



**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- 11/2015-**

**Dt:06.02.2016.**

**Sub: SEIAA, TS – M/s. Mylan Laboratories Ltd., Unit - 7, Plot No. 13, 14, 99 & 100, Phase II, IDA, Pashamylaram (V), Patancheru (M), Medak District– Environmental Clearance - Issued - Reg.**

- E. This has reference to your application and EIA report submitted vide letter dt. 24.08.2015 & subsequent lr. dt. 06.10.2015 seeking Environmental Clearance for the proposed expansion of **Synthetic organic chemicals manufacturing unit** in the name of **M/s. Mylan Laboratories Ltd., Unit - 7, Plot No. 13, 14, 99 & 100, Phase II, IDA, Pashamylaram (V), Patancheru (M), Medak District**. The nearest human habitation viz., Pashamylaram (V) exists at a distance of 0.5 km from the project site. The Sub-Committee constituted by the SEAC reported that the industry is located at a distance of 5.5 km from the nearest Critically Polluted Area i.e., IDA Patancheru -Bollaram. The total area of the site is Ac. 30.81; out of that area earmarked for Green belt is Ac. 10.78. The total cost of the project is Rs. 50 Crores and the production capacities of the project after expansion is as following:

S.No	Name of the product	Production Capacity	
		TPM	Kg/day
1	Acyclovir	30	1000
2	Aliskiren Hemifumarate	0.1	3.33
3	Almotriptan	0.1	3.33
4	Alprazolam	0.2	6.67
5	Amlodipine Besylate	1	33.33
6	Armodafinil	0.04	1.33
7	Asenapine Maleate	0.1	3.33
8	Atorvastatin	0.01	0.33
9	Azelnidipine	0.02	0.67
10	Azilsartan Medomoximil	0.02	0.67
11	Cetirizine	1	33.33
12	Clarithromycin	4	133.33
13	Cyclobenzaprine	0.11	3.67
14	Des Venlafaxine Fumarate	0.03	1
15	Des-Loratadine	0.1	3.33
16	Dexalansoprozole	0.5	16.67
17	Dronedarone	0.08	2.67
18	Fluconazole	1	33.33
19	Irbesartan	8	266.67
20	Itraconazole	0.05	1.67
21	Labetalol	0.02	0.67
22	Lamotrigene	0.25	8.33
23	Lansoprazole	1	33.33
24	Lisinopril	0.01	0.33
25	Ilapprazole Sulfide	0.08	2.67
26	Iloperidone	0.02	0.67
27	Loratadine	1	33.33
28	Losartan	1	33.33
29	O-Des methyl Venlafaine Succinate	0.03	1
30	Omeprazole	0.03	1
31	Oxybutynin HCl	0.05	1.67

S.No	Name of the product	Production Capacity		
		TPM	Kg/day	
32	Paliperidone	0.03	1	
33	Perindopril Arginine	0.03	1	
34	Perindropil Erbumine	0.05	1.67	
35	Pioglitazone	3	100	
36	Pitavastatin	0.1	3.33	
37	Rebeprazole	0.15	5	
38	Resperidone	0.15	5	
39	Rizatriptan	0.1	3.33	
40	Rosuvastatin	0.2	6.67	
41	Telmesetran	2	66.67	
42	Temazepam	0.01	0.33	
43	Terbinafine HCl	0.02	0.67	
44	Tetrabenazine	0.02	0.67	
45	Valacyclovir	25	833.33	
46	Zoledronic Acid	0.01	0.33	
47	Zolmitriptan	0.1	3.33	
48	Validation products	0.6	20	
<b>Total</b>		<b>81.52</b>	<b>2717.32</b>	
<b>Captive Coal based Power Plant</b>			<b>5 MW</b>	
<b>By-Products</b>				
S.No	Name of By-Product	Product Name	TPM	Kg/day
1	1,3 Di Cyclo Hexyl Urea	Valacyclovir	35.04	1168

