA notification,
2006**

**(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)

Issued Vide No. 248/11/19/EPCCO
Dated 23/5/2012

Issued Vide No. 312324
Dated 19.2.19

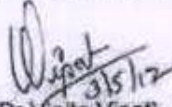
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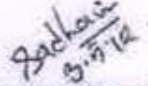
State Environment Impact Assessment Authority, M.P.

(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 DTMS 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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Officer-in-Charge


(Dr Vinita Vipat)
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(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. 943-1111/EPCO
Dated 23/5/2012

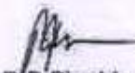
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Dated 19.2.15


State Environment Impact Assessment Authority, M.P.

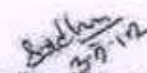
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29

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, 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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3 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. 3123-24/EPCO
Dated.....19.2.15

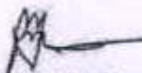
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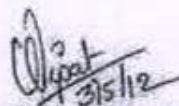
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31. Action plan with respect to suggestion/improvement and recommendations made and agreed during public hearing consultation shall be submitted to the Regional Office, MoEF, Gol, Bhopal, MP PCB within six months.
32. These stipulations would be enforced 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, 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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4 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)

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SEIA/NEPCO

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