

# 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: \$849 /SEIAA/2016 Date: 1.8./6

To, Mr. Rana Banerjee, Plant Head M/s UNICHEM Laboratories Ltd., Plot No. – 197, Sector-1, Pithampur, District Dhar (M.P.)-454775

Sub:- Case No. 1714/2013 Prior Environmental Clearance for Expansion/ Modification of Bulk Drug Intermediate Manufacturing Unit at Plot No. 197A,197B,197A-197B,196 & 196 B and Khasra No. 187 & 190 Sector-1, Industrial Area - Pithampur, District Dhar (M.P.); Plot Area — 79819 sq.m Existing: 155 MTPA.Proposed Expansion: 245 MTPA. After Expansion: 400 MT/Year of different API'S, by M/s UNICHEM Laboratories Ltd. through Mr. Rana Banerjee, Plant Head, Plot No. — 197, Sector-1 Pithampur, District—Dhar (M.P.)-454775 Email: ssthakur @ unichwmlabs.com, phone no. — 9826375204, Environmental Consultant Complete M/s Asian Consulting Engineers Pvt. Ltd. New Delhi.

Ref: Your application dtd. 25.06.13 received in SEIAA office on 02.08.2013

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), dtd. 14.09.06 & its amendments, on the basis of the mandatory documents enclosed with the application viz., Form I, prefeasibility report, ToR & 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) The proposed project is Bulk Drug Intermediate Manufacturing production unit comprises expansion and modification in an existing unit. The existing unit was established in 2005. Hence, Environmental Clearance was not required. The existing production capacity is 155 MTPA, which was issued with Air and Water Consent for the production of 16 APIs of which the production of four APIs have been stopped. The proposed and existing product are as follows:

Category I	(Bulk Drug) - 25	No.
Product Name	Existing (MTI	Proposed (MTPA
Setraline Hydrochloride	30	1 (Production Reduc
Losartan Potassium	20	7
Telmisartan/		8
Eprosartan Mesylate		35
Phenylphrine Hydrochloride/	- 20	30
Biaryl alcohol (Production Stopped)		
Phthaloyl Amlodopine	40	
Amlodopine Besylate		30

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Tamsulosin hydrochloride (Producti Discontinued)	ti 15	
Atomoxetine hydrochloride		2
Nateglinide		20
Leuflompnomide/ Venalafaxine hydrochloride (Production Discontinued)	10	
Lamotrigine	20	60
Alfuzosin hydrochloride		2
Zolpidem tartarate		1
Memantine hydrochloride	-	5
Buspirone hydrochloride	*	2
Irbesartan	-	5
Olmesartan	-	4
Valsartan	-	2
Quetiapine	-	36
Ranolazine	-	30
Candesartan		1
Dronadarone		2
Cinacalcet	-	2
Citrizine	-	10
Divalproate	-	15
Glipizide	-	5
Category II (Bulk Drug Intermediate 3 No.		
Diamine	-	2
Taxol	-	3
Phthaloyl amlodopine	*	60
Category III		
R & D /Validation/Pilot Plant Produc	-	20
TOTAL	155	400

- (ii) The project is of Synthetic Organic Chemical industry covered under 5 (f) category B of the Ministry of Environment, Forests & Climate Change, Gol, ElA Notification 2006 and its amendments.
- (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 79819 sq. m. PP has submitted notarized copy of lease deed for land area 53909 sq.m. and copy of sale deed dated 29.06.2016 for remaining area.
- (v) The project is located in notified Industrial area Pithampur, Distt. Dhar (M.P.), hence as per Gol, MoEF OM dtd 10.12.14 Public hearing is exempted.
- (vi) The total water requirement (Existing + Proposed Expansion) is 175.5 KLD (Fresh Water 130.5 KLD + Recycled 45.0 KLD). The source of water supply is AKVN. PP has submitted agreement dtd. 03.05.2006 between MPAKVN, Indore and M/s UNICHEM Laboratories Ltd, Pithampur Dhar.
- (vii) The total existing waste water generation is 31 KLD (26 KLD effluent + 5KLD sewage) and after expansion it will be 70 KLD (31 KLD existing + 29KLD effluent 10 KLD sewage). PP has proposed augmentation of the existing effluent treatment Plant of 40 KLD capacity to 90 KLD capacities. PP has proposed "Zero effluent discharge" from the unit. The total treated waste water is 45 KLD and is proposed to be used in green belt development. The ETP sludge is proposed to be filter press and evaporated in Multiple Effect

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Evaporator (MEE). PP has also proposed solvent recovery system upto 96% efficiency. While SEAC has recommended to increase solvent recovery efficiency upto 99%. PP has submitted copy of renewal of consents upto 28.02.2014 issued by MPPCB; dtd. 06.09.11 under water Act.