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 31.08.2015 & 17.11.2015. The project is exempted from the process of Public Hearing as the industry is located in a notified IDA 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 and submitted the report. 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, 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; 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; Orders dt.22.12.2014 & 09.03.2015 in M.A.No.302/2014 filed in the Hon'ble National Green Tribunal (NGT); 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 09.12.2015 & 12.01.2016 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 viz., 5 TPH (existing - as standby), 8 TPH (existing - as standby) & 30 TPH (proposed); and 5 TPH Oil fired Boiler (existing - as standby) shall be routed through Electro Static Precipitator / Bag filter followed by stacks of height 30 m each. The concentration of particulates in the emission shall not exceed 50 mg/Nm<sup>3</sup>. Thermic fluid heater (2 lakh k.cal) shall be provided with a stack of height 10 m. 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 capacities 3 x 750 kVA (existing), 1 x 1250 kVA (existing), 2 x 1500 kVA (existing) & 3 x 1500 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 21<sup>st</sup> July, 2010 and amended time to time shall be followed by the unit.
- iii The process emissions containing Hydrogen Chloride and Carbon Dioxide shall be routed through multi stage scrubber with lime solution. Scrubbed liquid shall be treated and reused or subjected to MEE. The process emissions containing derivatives of Hydrogen shall be 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. 10.78 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) / tankers supply. The total water requirement after expansion shall not exceed 1156 KLD. Quantity of water used for: Process is 144.3 KLD; washings is 10.0 KLD; boiler make-up is 236.0 KLD; Cooling tower makeup is 50.0 KLD; Process & Utility RO rejects to cooling tower makeup is 209.7 KLD (Fresh) & 351 KLD (Recycled); Solvent Recovery Plant is 10.0 KLD; DM Plant, Softner & Purified water system is 35 KLD; Detoxification is 5.0 KLD; ZLD Washings is 10.0 KLD; Scrubber is 5.0 KLD; Domestic purposes is 40 KLD & Gardening is 50 KLD.

- ii The total waste water generated after expansion is 351.2 KLD. Out of that, 103.8 KLD (HTDS) & 48.4 KLD (LTDS) is from Process; 10 KLD is from washings; 20 KLD is from Boiler blow down; 72 KLD is from cooling tower bleed of; 10.0 KLD is from Solvent Recovery system; 35.0 KLD is from DM Plant, Softner Plants Rejects; 5.0 KLD is from Detoxification; 10.0 KLD is from ZLD Washings; 5.0 KLD is from Scrubber; 32.0 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 th 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
<b>1. Hazardous Waste with Disposal Option :</b>			
1.	Spent Carbon	45.08 TPM	Sent to TDSF for incineration/ Cement Plants for Co-incineration.
2.	Process Organic waste (Dry basis)	70.04 TPM	
3.	Distillation bottom residue (Dry basis)	247.88 TPM	
4.	Off specified & Discarded Raw materials, lab chemicals & products	2 TPM	
5.	Spent Mixed Solvents (Colored)	300 KL/Month	
6.	Stripper VOCs	45 KL/Month	
7.	Process Inorganic Salts (Dry Basis)	30.89 TPM	Sent to TSDF for Secured Landfill
8.	ETP Sludge	67.5 TPM	
9.	Forced Evaporation Salts	142.32 TPM	
10.	Insulation Waste	15 TPM	
11.	DM Plant & Softner Plant Resins	2 TPM	
12.	Discarded RO Plant Membranes	5 TPA	

S. No.	Description	Quantity	Mode of Disposal
13.	Lab Vials	0.1 TPM	Sent to TDSF for incineration/ Cement Plants for Co-incineration.
14.	Used Filters (HEPA, Oil Filters etc.)	20 No's / Month	
15.	Discarded PPE	5 TPM	
16.	Used Filter Bags	5 TPM	
<b>2.Hazardous Waste with Recycling Option :</b>			
17.	Spent Mixed Solvents / Recovered Solvents (Colorless)	450 KL/Month	Sent to Authorized recyclers
18.	Used Oil / Waste Lubricating oil	3000 Ltrs / Month	
19.	Detoxified Container	3000 No's / Month	Sent back to suppliers after complete detoxification
20.	Detoxified Liners	30 TPM	
21.	Lead acid batteries	75 No's / Year	
22.	Electrical & Electronic	15 TPA	Sent to authorized recyclers
<b>3.Non Hazardous Solid Waste</b>			
23.	Coal Ash	1000 TPM	Sent to Brick manufacturers
24.	Paper waste	10 TPM	Sent to recyclers
25.	Wood waste , carton boxes	10 TPM	
26.	Packing materials	25 TPM	
27.	Broken glass	5 TPM	
28.	Metal scrap	25 TPM	After detoxification to sale
29.	Canteen waste	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 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 1<sup>st</sup> June and 1<sup>st</sup> December of each calendar year.
- vii. Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone for RSPM, SPM, PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub> 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.

- viii. Data on ambient air quality (RPM, SPM, PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub>) 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.
- ix. Usage of Personnel Protection Equipments by all employees / workers shall be ensured.
- x. 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.
- xi. 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.
- xii. The Industry shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire lighting system shall be as per the norms.
- xiii. 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.
- xiv. The funds earmarked for environmental protection measures (capital cost of Rs. 804 Lakhs and recurring cost of Rs. 1693.2 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.
- xv. 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.
- xvi. 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.
- xvii. 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.
- xviii. 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.
- xix. The company shall undertake eco-development measures including community welfare measures in the project area.
- xx. The proponent shall obtain all other mandatory clearances from respective departments.
- xxi. 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.
- xxii. 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.

xxiii 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

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