



State Level Environment Impact Assessment Authority (SEIAA)

Telangana State

Government of India

Ministry of Environment, Forests & Climate Change

A-3, Industrial Estate, Sanathnagar, Hyderabad - 500 018.

REGD.POST WITH ACK.DUE

Order No. SEIAA/TS/OL/MDCL-06/2017- 3220

Dt:29.12.2017.

Sub: SEIAA, TS – M/s. Inogent Laboratories Pvt. Ltd., Plot No. 28/A, IDA Nacharam, Uppal (M), Medchal District – Environmental Clearance - Issued - Reg.

I. This has reference to your application submitted vide letter dt. 09.02.2016 received on 20.02.2016; subsequent lrs. dt. 02.05.2016 & 08.03.2017 received on 27.03.2017; and EIA report uploaded online on 19.07.2017 (proposal no. SIA/TG/IND2/18768/2017) received on 26.07.2017 seeking Environmental Clearance for the proposed expansion of **Synthetic Organic Chemicals manufacturing unit** in the name of **M/s. Inogent Laboratories Pvt. Ltd., Plot No. 28/A, IDA Nacharam, Uppal (M), Medchal District**. The nearest human habitation viz., Chilkanagar exists at a distance of 0.38 km from the project site. It was reported that Musi River exists at a distance of 4.3 km and several other water bodies exists within 10 kms from the plant. It was also reported that Medpalli RF exists at a distance of 5.5 km and several other RFs exists within 10 kms from the project site. The total area of the site is Ac.15.66; Out of that, area earmarked for development of Green belt is Ac. 5.17. The total cost of the proposed Expansion project is Rs. 25.0 Crores and the production capacity of the project after expansion is as following:

Products:

S.No	Name of the Product	Capacity	
		TPM	Kg/day
1	Aripiprazole	6.67	222.33
2	Atazanavir Int	0.2	6.67
3	Betahistine	0.08	2.67
4	Carvedilol	2	66.67
5	CCS	0.5	16.67
6	Voriconazole Int	3.03	101.00
7	Crezotinib	0.5	16.67
8	Dacomitinib	0.08	2.67
9	Dapagliflozin Intemediate	1	33.33
10	Darifenacin	0.02	0.67
11	Darunavir	0.33	11.00
12	Defacitinib	0.2	6.67
13	Deferasirox	0.02	0.67
14	Des Venlafaxine	0.5	16.67
15	Dobutamine Hcl	0.5	16.67
16	Dopamine	0.15	5.00
17	Doxapram HCL	0.75	25.00
18	Etoricoxib	0.5	16.67
19	Ezetimibe	0.33	11.00
20	Febuxostat	0.02	0.67
21	Fingolimod	0.01	0.33
22	Fluvastatin	0.02	0.67
23	Glycopyrronium bromide	0.33	11.00
24	Lacosamide Intermediate	0.04	1.33
25	Lamotrigine	8	266.67
26	Lansoprazole	1.5	50.00
27	Linezolid	0.01	0.33
28	Lorcaserine Int	0.02	0.67
29	Mesalamine	0.01	0.33
30	Montelukast Sodium	0.03	1.00
31	Moxifloxacin Hcl	1	33.33

S.No	Name of the Product	Capacity	
		TPM	Kg/day
32	Nadolol	0.5	16.67
33	Nebivolol	0.25	8.33
34	Olmesartan	0.12	4.00
35	Pentosan Polysulfate Sodium	0.5	16.67
36	Rosuvastatin	0.1	3.33
37	Sildenafil Citrate	0.17	5.67
38	Solifenacin Succinate	0.02	0.67
39	Tafacitinib	0.17	5.67
40	Tapentadol HCl	0.02	0.67
41	Tadalafil	0.02	0.67
42	Tramadol Hcl	7	233.33
43	Trimetadizine DiHcl	2	66.67
44	Vilazodine	0.02	0.67
45	Zolpidic Acid	0.02	0.67
46	Teneligliptin	0.03	1.00
47	Linagliptin	0.33	11.00
48	Quetiapine	0.83	27.67
49	Aprenilast	0.17	5.67
50	Eliglustat Tartarate	0.13	4.33
51	Sofusbuvir	0.04	1.33
52	Macetentan	0.13	4.33
53	Meglunine	0.17	5.67
54	Eberconazole	0.3	10.00
55	Asenapine	0.17	5.67
56	Bosentan	0.02	0.67
57	Cinacalcet	0.13	4.33
	Total	41.67	1390.33

By-products:

S.No	Name of Product	Stage	By-product	Capacity	
				Kg/day	TPM
1	Lamotrigine	I	Cuprous Chloride	105	3.15
		II	Spent Sulfuric Acid (50%)	8800	264

