


**ANDHRA PRADESH POLLUTION CONTROL BOARD**

D. No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,  
Chalamalavari Street, Kasturibaipet, Vijayawada - 520 010

Website: [www.pcb.ap.gov.in](http://www.pcb.ap.gov.in)

**CONSENT ORDER FOR ESTABLISHMENT**

**Order No.155/APPCB/CFE/RO-VSP/HO/2014**

**25/08/2022**

Sub: APPCB – CFE - **M/s. Mylan Laboratories Ltd., Unit – 9, Plot No. 5, JNPC, Parawada, Visakhapatnam** – Consent for Establishment of the Board for **Change of Product Mix** under Sec. 25 of Water (P & C of P) Act, 1974 and under Sec. 21 of Air (P & C of P) Act, 1981 - Issued - Reg.

- Ref:
1. Industry's CFE(CPM) application received through A.P.OCMMS on 30.06.2022.
  2. R.O's inspection report dt.12.07.2022.
  3. CFE Committee meeting held on 26.07.2022.
  4. T.O. lr. dt.29.07.2022
  5. Industry's reply lr. dt.12.08.2022.

In the reference 1<sup>st</sup> cited, an application was submitted to the Board seeking Consent for  
1. Establishment (CFE) for **Change of Product Mix** within the existing premises to produce the products with installed capacities as mentioned below, with a project cost of Rs.203.29Crores.

S. No.	Name of the products	Qty (kg/day)	Qty (kg/ annum)	Name of the Starting raw material	Qty (kg/day)	No. of Stages
<b>Regular products:</b>						
1	Celecoxib	166.67	60001.2	4-Methyl acetophenone (Para Methyl acetophenone)	88.58	2
2	Dolutegravir sodium	500.00	180000	DSSI	636.22	3
3	Etoricoxib(ETO)	66.67	24001.2	ketosulphone	80.00	2
4	Lamivudine	733.33	263998.8	Cyclohexyl Ester	1566.05	3
5	Levofloxacin Hemihydrate	233.33	83998.8	Levo ethyl ester	258.54	3
6	Zidovudine	150.00	54000	Betathymidine	209.47	2
7	Sertraline HCL	150.00	54000	Tetralone	801.51	4
	<b>Total</b>	<b>2,000.00</b>	<b>7,20,000</b>			

<b>Campaign products</b>						
1	BIC-II	100.00	36000	Thiourea	61.40	2
2	Febantel (FBN I)	100.00	36000	Febantel (DM) II	81.30	1
3	Dipyridamole	267.00	96120	DiCl.dipiperidinopyrimido[5,4d]pyin HM*	250.23	2
4	Tadalafil	33.33	11998.8	D-Tryptophan	38.06	4
5	Molnupiravir	166.67	60001.2	Cytidine	148.81	1
6	Milnacipran Hydrochloride	100.00	36000	2 OXO 1 PHENYL 3 OXABICYCLO [3.1.0HEXANE	204.17	4
7	Chlorthalidone	155.00	55800	Chlorthalidone (CHA) II	155.00	3
8	Emitricitabine	185.00	66600	FCE	602.41	2
9	Etoricoxib(ETX)	66.67	24001.2	ketosulphone	82.54	2
10	Etravirine	86.00	30960	6-AMINO-4-CHLORO-2-(4-CY.PA) PYRIMIDINE	160.20	5
11	Felbamate	33.33	11998.8	2-Phenyl-1,3-Propane Diol	81.30	2
12	Lumefantrine	200.00	72000	LMN Lumefantrine (LMF) I	214.77	3
13	Mirtazapine (anhydrous)	83.33	29998.8	Mirtazapine Acid	123.74	2
14	Mirtazapine hemihydrate (ABK)	66.67	24001.2	Mirtazapine Acid II SK	112.04	2
15	Pantoprazole sodium	267.00	96120	2-Chloromethyl 3,4-Dimethoxy Pyridine	257.97	2
16	Pirfenidone	96.00	34560	2-Amino-5-Methylpyridine	123.87	2
17	Pretomanid	150.00	54000	Pretomanid (PTM) II (Benzyloxy Propyl pivalate solution in toluene as 100%)	421.35	2
18	Sildenafil citrate	207.00	74520	Sildenafil Citrate (SDC) I	129.27	3

				EMP		
19	Validation products	33.33	11,998.8			
	<b>Any one product</b>	267.00	96,120			
	<b>Regular products along with any one product from campaign products</b>	2267.00	8,16,120			

The industry shall manufacture Regular products along with any one product form campaign products.

