

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

Environmental Planning Coordination Organization (EPCO)
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No: 7646 /SEIAA/2015 Date: /3.11.10

To, Shri S. Sunderganesh, Authorized Signatory (Sr. Director–Technical Operations) M/s Teva API India Limited, Plot No. Q1 to Q4, Malanpur Industrial Area, Malanpur, District Bhind (M.P.) – 477116.

Sub:- Case No. 713/2012 Prior Environmental Clearance for Bulk Drugs - Change in Product mix and introduction of new products; Intermediates and API for total 66 products with production capcity of 2951 MTPA at Plot no. Q-1 to Q-4 Ghirongi Industrial Area, Village Malanpur, Teh – Gohad Distt.- Bhind (M.P.) by M/s Teva API India Limited through Shri S. Sunderganesh Authorized Signatory (Sr. Director – Technical Operations), Plot No. Q1 to Q4, Malanpur Industrial Area, Malanpur, Distt. - Bhind (M.P.) – 477116, Phone. No. 7539-306199, Email-sarangi.nc@teva.co.in, EIA Env.Consultant :Kadam Environmental Consultant Ahmedabad (Gujrat).

Ref: Your application dtd. 24.05.2012 received in SEIAA office on 29.05.2012.

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 14th September 2006 and its amendments, on the basis of the mandatory documents enclosed with the application viz., Form I, pre-feasibility report, ToR, EIA Report, ppt. 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) The proposed project is Bulk Drugs - Change in Product mix and introduction of new products; Intermediates and API for total 66 products with production capcity of 2951 MTPA. Earlier prior Environmental Clearance was granted by MP-SEIAA (case no. 16/2008) vide letter No. 307/EPCOSEIAA/09, dated 11.02.09 for 17 products with production capacity of 2977.22 MTPA. PP has now applied for Prior Environmental Clearance for change in products mix and

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introduction of new products totaling 66 products with production capacity of 2951 MTPA as follows:-

Change in Products mix / New products (66 nos and 2951 MTPA total production capacity)

Famciclovir, CI-AP, NFOS, RLT-9, Raltegravir potassium, Aliskiren, Hemifumarate (Intermediate & API), Hydrochlorothiazide, Losartan Potassium, TRB Spain, Trityl Candesartan, Cilexetil, Valsartan, Irbesartan, Olmesartan, Trityl Olmesartan, Telmisartan, Trityl Valsartan, Trityl Irbesartan, Trity Losartan, Carbamazapine, DBTP 2HCl, Desvenlafaxine Base, Duloxetine. HCl (intermediate & API), Milnacipran amide, Quetiapine Fumarate, Venlafaxine free base, SRT HCI racemate, SRT mandelate, SRT.HCl, Desvenlafaxine fumarate, Olanzapine, Clarithromycin (intermediate & API), Levofloxacin, Trimethoprim, Eleptriptan HBr, Eletriptan PTSA, Flupirtine Maleate, Phenyl piracetam, 7-Ethyl Tryptophol (7-ET), Narproxen- DL, 3-amino-4 Carboxamido Pyrazole (ACP), Furosemide, 2,4-Dichloro-5-Sulfonamide benzoic acid (DSBA), Clopidrogel Bisulfate (intermediate & API), CLD-CSA, Pentoxifylline, CMH Diacid, Pregablin crude & API, RML-12, 1,1 Cyclohexane Diacetic acid (CDA), 19-TBPO (TB-19), Atorva Ca and Intermediate, Diketone, TBIN, PAE, EZE-06 Intermediate & API, Ezetamibe, Fluvastatin Sodium, TB-17, TBRE, Fluvadial, Pioglitazone HCl, PIE. Sitagliptin Phosphate, Sitagliptin sulphate, Sitagliptin maleate, Montelukast Sodium.

