

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

Environmental Planning Coordination Organization (EPCO)
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No: 4518 /SEIAA/2016 Date: 29.//./6

To,
Shri Ravindra Ramakant Gulgule,
(Joint Managing Director)
M/s Thinq Pharma – CRO Ltd
A/30, Thinq House Road No. 10,
MIDC Wagle Estate,
Thane West (Maharashtra) 400604

Sub:- Case No. - 5064/2016: Prior Environment Clearance for Proposed Active Pharma Ingredients at Khasra No. M 40 & 42, Industrial State, Sector-3, village Pithampur, District Dhar, MP by M/s Thinq Pharma – CRO Ltd. through Joint Managing Director Shri Ravindra Ramakant Gulgule, A/30, Thinq House Road No. 10, MIDC Wagle Estate, Thane West 400604, Mob. No. 09821504027, E-mail – ravi.gulule@thinqcro.com Env. Consultant: Ultra-Tech Environmental Consultancy & Lab.Thane (W) Maharastra.

Ref: Your application dtd. 07.03.16 received in SEIAA office on 09.03.2016

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, pre-feasibility 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 project is comprised of manufacturing of intermediates and iodine based APIs unit at Plot No. M40-42, Pithampur industrial estate-3, Bugdoon, Dhar, Madhya Pradesh. Total 15 products are proposed in this project. The total production capacity of the products are as follows:-

Sr.No.	Product	Qty MT/PA
1	(2S)-1-{[3,5-bis(chlorocarbonyl)- 2,4,6 triiodophenyl] amino}-1-oxopropan-2-yl acetate (lopamidol stage-III)	82.71
2	5-amino-2,4,6-triiodobenzene-1,3-dicarbonyl dichloride(lopamidol stage-II)	80.29
3	Paroxetine Hydrochloride	0.4
4	QuetiapineFumatate	0.8
5	Valacyclovir hydrochloride	0.2
6	Ractopamine hydrochloride	6

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7	OctopamineHydrochloride	10
3	Benzocaine	2
9	Benfothiamine	
10	5-Phenyl valariac acid methyl ester (5-PVM)	3
11	Trans Retinoic acid, 1-hydroxy-3,3-dimethyl-2-butanone ester(G-101)	0.2
12	Chlorothymol	0.3
13	N-Boc-4-Hydroxy-L-Proline	3
	2-Nitro benzene sulfanyl chloride(NSC)	0.2
14		0.02
15	Sharpless catalyst	4- will be 10

Total Production Capacity with all the proposed products will be 195.12 MT/annum or 0.534 MT/day. PP has submitted an affidavit regarding production of products will be followed by PP as per CTE-46027 as mentioned above.

- (ii) The project is production of Intermediates and APIs hence covered under 5 (f) category B of the Schedule of EIA Notification issued by the Ministry of Environment & Forests vice S.O.1533 (E) dtd.14.09.06 & its amendments.
- (iii) There is no inter-state boundary within 05 km and no Wildlife Sanctuaries, National Parks, and Tiger Reserves within 05 km of the boundary (DFO letter dtd. 27.07.16) hence, general conditions are not attracted.
- (iv) PP has submitted copy of registered lease deed dated 23.03.2009 between MD, Audyogik Kendria Vikas Nigam (Indore) LTD and M/s Thinq Pharma CRO Ltd. through Joint Managing Director Shri Ravindra Gulgule an area of 21794 Sq. meters for the period of 30 years (w.e.f. 07.06.2016 to 06.06.2046).
- (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 source of water supply for the project is MPAKVN (processing letter dtd. 03.02.2016). The total water requirement for the proposed project is 70 KLD (domestic 5.0 KLD, process 50 KLD, Boiler KLD, Cooling water 01.0 KLD & washing 05 KLD).
- (vii) The total waste water generation for the proposed project is 58.0 KLD. Out of 58 KLD High COD Value water i.e. 29 KLD is proposed to sent TSDF Site for disposal, If TSDF refuses to take this effluent the same shall be disposed through in-house MEE and remaining 29 KLD will be disposed through ETP. Thus the production process is zero discharge.
- (viii) The main sources of air emission expected from boiler, DG set and manufacturing processes Generation of particulate matter, SO_x & No_{x.} PP has proposed following control measures to control the air emission:

Activities	Impacts	Mitigation Measures	
Activities		 Indian Coal is low sulphur fuel Stack height 35 meter 	
Boiler	Generation of PM, SO2, Nox		

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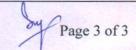
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DG	Generation of SO2, Nox	 Acoustic enclosure HSD as fuel Vent height 9 m above roof Less running hrs due to uninterrupted supply of power 	
Production process	VOC, SOx Dust Chemical fumes	 Mfg Lay out – Well ventilated Scrubber with each building Solvent recovery 	

(ix) The solid waste generated from the process namely plant dust, mill scale, papers etc is proposed to be sold to local vendor. The Hazardous waste such as used / spent oil, oil soaked waste, process residue & waste, spent solvents etc. are proposed to disposed off as follows:

Sources	Type of pollutants	Waste category as per HW Rules 2016	Annual Generation	Disposal
DG Sets	Used / Spent Oil	5.1	2 KL	Sell to authorized recycler within the State
Process/ Utility equipment maintenance	Oil Soaked Waste	5.2	2 MT	MPWMP, TSDF, Pithampur/ Cement plant for use as alternate fuel
Production Processes	Process residue & waste	28.1	107 MT	Disposal to TSDF /Cement Plants for co processing
	Spent Carbon	28.3	31.17 MT	Disposal to TSDF
	Off- specificatio n products	28.4	2 MT	Purification and sale. This will generate process waste (28.1) and the qty already considered.
	Spent solvents	28.6	88.05 MT	Sale to authorized recyclers
Handling of hazardous chemicals	Emptybarre Is/Containe rs/liners	33.1	5 MT	Buy back/Sell to authorized recycler
Treatment of wastewater	Chemical Sludge	35.3	10 MT	Disposal to TSDF
Purification process for organic compound / solvents	Any process or distillation residue	36.1	0.2 MT	Disposal to TSDF /Cement Plants for co processing

- (x) PP has proposed roof top rain water harvesting for recharging of ground water.
- (xi) PP has included disaster management plan, fire fighting plan on-site, off-site emergency plan in the EIA report.
- (xii) PP has submitted 11986 sq.m. area has been developed as green belt by planting.