- (viii) The expected air emission from the product are HCL gas, CO², gas, ammonia gas, hydrogen gas, SO₂, Methylamine etc. For control of air pollution PP has proposed wet alkali (caustic) based scrubber and wet water based scrubber. 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; PP has also submitted copy of renewal of consents up to 28.02.2014 issued by MPPCB; dtd. 06.09.2011 under Air Act.
- (ix) For disposal of hazardous waste, PP has proposed to dispose spent oil through authorized re-processors/refiners registered with CPCB/MPPCB and other hazardous waste is proposed to be incinerated or sent to common TSDF site Ramky, Pithampur, Dhar near Indore.
- (x) PP has proposed to provide fire extinguishers, hydrant system and sprinkler system. PP has also proposed water storage lightening arrestor and self contained breathing apparatus for controlling leakage or spillage type emergency.
- (xi) The total power requirement in operation phase shall be 1000 KVA and DG set back-up 1no. (1x1000 KVA).
- (xii) PP has proposed 02 underground storage tanks for collection of rainwater.
- (xiii) PP has proposed green belt area of 26,341 sq.m. (33% of the total plot areaexisting & proposed)).15000 sq.m. area already developed into green belt with species like Gulmohar, Karanj, Jambhool, Astumbul and Neem.
- (xiv) Under CSR activities PP has proposed 04 public toilet. Drinking water facility in primary school and repair of building industry surrounding village. Selection of the tribal people working in Government agency (Contractual) for skill development and engaged them in the expansion in the project in various operation in the Plant with budgetary provision of 3.00 lacs.

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 350<sup>th</sup> meeting held on 05.07.2016 and decided to accept the recommendations of 231<sup>st</sup> SEAC meeting held on dtd 27.10.2015.

Hence, Prior Environmental Clearance is accorded under the provisions of EIA notification dtd. 14<sup>th</sup> September 2006 to the Expansion/ Modification of Bulk Drug Intermediate Manufacturing Unit at Plot No. 197A,197B,197A-197B,196 & 196 B and Khasra No. 187 & 190 Sector-1, Industrial Area - Pithampur, District Dhar (M.P.); Plot Area - 79819 sq.m Existing: 155 MTPA.Proposed Expansion: 245 MTPA. After Expansion: 400 MT/Year of different API'S, by M/s UNICHEM Laboratories Ltd. through Mr. Rana Banerjee, Plant Head, Plot No. - 197, Sector-1 Pithampur, District-Dhar (M.P.)-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.

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

The entire demand of fresh water should be met from AKVN, supply and there should be no extraction of ground water.

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- (2). The inlet and outlet point of natural drain system should be maintained with adequate size of channel for ensuring unrestricted flow of water.
- (3). Waste water management:
  - (a) PP should reduce the chloride contents by adopting proper pollution control measures to fit for proper land use.
  - (b) PP should conduct performance study of existing ETP
  - (c) PP should ensure to solvent recovery efficiency upto 99%.
  - (d) PP should maintain zero discharge from the Industry.
  - (e) Industrial effluent generation shall be completely evaporated with help of Evaporator so as to achieve zero discharge.
  - (f) There shall be no industrial effluent discharge within the project premises.

# (4). Air Quality Management:-

- (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) Transportation of raw material and finished goods should be carried out in covered trucks.
- (f) Dust suppression system including water sprinkler system/ foaming arrangement shall be provided at loading and unloading areas to control dust emission.
- (g) Fugitive emission in the work zone environment, product, raw material storage areas etc. shall be regularly monitored.
- (h) High efficient four stage ventury scrubber should be provided.
- (i) 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.

