



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/MDK-39/2015-

Dt:09.05.2016.

Sub: SEIAA, TS – M/s. Mylan Laboratories Ltd., Unit - 1, Sy.No: 10, IDA, Gaddapotharam, Medak District – Environmental Clearance - Issued - Reg.

- I. This has reference to your application submitted vide letter dt. 30.11.2015 & subsequent lr. dt. nil, received on 18.02.2016 & lr.dt. 22.03.2016 seeking Environmental Clearance for the proposed expansion of **Bulk Drugs & Intermediates manufacturing unit** in the name of **M/s. Mylan Laboratories Ltd., Unit - 1, Sy.No: 10, IDA, Gaddapotharam, Medak District**. It was reported that the nearest human habitation viz., Sambhupur (V) exists at a distance of 1.06 km from the project site. It was also reported that Kishtaiahpally RF (0.45 km), Dundigal RF (0.5 km), Kazipally RF (0.6 km) and several other RFs exists within 10 km from the project site. The total area of the site is Ac.15; Out of that, area earmarked for development of Greenbelt is Ac.5.2. The total cost of the project is 25.0 Crores and the production capacities of the project after expansion is as following:

S.No	Name of Product	Capacity (TPM)
1	Lopinavir	5.00
2	Pregabiline	7.00
3	Zidovudine	6.00
4	Quetipine Fumarate	5.00
5	Tenofavir	7.00
6	Oxcarbazepine	3.00
7	Febantel	2.00
8	Zolpidem	3.00
9	Lamivudine	4.00
10	Montelukast	1.00
11	Enrofloxacin	2.00
12	Paroxetine HCl	2.00
13	Nadolol	0.50
14	Atavaquone	0.50
15	Valgancyclovir	1.00
16	Duloxetine HCl	1.00
17	Effavirenz	0.50
18	Levetiracetam	1.00
19	Olmesartan Medoxomil	1.00
20	Nevirapine(RAP)	0.50
21	Atomoxetine HCl	0.50
22	Tolmetan	1.00
23	Sumatriptan	0.25
24	Clindamycin Palmitate HCl	0.34
25	Mirtazapine	0.25
26	Lisinopril	0.20
27	Moxifloxacin	0.20
28	Irbesartan	0.45
29	Oseltamivir	0.25
30	Atenolol	0.25
31	Quinapril	0.10
32	Stavudine	0.30
33	Citalopram	0.25
34	Darunavir	0.25
35	Voriconzole	0.25
36	Triclabendazole	0.25
37	Eletripton Hydrobromide	0.08
38	Sitaglipton phosphate	0.15
39	Pironaridine Tetrphosphate	0.25

S.No	Name of Product	Capacity (TPM)
40	Gatifloxacin	0.25
41	Clarithromycin	0.02
42	Bosentan	0.02
43	Artemether	0.02
44	Artesunate	0.02
45	Ezetamibe	0.02
46	Milnacipran	0.02
47	Barnidipine	0.02
48	Febuxostat	0.02
49	Candesartan	0.02
50	Fosamprenavir	0.02
51	Atazanavir sulfate	0.02
52	Piperaquine Phosphahate	0.02
53	Raltegravir	0.02
54	Levofloxacin	0.02
55	Prasugrel	0.02
56	Aripiprazole	0.02
57	Dihydro Arstemisinin	0.02
58	Deasmopression Acetate	0.01
59	Blonanserin	0.02
60	Etoicoxib	0.02
61	Mitiglinide Calcium Dihydrate	0.02
62	Octreotide Acetate	0.02
63	Tetrabenazine	0.02
64	Vardenafil Hydrochloride Trihydrate	0.02
65	Aliskiren Hemifumarate	0.02
66	Atrovastatin	0.02
67	Amolodiphine	0.02
68	Azilsartan medoxomil potassium	0.02
69	Cabazitaxel	0.02
70	Fingolimod	0.15
71	Vilazadone	0.02
72	Linagliptin	0.02
73	Bocepravir	0.02
74	Telepravir	0.02
75	Miglitol	0.02
76	Finasartan	0.02
77	Other Validation Products	0.85
	Total	60.51

List of By-products after expansion:

S.No	Name of product	Stage	Name of By-product	Quantity (Kg / Day)
1	Pregabalin	II	Sodium Bromide salts	534.8
2	Tenofovir	II	Spent sodium Bromide	423.7
3	Febantel	II	Para toluene Sulphonic acid	30.0
4	Zolpidem Tartrate	I	Sodium Salts	186.5
		II	Phosphoryl chloride	83.9
5	Lamivudine	II	Dipotassium Hydrogen orthophosphate	113.0
6	Valganciclovir	II	Ammonium acetate	70.3
		III	Ammonium salts	61.0
7	Tolmetin Sodium Dihydrate	II	Sodium phosphate	140.1
8	Sumatriptan Succinate	I	Sodium Phosphate	177.7
		I	Ammonium phosphate	22.9
9	Pyronaridine	III	Spent Phosphoric acid	8.5
10	Blonanserin	II	Chlorophenyl Phosphinic Acid	0.8

- II. In the process, synthetic organic chemicals are produced by using various chemicals, solvents.
- 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 11.12.2015, 23.02.2016 & 22.03.2016. The project is exempted from the process of Public Hearing as the industry is located in a Notified Industrial Area existing since 1990's, as per OM dt. 10.12.2014 of the MoEF&CC, GoI. The Sub-Committee constituted by the SEAC inspected the site on 11.12.2015 and submitted the report. The Sub-Committee constituted by the SEAC reported that the industry is located at a distance of 5.56 km from the nearest Critically Polluted Area i.e., IDA Patancheru - Bollaram. Based on the information furnished, presentation made by the proponent and the consultant M/s. Team Labs & Consultants, Hyderabad; Certified Compliance Report issued by the Regional Office, MoEF&CC, GoI, to the conditions mentioned in the EC order dt.07.07.2005, 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., GoAP; G.O.Ms. No. 120, dt.22.10.2013 of the I&C Dept., GoAP; G.O.Ms. No. 80, dt. 27.10.2015 of the I&C Dept., GoTS; OMs dt.13.01.2010, 17.09.2013 & 10.06.2014 of MoE&F, GoI w.r.t. moratorium on Patancheru – Bollaram; S.O.1599 (E) dt.25.06.2014 amending EIA Notification, 2006 w.r.t. modification in general condition reducing distance of the project from Critically Polluted Area; Copies of Land Registration Documents; 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 10.03.2016, 21.03.2016 & 07.04.2016 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:

i. Air pollution:

- i The emissions from the coal fired Boilers of capacities 1 x 8 TPH (existing), 1 x 1 TPH (existing) & 2 x 2 TPH (existing - standby) shall be routed through bag filters followed by stacks of height 30 m (8 TPH boiler) and 30 m (1 TPH & 2 x 2 TPH boilers). 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. Adequate stack height shall be provided for D.G. Sets of capacity 2 x 500 kVA (existing), 3 x 750 kVA (Existing) 1 x 1010 kVA (Existing) and 3 x 1500 kVA (Proposed) as per CPCB norms. It was informed that Surplus Steam (with 30 TPH coal fired boiler) generated for 5 MW Captive power generation plant of Mylan Laboratories Limited, Unit 2, will be utilized in Mylan Laboratories Limited, Unit – 1, which is adjacent to this plant.