- II. In the process, synthetic organic chemicals are produced by using various chemicals, solvents, etc.,
- III. The proposal has been examined and processed in accordance with EIA Notification, 2006 and its amendments thereof. The State Level Expert Appraisal Committee (SEAC) examined the application in its meetings held on 24.02.2016, 23.05.2016, 19.07.2016, 07.04.2017 & 01.08.2017. The project is exempted from the process of Public Hearing as the industry is located in a Notified IDA existing prior to 2006, as per OM dt. 10.12.2014 of the MoEF&CC, GoI. The Sub-Committee constituted by the SEAC inspected the site on 10.06.2016 and submitted the report. Based on the information furnished, presentation made by the proponent and the consultant M/s. Team Labs & Consultants, Hyderabad; Sub-Committee's Report; EC order dt.17.02.1997 issued by the MoE&F, GoI, Certified Compliance Reports dt. 05.10.2015 & 02.03.2017 issued by the Regional Office, MoEF&CC, GoI, as per Circular dt.30.05.2012 of MoE&F, GoI; report of the Sub-Committee; G.O.Ms. No. 95, dt. 21.09.2007 of the EFS&T Dept., GoAP; G.O.Ms. No. 64, dt. 25.07.2013 of the EFS&T Dept., GO.Ms.No.20, dt.01.03.2013 of I&C Dept., GoAP; Undertaking on Rs.100/- Stamp paper dt.05.08.2017 stating that they will abide by any specific G.O. w.r.t. G.O.Ms.No.20 that apply to all pharmaceutical companies located inside the ORR to move outside the ORR, the Committee considered the project proposal and recommended for issue of Environmental Clearance. The State Level Environment Impact Assessment Authority (SEIAA) in its meetings held on 08.09.2017, 16.10.2017 & 21.11.2017 examined the proposal and recommendations of SEAC for issue of Environmental Clearance for Expansion. Accordingly, after discussions in the matter and considering the recommendations of the SEAC, **the SEIAA, Telangana hereby accords Environmental Clearance to the project for Expansion** as mentioned at Para no. I under the provisions of the EIA Notification 2006 and its subsequent amendments issued under Environment (Protection) Act, 1986 subject to implementation of the following specific and general conditions:

A. Specific Conditions:

a) Air Pollution:

- i After expansion, the emissions from the coal fired Boilers of capacities 5 TPH (Existing – Standby) & 10 TPH (Proposed), shall be routed through multi cyclone separators & bag filter followed by stacks of height 33m & 35m respectively. The concentration of particulates in the emission shall not exceed 115 mg/Nm³. Sampling Port with removable dummy of not less than 15cm diameter in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc, shall be provided to monitor stack emissions. Stacks of adequate height shall be provided for D.G. Sets of capacity 2 x 380 kVA (Existing), 1 x 1165 kVA (Existing) & 3 x 1165 kVA (Proposed) as per CPCB norms.
- ii National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.
- iii The process emissions containing Hydrogen Bromide, Hydrogen Flouride, Sulphur Dioxide, Hydrogen Chloride, Hydrogen Iodide & Ammonia shall be routed through Multi Stage Scrubber system. Scrubbed liquid shall be treated and reused or subjected to MEE. The process emissions containing derivatives of Carbon dioxide, Nitrogen, Carbon monoxide & Oxygen shall be safely dispersed into the atmosphere. The process emissions containing derivatives of Hydrogen & Hydrogen gas are to be safely dispersed into the atmosphere through water column. The industry shall also provide online pH monitoring system for scrubber. The industry shall meet the emission standards notified by the MoEF.
- iv Necessary measures shall be taken to control odour as far as possible. Chillers (brine solution) shall be installed to reduce solvent evaporation losses into the atmosphere. All the solvent storage tanks shall be connected to vent condensers. Regular monitoring of the VOCs shall be carried out using sensors.
- v The solvents shall be recovered by installing fractional distillation columns. The recovered solvents shall be reused in the process or sold to recyclers authorized by TSPCB. The volatile vapours generated during process shall be routed through condensers and the condensate shall be reused in the plant.
- vi As proposed, green belt of Ac.5.17 shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction and along road sides etc., Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.
- vii Raw materials shall be transported in covered trucks. Raw materials shall be stored under sheds. All the belt conveyors shall be covered with G.I. sheets. Appropriate dust suppression system shall be provided all around the stockpiles and conveyor system. All the roads in the plant area shall be asphalted / concreted and water shall be sprinkled to suppress the dust.
- viii Ambient air quality including ambient noise levels must not exceed the standards stipulated under Notification dt. 16.11.2009 issued by the MoEF&CC, GoI. Monitoring of ambient air quality and stack emissions shall be carried out regularly in consultation with TSPCB.

b) Water Pollution:

- i The source of water is Ground water / TSIIC (Industrial supply). The total water requirement after expansion shall not exceed 498.6 KLD (Fresh – 306.6 KLD & Recycled – 192.0 KLD). Quantity of water used for: Process is 80.6 KLD; Washings is 10.0 KLD; Boiler make-up is 85.0 KLD; Cooling tower makeup is 205.0 KLD; RO/DM Plant is 15.0 KLD; Scrubber is 5.0 KLD; R&D is 5.0 KLD; Domestic purpose is 40.0 KLD & Greenbelt development is 53.0 KLD.