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#### (5). Hazardous Waste Management:

- (a) As proposed above, 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 obtained 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) All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of hazardous chemicals.
- (f) All the storage tanks shall be fitted with appropriate controls to avoid any leakages. Bund/dyke walls shall be provided for storage tanks for Hazardous Chemicals. Close handling system for chemicals shall be provided
- (g) The entire process area should be provided with doubled liner HDEP geo membrane system of thickness 2.5 mm and double leachate collection system for detection of any leachate.
- (h) The storage area shall be designed in such a way that the floor level is at least 450 mm above the maximum flood level with 2.5 mm thickness of HDPE geo membrane and two layers of RCC in storage as proposed.
- (i) PP should obtain authorization from MPPCB for collection / treatment / storage / disposal of hazardous wastes.
- (6). 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.
- (7). PP should obtain fire NOC from the competent authority before commencing the operation of the unit.
- (8). PP should ensure the rain water harvesting and provide 02 nos of pits for ground water recharging.
- (9). PP should ensure installation of photovoltaic cells (solar energy) for lighting in common areas, LED light fixtures and energy efficient equipments.

#### (10). Traffic Management:

- (a) PP should ensure proper vehicular movement with separate entry and exit.
- (b) PP should ensure transportation of materials in trucks covered with tarpaulins; PUC certified vehicles.
- (c) Transportation of raw material and finished goods should be carried out in covered trucks with tarpaulins; PUC certified vehicles.
- (11). PP should ensure the implementation of CSR activities to the extent on regular basis in consultation with the Gram Panchayat of the respective village.

#### (12). Green Belt:-

(a) PP should ensure plantation as proposed in 26,341sq.m. (33% of the total plot area-existing & proposed) completely in first year. At least 3 years old saplings should be planted.

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- (b) No existing trees of the plant premises will be cut for expansion of plant and PP should ensure the plantation in additional 11341 sq.m. area by planting minimum 1000 indigenous trees. Besides this all vacant area within plant premises should be covered by planting more trees.
- (c) Green belt should be developed around the site with noise absorbing trees.
- (d) Plantation should be done in two rows all along the periphery of the project area, along, avenue plantation along the roads. PP should ensure plantation of the trees of indigenous local varieties like Neem, Peepal, Kadam, Karanj, Kachnaar, Mahua etc along with ornamental varieties.
- (e) Every effort should be made to protect the existing trees on the plot.
- (13). In the event of failure of any pollution control system adopted by the unit, the unit shall be safely closed down and shall not be restarted until the desired efficiency of the control equipment has been achieved.
- (14). Total quantity of runoff water generated and green belt area should be collected in underground tank & used for process in plant to minimize fresh water requirement.

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

- (15). All the process effluent should be treated in MEE & ATFD and the generated sludge should be disposed off in CTSDF.
- (16). Zero discharge condition should be maintained.
- (17). Efforts should be made for solvent recovery upto 99% as PP is proposing a new solvent recovery plant.
- (18). As the 65 KL/D treated waste water will be available and being zero discharge unit, PP should carryout additional plantation efficient utilization of water.
- (19). Explore the possibility of having two modules of MEE's aggregating to 50 cum/day.

Standard Conditions - Encl: Annex-I

Dated 1.8./6 / SEIAA/ 2016 Endt No.

(Anupam Rajan) Member Secretary

Copy to:-

Bhawan, Bhopal.

Principal Secretary, Urban Development & Environment Deptt. 3<sup>rd</sup> Floor, Mantralaya Vallabh (1).

Secretary, SEAC, Research and Development Wing Madhya Pradesh Pollution Control Board, (2).Paryavaran Parisar, E-5, Arera Colony Bhopal-462016.

Member Secretary, MPPCB, Paryavaran Parisar, E-5, Arera Colony, Bhopal-462016. (3).

The Collector, District Dhar, M.P. (4).

Managing Director, M.P. Audyogik Kendra Vikas Nigam (Indore) Limited, Free Press House First Floor, 3/54 Press Complex, Agra-Mumbai Highway Indore(M.P).

Director, I.A. Division, Monitoring Cell, MoEF, Gol, Ministry of Environment & Forest Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi - 110 003

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)

(Dr. Sanjeev Sachdev) Officer-in-Charge

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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)

- 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.
- 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.
- 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 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, GoI at Bhopal.
- The company shall comply with the CREP guidelines prepared by MPPCB for Bulk Drug Plants.
- 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) Officer-in-Charge

5 (f) Synthetic Organic Chemicals Industry (dyos-6 dyo intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates

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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.
- 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.
- 15. 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.

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

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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 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.
- 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.
- 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

Officer-in-Charge

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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- 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.
- 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, 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.
- 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

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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