- 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 Chloride and Sulphur dioxide 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 Hydrogen, Carbon dioxide & Oxygen shall be routed through scrubber and safely dispersed into the atmosphere. 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. 5.2 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 TSIIC (Industrial Supply). The total water requirement after expansion shall not exceed 790.51 KLD. Quantity of water used for: Process & washings is 181.64 KLD; boiler make-up is 65.0 KLD; Cooling tower makeup is 428.88 KLD (Fresh - 296.05 KLD & Recycled - 296.05 KLD); DM Plant, Softener & Purified water system is 20.0 KLD; Scrubber is 5.0 KLD; Solvent recovery plant is 5.0 KLD; Detoxification is 5.0 KLD; ZLD washings is 10 KLD; Domestic purposes is 40 KLD & Gardening is 30 KLD.
- ii The total waste water generated after expansion is 296.05 KLD. Out of that, 128.21 KLD (HTDS) & 47.88 KLD (LTDS) is from Process; 9.96 KLD is from washings; 10 KLD is from Boiler blow down; 15.0 KLD is from cooling tower bleed of; 5.0 KLD is from Solvent Recovery system; 20.0 KLD is from DM Plant, Softener Plants Rejects; 5.0 KLD is from Detoxification; 10.0 KLD is from ZLD Washings; 5.0 KLD is from Scrubber; 40.0 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 shall be reused in cooling towers after necessary treatment. The LTDS effluents along with domestic sewage shall be treated in an ETP followed by RO system. The permeate is to be re-used in the plant and rejects are to be sent to 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 outside the factory premises. The volatile organics 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. 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 Wastes (Management, Handling, and Transboundary movement) Rules, 2008 and its amendments thereof 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. Hazardous Waste with Disposal Option :			
1.	Spent Carbon	31.0 TPM	Sent to TDSF for incineration/ Cement Plants for Co-incineration.
2.	Process Organic waste (Dry basis)	90.0 TPM	
3.	Distillation bottom residue (Dry basis)	246.0 TPM	
4.	Off specified & Discarded Raw materials, lab chemicals & products	5.0 TPM	
5.	Spent Mixed Solvents (Colored)	750.0 TPM	
6.	Stripper Distillate (VOC)	120.0 TPM	
7.	Process Inorganic Salts (Dry Basis)	39.0 TPM	Sent to TSDF for Secured Landfill
8.	ETP Sludge	75.0 TPM	
9.	Forced Evaporation Salts	211.0 TPM	
10.	Insulation Waste	2.0 TPM	
11.	DM Plant & Softener Plant Resins	10.0 TPA	
12.	Thermocol	2.0 TPM	
13.	Glass wool	2.0 TPM	
14.	Lab Vials	1.0 TPM	Sent to TDSF for incineration / Cement Plants for Co-incineration.
15.	Used Filters (HEPA, Oil Filters, etc.)	100 No's / Month	
16.	Discarded PPE	5.0 TPM	
17.	Used / Discarded Filter Bags	5.0 TPM	
18.	Used / Discarded RO / UF Membranes	10.0 TPA	
2. Hazardous Waste with Recycling Option :			
19.	Spent Solvents	750.0 TPM	Recovered within the premises / Sent to Authorized recyclers
20.	Detoxified HDPE Containers	3000 No's / Month	Sent back to suppliers after

21.	Glass bottles	5000 No's / Month	complete detoxification
22.	Detoxified Liners & Bags	500 TPM	
23.	Lead acid batteries	100 No's / Year	Sent to authorized recyclers
24.	Used Oil	1500 LPM	
25.	E-waste	5000 TPM	
3.Non Hazardous Solid Waste			
26.	Coal Ash	400 TPM	Sent to TSDF to use as a stabilizing agent / Sent to Brick manufacturers
27.	Paper, Cotton waste & Packing materials ie., wood, Carton, ropes.	25 TPM	Sent to outside agencies / authorized recyclers
28.	Plywood containers / broken glass, etc.,	10 TPM	
29.	Broken glass	5 TPM	
30.	Metal scrap	25 TPM	After detoxification to sale to outside agencies / recyclers
31.	Canteen waste	1.5 TPM	Composting at site / Piggeries

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.
- 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. 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.
- v. 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.
- vi. 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. Mylan Laboratories Ltd.
- vii. 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.
- viii. 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.
- ix. 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.

- x. Data on ambient air quality (RPM, 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.
- xi. Usage of Personnel Protection Equipments by all employees / workers shall be ensured.
- xii. 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.
- xiii. 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.
- xiv. 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.
- xv. 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.
- xvi. The funds earmarked for environmental protection measures (capital cost of Rs. 500 Lakhs and recurring cost of Rs. 979.2 Lakhs per 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. Year wise expenditure should be reported to the SEIAA, Ministry and its Regional Office located at Chennai.
- xvii 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.
- xviii 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.
- xix. 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.
- xx. 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.
- xxi. The company shall undertake eco-development measures including community welfare measures in the project area.
- xxii The proponent shall obtain all other mandatory clearances from respective departments.
- xxiii 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.
- xxiv 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.

xxv. 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 G. Srinivasa Rao, GM-EHS,
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//T.C.F.B.O//


SENIOR ENVIRONMENTAL ENGINEER
(Unit Head – III)