- ii The total waste water generated after expansion shall not exceed 197.9 KLD (HTDS – 114.9 KLD & LTDS – 83.0 KLD). Out of that, 84.9 KLD is from Process; 10.0 KLD is from washings; 5.0 KLD is from Boiler blow down; 35.0 KLD is from cooling tower bleed of; 15.0 KLD is from RO/DM Plant; 5.0 KLD is from Scrubber; 5.0 KLD is from R&D; and 38.0 KLD is from Domestic section.
- iii The high TDS and low TDS effluents generated from the process are to be separated and treated separately. The high TDS effluents shall be disposed into Stripper followed by MEE and ATFD. The condensate from MEE shall be treated along with LTDS effluents. The LTDS effluents shall be treated in an ETP followed by RO system. The RO permeate is to be re-used in the plant and rejects shall be evaporated in MEE system. The treated effluents shall be recycled completely. The project proponent shall achieve **Zero Liquid Discharge** and in no case the effluent shall be discharged within or outside the factory premises. The sewage generated is to be treated in STP and Outlet of STP shall be connected to the Biological ETP. The volatile organics collected from Stripper shall be sent to recyclers authorized by TSPCB.
- iv The proponent shall provide separate storm water drains and harvest the rainwater from the rooftops to recharge the ground water.
- v Automatic / online monitoring system (24 x 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed and the data to be made available to the respective SPCB and in the Industry's website.
- vi The industry shall install IP Camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability and flow meters in the channel / drain provided for carrying the effluent from within the premises of the unit.

c) Solid Waste :

- i. Hazardous waste generated from the industry such as waste oils, used oils etc., shall be disposed as per the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2016 to the recyclers authorized by TSPCB.
- ii. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All Transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
- iii. The proponent shall comply with the following w.r.t. solid waste generated after expansion:

S.No	Description	Quantity	Mode of Disposal
1	Process residue	0.87 TPD	Sent to TDSF/Cement Plants for Co-incineration having pre-processing plants / authorized pre-processing units
2	Solvent Residue	0.69 TPD	
3	Stripper Distillate	0.86 KLD	
4	Spent Carbon	77.8 Kg/day	
5	Spent Mixed Solvents	2.43 KLD	Sent to authorized recovery units/Cement plants for co-incineration having pre-processing plants / authorized pre-processing units
6	Evaporation salts	2.08 TPD	Sent to TSDF
7	ETP Sludge	5 TPM	
8	Inorganic Residue	245.6 Kg/day	
9	Hyflow	60.3 Kg/day	
10	Catalyst	41.7 Kg/day	
11	Off-Separation & discarded product	0.5 TPM	
12	Insulation Waste	2 TPM	
13	STP Sludge	40 Kg/day	

S.No	Description	Quantity	Mode of Disposal
14	Ash from Boiler	22.2 TPD	Sold to Brick manufactures
15	Spent Solvents	21.2 KLD	Recovered within plant premises and reused
16	Detoxified containers & liners	4500 Nos./month	Sent to authorized vendors/suppliers after complete de-toxification
17	Waste oil	6 KLPA	Sent to Authorized Recyclers
18	Used batteries	50 Nos./Yr	
19	Used Filter PP Bags	300 Nos./month	Sold to recyclers
20	MS/SS Scrap	9 TPM	
21	Used PPE	2.5 Kg/day	