(xiii) PP shall partially use the old structure as a warehouse for stocking of raw material and rest of the structure shall be demolished.

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 377th meeting held on 18.10.2016 and decided to accept the recommendations of 280th dtd SEAC meeting held on dtd 31.08.2016.

Hence, Prior Environmental Clearance is accorded under the provisions of EIA notification dtd. 14th September 2006 to the Proposed Active Pharma Ingredients at Khasra No. M 40 & 42, Industrial State, Sector-3, village Pithampur, District Dhar, MP by M/s Thinq Pharma – CRO Ltd. through Joint Managing Director Shri Ravindra Ramakant Gulgule, A/30, Thinq House Road No. 10, MIDC Wagle Estate, Thane West (Maharashtra) 400604, 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). The entire demand of fresh water should be met through MPAKVN water supply and there should be no extraction of ground water.
- (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 maintain zero discharge from the Industry as proposed.
- (b) Industrial effluent generation shall be completely evaporated with help of MEE so as to achieve zero discharge.
- (c) There shall be no industrial effluent discharge from the unit.

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

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- (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.

(5). Hazardous Waste Management:

- (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 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)PP should provide RCC layer and double layered HDPE lining for primary and secondary leachate collection.
- (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 pits for ground water recharging from the administrative block and security room.
- (9). PP should ensure installation of photovoltaic cells (solar energy) for lighting in common areas, LED light fixtures and energy efficient equipments.

(10). Green Belt:-

- (a) PP should ensure plantation as proposed in 11986 sq.m. 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.
- (d) Pollution control trees should be planted in the green belt area PP should avoid to plant fruity trees in the project area.
- (11). PP should ensure CSR activities as per norms of MPAKVN.

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- (12). No other product is allowed to manufacture except the list given in the CTE-46027/ lease deed.
- (13). PP should obtain manufacturing license from FDA if applicable for project.
- (14). PP should ensure to utilize only some pillars/columns with some roof for ware house purpose. No other old structure/equipment will be allowed to be utilized for the proposed project.

B. Specific Conditions as recommended by SEAC

- (15). 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. Solvent stripper should be provided with the ETP.
- (16). RO and MEE should be provided for treatment of high COD waste streams and only in case of emergency/breakdown high COD wastes should be disposed off through CTSDF, Pithampur, Dhar.
- (17). Zero liquid discharge shall be observed and no treated waste water should be discharged outside the plant premises.
- (18). Log-books shall be maintained for disposal of all types hazardous wastes and shall be submitted with the compliance report.
- (19). Bag filters should be provided in the boiler stack.
- (20). Dedicated power supply shall be ensured for uninterrupted operations of treatment systems.
- (21). The project authorities should comply with the provisions made in the Hazardous Waste (management, handling & Trans-boundary Movement) Rules 2016, Manufacture. Storage and Import of Hazardous Chemicals Rules 1989, as amended and the Public Liability Insurance Act for handling of hazardous chemicals etc.
- (22). Water intensive green area including thick green-belt as proposed shall be developed in to mitigate the effect of fugitive emissions all around the plant in consultation with the forest department as per the guidelines of CPCB.
- (23). VOC's shall be regularly monitored in the work zone in the plant along with the other parameters and data shall be submitted to MPPCB and R.O of MoEF& CC.
- (24). All the storage tanks of raw materials/products shall be fitted with appropriate controls to avoid any spillage / leakage. Bund/dyke walls of suitable height shall be provided to the storage tanks. Closed handling system of chemicals shall be provided.
- (25). PP shall be responsible for discrepancy (if any) in the submissions made by the PP to SEAC & SEIAA.
- (26). Necessary consents shall be obtained from MPPCB and the air/water pollution control measures have to be installed as per the recommendation of MPPCB.
- (27). The validity of the EC shall be as per the provisions of EIA Notification subject to the following: Expansion or modernization in the project, entailing capacity

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addition with change in process and or technology and any change in product mix in proposed mining unit shall require a fresh Environment Clearance.

Standard Conditions - Encl: Annex-I

(Anupam Rajan) Dated 29.11.16 To Member Secretary

Endt No. / SEIAA/ 2016

Copy to:-

- Principal Secretary, Urban Development & Environment Deptt. 3rd Floor, (1). Mantralaya Vallabh Bhawan, Bhopal.
- Secretary, SEAC, Research and Development Wing Madhya Pradesh Pollution (2). Control Board, Paryavaran Parisar, E-5, Arera Colony Bhopal-462016.
- Member Secretary, MPPCB, Paryavaran Parisar, E-5, Arera Colony, Bhopal-462016.
- The Collector, District Dhar, M.P.
- 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.
- Guard file. (8).

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, GoI 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

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5 (f) Synthetic Organic Chemicals Industry (dyoc-8, 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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- 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,
- 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

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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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- 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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- 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.
- 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

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(Dr Vinita Vipat) Officer-in-Charge

(Dr Sadhna Tiwari) Officer-in-Charge 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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