- (ii) The proposed 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. 14.09.2006, hence is required to obtain prior EC.
- (iii) There is no interstate boundary within 10 km and no National Park / Sanctuary within the 5 km of the project area hence the general conditions are not attracted.
- (iv) The total land area of the project is 2,92,500.00 sq. m. (29.25 ha) for which lease deed executed (dtd 01.02.2008) for 30 years (01.02.2008 to 31.01.2038) for plot no. Q1 to Q4 Ghirongi Industrial Area,(2,92,500.00 sq. m) Village Malanpur, Distt.- Bhind (M.P.) with MPAKVN (Gwalior) Ltd. Gwalior through Managing Director.
- (v) The project is located in notified Industrial area Malanpur, District Bhind, hence as per GoI, MoEF OM dtd 10.12.14 Public hearing is exempted.
- (vi) The source of water supply is Industrial Infrastructure Development Corporation (IIDC) Gwalior (letter dtd 04.09.15 for supply of 920 KLD water). The total water requirement after chamge in product mix is 1520 KLD (Fresh 920 KLD + Recycled 600 KLD) & shall be used for process, utilities (boiler & cooling tower) and domestic purpose.
- (vii) The total existing waste water generation is 408 KLD and after change in product mix it will be 640 KLD. PP has proposed augmentation of the existing effluent treatment Plant of 250 KLD capacity to 650 KLD capacities with following implementation schedule:-
 - (a) 1st Phase Production of 1150 MT/Annum waste generated would be 250 KLD which can be treated in existing ETP

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(b) 2nd Phase – Production of 2951 MT/Annum – Effluent Treatment System would be augmented from 250 KLD to 650 KLD by providing additional treatment system of 400 KLD.

PP has proposed "Zero effluent discharge" from the unit. The total treated waste water is 600 KLD and is proposed to be used in horticulture (470 KLD), Floor washing (30KLD) and Cooling Tower (100 KLD). The ETP sludge is proposed to be filter press and evaporated in Multiple Effect Evaporator (MEE). During rainy season 395 KLD out of 470 KLD will be used for utilities (Cooling Tower, chilled water and boiler). Remaining 75 KLD will be stored in a tank and will be used for horticulture after the rain.

- (viii) The existing hazardous waste generation is 4323.085 MT/annum; and the total after change in product mix / new products shall be 13842.085 MT/annum. Hazardous Waste will be generated from used/spent oil, spent solvent, Process residues and waste, spent catalyst, spent carbon, date expired/ discarded/off specification drugs/ medicines, Chemical containing residue, Ash from incineration of hazardous waste, flue gas cleaning residues, Distillation residue from contaminated organic solvent etc and will be disposed by selling to authorized, re-processors/refiners registered with CPCB/MPPCB. or common TSDF (letter from MPPCB dtd 07.05.15 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.
 - (ix) For control of air pollution from boiler & DG sets, PP has proposed to provide suitable stack height as per CPCB norms to ensure proper dispersion of gases; For raw chemical and solvent specially designed Powder Transfer System (PTS) with vacuum of Nitrogen cycle; double condenser; sub-coolers for solvent recovery; solvent handlings pumps with mechanical seals to avoid leakage & fugitive emissions of VOCs; scrubbing system for VOCs etc.
 - (x) For firefighting measure PP has proposed to provide fire extinguishers, hydrant system and fire. PP has also proposed Fire detection, heat detection, and alarm system to detect fire/heat/smoke in the vulnerable areas of the plant.
- (xi) PP has provided rooftop rainwater harvesting system with 5 nos. of recharging pits.
- (xii) The total power requirement in operation phase shall be 15110 KW and DG set back-up 11nos. (3x1000 KVA each and 8x1250 KVA each).
- (xiii) PP has submitted plantation details with name of species including number of existing trees (10715) and proposed trees (15000).
- (xiv) Under CSR activities PP has proposed drinking water facilities for Malanpur village, providing ambulance in case of emergency in local area, toilet facility to local villages Ghirongi and Malanpur, Scholarship for village brilliant students Malanpur, providing additional instrument for health centre, constructed additional rooms for existing school at village Ghirongi & Malanpur etc with budgetary provision of Rs. 100 lacs (1.00 crores) upto five years. PP has also proposed plantation outside the factory in the industrial road, training and awareness

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program for health safety and organizing the health camps at village Malanpur & Ghirongi.