B. General Conditions:

- i. **This order is valid for a period of 7 years.**
- ii. "Consent for Establishment" shall be obtained from Telangana State Pollution Control Board under Air and Water Act before the start of any activity / construction work at site w.r.t. Expansion.
- iii. This order is issued subject to outcome of the cases (if any), pending in the National Green Tribunal, Southern Zone, Chennai or in any other court.
- iv. The industry shall not manufacture any other products and exceeding capacities except those mentioned in this order, without permission.
- v. The proponent shall take necessary measures w.r.t. non-compliances (if any) mentioned in the compliance report of Regional Office, MoEF&CC, Chennai.
- vi. The proponent shall shift the industry whenever the Government directs the polluting industries and non-polluting industries from within the Outer Ring Road (ORR) to outside ORR, as committed by the proponent.
- vii. Provision shall be made for the housing of the construction labour within the site with all necessary infrastructure and facilities such as safe drinking water, fuel for cooking, mobile toilets, mobile STP, medical health care, crèche etc., The housing may be in the form of temporary structures to be removed after the completion of the project. The safe disposal of wastewater and solid wastes generated during the construction phase should be ensured.
- viii. No change in the process technology and scope of working should be made without prior approval of the SEIAA, TS. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA, TS/ MoEF&CC, GoI, New Delhi, as applicable.
- ix. The environment safeguards contained in the EIA Report should be implemented in letter and spirit. The responsibility of implementation of environmental safeguards rests fully with the proponent ie., M/s. Inogent Laboratories Pvt. Ltd.
- x. All the conditions, liabilities and legal provisions contained in the EC shall be equally applicable to the successor management of the project in the event of the project proponent transferring the ownership, maintenance of management of the project to any other entity.
- xi. The proponent shall submit half-yearly compliance reports in respect of the terms and conditions stipulated in this order in hard and soft copies to the SEIAA; and CCF, Regional office of MoEF&CC, GoI, Chennai on 1st June and 1st December of each calendar year.

- xii. Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone for RSPM, SPM, PM₁₀, PM_{2.5}, SO₂, NO_x monitoring. Location of the stations should be decided based on the meteorological data, topographical features and environmentally and ecologically sensitive targets and frequency of monitoring should be undertaken in consultation with the State Pollution Control Board.
- xiii. Data on ambient air quality (RSPM, SPM, PM₁₀, PM_{2.5}, SO₂, NO_x) should be regularly submitted to the Ministry including its Regional Office located at Chennai and the State Pollution Control Board/ Central Pollution Control Board once in six months.
- xiv. Usage of Personnel Protection Equipments by all employees / workers shall be ensured.
- xv. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- xvi. Occupational health surveillance program of the workers should be undertaken periodically to observe any contractions due to exposure to dust and take corrective measures, if needed.
- xvii The Industry shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.
- xviii A separate environmental management cell with suitable qualified personnel should be set-up under the control of a Senior Executive, who will report directly to the Head of the Organization.
- xix. The funds earmarked for environmental protection measures (capital cost of Rs. 5.0 Crores and recurring cost of Rs. 13.37 Crores / Annum) & also the funds earmarked for Corporate Social Responsibility (CSR) activities, should be kept in separate account and should not be diverted for other purpose. The budget allocated for the EMP shall be subsequently increased if the project cost increases at the time of CFO. Year wise expenditure should be reported to the SEIAA, Ministry and its Regional Office located at Chennai.
- xx. Officials from the Regional Office of MoEF&CC, GoI, Chennai who would be monitoring the compliance of the stipulated conditions and implementation of environmental safeguards should be given full co-operation, facilities and documents/data by the project proponents during their inspection. A complete set of all the documents shall be submitted to the CCF, Regional Office to MoEF&CC, GoI, Chennai.
- xxi. The project proponent shall submit the copies of the environmental clearance to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.
- xxii The project authorities should 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 SEIAA, Telangana. This order shall be displayed in the website of the project proponent.
- xxiii The proponent shall explicitly follow the suggestions and commitments made in the public hearing in protection of the environment.
- xxiv Any appeal against this Environmental Clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
- xxv. The company shall undertake eco-development measures including community welfare measures in the project area.
- xxvi The proponent shall obtain all other mandatory clearances from respective departments.

xxvii Concealing the factual data or 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.

xxvii The SEIAA may revoke or suspend the order, if implementation of any of the above conditions is not satisfactory. The SEIAA reserves the right to alter/modify the above conditions or stipulate any further condition in the interest of environment protection.

xxix The above conditions will be enforced inter-alia, under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

Sd/-
MEMBER SECRETARY
SEIAA, T.S.

Sd/-
MEMBER
SEIAA, T.S.

Sd/-
CHAIRMAN,
SEIAA, T.S.


To

Sri R. Bangaru Babu, Vice-President,
M/s. Inogent Laboratories Pvt. Ltd.,
Plot No. 28/A, IDA Nacharam,
Uppal (M), Medchal District – 500 075
Ph.No. 9701055479
E-mail: chakraborty.tapas@inogent.com

Copy to:

1. Prof. Ch. Krishna Reddy, Chairman, SEAC, T.S. for kind information.
2. The Member Secretary, TSPCB for kind information.
3. The EE, RO: RR-I, TSPCB for information.
4. The Regional Officer, MoEF&CC, GOI, Chennai for kind information.
5. The Secretary, MoEF&CC, GOI, New Delhi for kind information.

//T.C.F.B.O//


Senior Environmental Engineer (FAC)
(Unit – III)