Based on the information submitted at Para i to xiv above and others, the State Level Environment Impact Assessment Authority (SEIAA) considered the case in its 247th meeting held on 07.10.15 and decided to accept the recommendations of SEAC meetings 125th dtd. 09.04.2013, 132nd dtd. 14.05.13, 143rd dtd. 29.10.13, 148th dtd. 25.08.14 and 170th dtd. 28.01.15.

Hence, Prior Environmental Clearance is accorded under the provisions of EIA notification dtd. 14.09.06 to the proposed Bulk Drugs - Change in Product mix and introduction of new products; Intermediates and API for total 66 products with production capacity of 2951 MTPA at Plot no. Q-1 to Q-4 Ghirongi Industrial Area, Village Malanpur, Teh – Gohad Distt.- Bhind (M.P.) by M/s Teva API India Limited through Shri S. Sunderganesh Authorized Signatory (Sr. Director -Technical Operations), Plot No. Q1 to Q4, Malanpur Industrial Area, Malanpur, Distt. - Bhind (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

- PP should ensure the implementation of the observations of MOEF & CC RO, Bhopal report dtd 18.08.2015.
- 2. The entire demand of fresh water should be met through IIDC water supply.
- 3. Waste water:
 - (a) PP should maintain zero discharge from the Industry as proposed.
 - (b) Industrial effluent generation shall be completely evaporated with help of Evaporator so as to achieve zero discharge.
 - (c) There shall be no industrial effluent discharge from the unit.

For Air Pollution:

- (a) PP should ensure air pollution control measures and stack height as proposed in the EIA/ EMP.
- (b) The performance of air pollution control system should be regularly monitored and maintained.
- (c) PP should ensure regular Stack monitoring & Ambient air quality monitoring and should be carried out as per the guidelines/norms of MPPCB/CPCB.
- (d) In plant control measures for checking fugitive emission from all the vulnerable sources shall be provided. Fugitive emission shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator/bag filters and water sprinkling system.
- (e) Dust suppression system including water sprinkler system/ foaming arrangement shall be provided at loading and unloading areas to control dust emission.

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- (f) Fugitive emission in the work zone environment, product, raw material storage areas etc. shall be regularly monitored.
- (g) High efficient four stage ventury scrubber should be provided.
- (h) Transportation of raw material and finished goods should be carried out in covered trucks.
- (i) Company shall carry out the HAZOP study and report shall be submitted to ministry MoEF & CC Regional Office, Bhopal.
- (j) For control of fugitive emission and VOCs following steps should be followed:-
 - Chilled brine circulation system shall be provided and it should be ensured that the solvent recovery efficiency is not be less than 95%.
 - Reactor and solvent handling pump shall be provided with mechanical seal to prevent leakage.
 - Closed handling system should be provided for chemicals.
 - System of leak detection and repair of pump/pipeline should be based on preventive maintenance.
 - Solvent shall be taken from underground storage tank to reactor through closed pipeline. Storage tank shall be vented through trap receiver and condenser operated on chilled water.

5. Hazardous Waste:

- (a) PP should ensure disposal of hazardous waste regularly and there should be no dumping of these materials in the premises/outside.
- (b) PP should ensure handling, disposal and management of hazardous waste as per the related prescribed rules.
- (c) PP should obtain Renewal of authorization regularly from MPPCB for collection storage and disposal of hazardous waste (Management, handling & transboundary Movement) Rules 2008 and its amendments. Membership of the TSDF should be obtain for hazardous waste disposal.
- (d) Hazardous chemicals should be stored in sealed tanks, drums etc. Flame arrestors shall be provided on tanks. To avoid the spillage from processing unit, Industry shall provide fully mechanized filling and packaging operation unit.
- (e) PP should provide RCC layer and double layered HDPE lining for primary and secondary leachate collection.
- (f) PP should obtain NOC /approval from competent authority for health & safety measure, Onsite & Offsite disaster management, and Risk management plan before commencing the operation of the unit.
- PP should obtain fire NOC from the competent authority before commencing the operation of the unit.

 PP should ensure the rain water harvesting and provide pits for ground water recharging.

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- PP should ensure installation of photovoltaic cells (solar energy) for lighting in common areas, LED light fixtures and energy efficient equipments.
- 9. Green Belt:
 - (a) PP should ensure plantation as proposed in 102375 sq.m. (35% of the total plot area) and it should be as per the CPCB guidelines.
 - (b) Plantation in the project area of indigenous local varieties like Neem, Peepal, Kadam, Kachnaar etc.
 - (c) Every effort should be made to protect the existing trees on the plot.
- 10. PP should ensure the implementation of CSR activities to the extent of Rs. 100 lacs up to five years on regular basis in consultation with the Gram Panchayat of the respective villages.

B. Specific Conditions as recommended by SEAC

- Possibilities shall be explored for using the gases generated from ETP in power production instead of flaring the same.
- ETP should be based on modular type.
- 13. Worst Case total effluent quantity (out of the 66Products) generated would be 250 KLD which may be treated in existing ETP, but the installation of the proposed ETP scheme (proposed as IInd Phase) shall be completed before enhancing the production beyond 1150 MT/Annum and or increase in the volume of effluent beyond 250 KLD.

14. All other conditions as laid in the earlier EC and the consents of MPPCB shall be applicable.

Standard Conditions - Encl: Annex-I

(Ajatshatru Shrivastava) Member Secretary

Endt No. 7/SEIAA/15 Dated / 31/11/1 SEIAA/15 Dated / 31/11/1 Secretary Copy to:- (1). Principal Secretary, Urban Development & Environment Deptt. 3rd Floor, Mantralaya Vallabh Bhawan, Bhopal.

- Secretary, SEAC, Research and Development Wing Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5, Arera Colony Bhopal-462016.
- (3). Member Secretary, MPPCB, Paryavaran Parisar, E-5, Arera Colony, Bhopal-462016.
- (4). The Collector, Distt-Bhind M.P.
- (5). M.D. M P Audyogik Kendra Vikas Nigam (Gwalior) Ltd 52, Ravi Nagar Gwalior 474002.
- (6) Director, I.A. Division, Monitoring Cell, MoEF, Gol, 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

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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

Annex-I

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

(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)

- 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.
- 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.
- 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.
- The process emissions, VOCs and particulate matter form 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.
- Fugitive emissions in the work zone environment, product, raw materials storage 5. area etc. shall be regularly monitored. The emissions shall conform to the limits imposed by MPPCB.
- The company shall carry out the HAZOP study and the report shall be submitted to Regional Office of MoEF, Gol at Bhopal.
- 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.
- 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)

1 of 4

Officer-in-Charge

5 (t) Synthetic Organic Chemicals Industry (Cyce & dye Intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical informediates

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Research and Development Wing, Madhya Pradesh Pollution Control Board,
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- Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- 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.
- 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.
- Any enhancement of capacity, change in technology, modernization and scope of working shall again require prior environmental clearance as per EIA notification, 2006.
- All activities / mitigative measures proposed by PP in Environmental Impact Assessment must be ensured.
- All activities / mitigative measures proposed by PP in Environmental Management Plan and approved by SEAC must be ensured.
- 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.
- 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.

Commitment towards CSR have to be followed strictly.

(Dr R P Singh) Officer-in-Charge

(Dr Vinita Vipat) Officer-in-Charge (Dr Sedhna 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

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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.
- 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.

(Dr R P Singh)
Officer-in-Charge

(Dr Vinita Vipat) Officer-In-Charge (Dr Sadhna Tiwari) Officer-in-Charge 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

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Dated 13.11.15

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Research and Development Wing, Madhya Pradesh Pollution Control Board,
Paryavaran 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.
- 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.
- 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.
- 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.
- 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, NOx (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.

(Dr'R P Singh) Officer-in-Charge (Dr Vinita Vipat) Officer-in-Charge (Dr Sadhna Tiwari) Officer-in-Charge 4 nf 4

5 (f) Synthetic Organic Chemicals Industry (dyes & dye intermediates, bulk drugs and intermediates excluding drug formulations, synthetic robbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates

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