**By-Products:**

S. No.	Products name	Stage	By products name	Qty (kg /day)	Qty (kg/annum)
<b>Regular products</b>					
1	Zidovudine	I	TEA salts	187.5	67,500
		II	TTA salts	214.29	77144.4
2	Setraline HCl	II	Trans isomer	450	162000
			Aq. Mandelic Acid (Including water)	351.9	126684
3	Lamivudine	I	potassium orthophosphate salt	704.73	253702.8
		I	Menthol	595.10	214236
		II	Tech Salicylic Acid	937.20	337392
	<b>Total</b>			<b>3440.72</b>	<b>12,38,659.2</b>

<b>Campaign products</b>					
1	Pretomanid		potassium bromide	95.70	34452
2	Emitricitabine		DPHOP	397.12	142963.2

	Layer TOL + Menthol	574.30	206748
<b>Any one product</b>		<b>971.42</b>	349711.2
<b>Regular products along with one product from campaign products</b>		<b>4412.14</b>	1,58,837.4

2. As per the application, the above activity is to be located within the existing industry premises located at Plot No. 5, JNPC, Parawada, Visakhapatnam in an area of 6.67 acres.

3. The industry was inspected by the Asst. Environmental Engineer, Regional Office, Visakhapatnam, A.P Pollution Control Board on 08.07.2022 and observed that the site is surrounded by

**North** : Road followed by Tadi (V) at a distance about 100m  
**South** : M/s. Admiron Life Sciences  
**East** : M/s. Vandana Life Sciences  
**West** : Hilly area

4. The Board, after careful scrutiny of the application and verification report of the Regional Officer, hereby issues **CONSENT FOR ESTABLISHMENT FOR Change of Product mix** to the project under Section 25 of Water (Prevention & Control of Pollution) Act 1974 and Section 21 of Air (Prevention & Control of Pollution) Act, 1981 and the rules made there under. **This order is issued to manufacture the products as mentioned at para (1) only.**

5. This Consent order now issued is subject to the conditions mentioned in the Annexure.

6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

7. This order is valid for a period of 7 years from the date of issue.

**Encl:** Annexure.

**VIJAY KUMAR**  
**GSRKR IAS, MEMBER SECY(GSRKRVK), O/o MEMBER SECRETARY-APPCCB**

**To**  
**M/s. Mylan Laboratories Ltd., Unit – 9, (CPM)**  
**Plot No. 5, JNPC, Parawada,**  
**Visakhapatnam District.**  
**(Presently Anakapalli District)**

**Email:** rajashekar.kondepudi@viatris.com

**Copy to:** 1. The JCEE, Z.O: Visakhapatnam for information and necessary action.  
2. The E.E., R.O: Visakhapatnam for information and necessary action.



**ANNEXURE**

1. The proponent shall obtain Consent for Operation (CFO) from APPCB, as required Under Sec.25/26 of the Water (P&C of P) Act, 1974 and under sec. 21/22 of the Air (P&C of P) Act, 1981, before commencement of the trial runs.
2. The applicant shall provide separate energy meters for Effluent Treatment Plant (ETP) and Air pollution Control equipments to record energy consumed. An alternative electric power source sufficient to operate all pollution control systems shall be provided.
3. The industry shall construct separate storm water drains. No effluents shall be discharged in to the storm water drains.

**Water:**

4. The source of water is JNPC and the maximum permitted water consumption is as following:

<b>S. No</b>	<b>Purpose</b>	<b>Qty as per CFO Order dt.18.09.2020 (KLD)</b>	<b>Qty after CFE change of product mix (KLD)</b>
1.	Process & Washings	85.2	84.09
2.	Boiler feed	110.00	110.00
3.	Cooling makeup	247.318	247.318
4.	Softener & DM Plant	4.00	4.00
5.	Domestic	20.00	20.00
6.	Green Belt	20.00	20.00
	<b>Total</b>	<b>486.52</b>	<b>485.41</b>

Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned above.

5. The maximum waste water generation shall not exceed the following:

<b>S. No.</b>	<b>Source</b>	<b>Qty as per CFO Order dt.18.09.2020 (KLD)</b>			<b>Qty after CFE change of product mix (KLD)</b>		
		<b>HTDS</b>	<b>LTDS</b>	<b>Total</b>	<b>HTDS</b>	<b>LTDS</b>	<b>Total</b>
1.	Process Effluents	62.39	45.60	107.99	62.03	45.23	107.26
2.	Process washings	---	5.00	5.00	---	5.00	5.00
3.	Cooling tower Blow down	---	6.00	6.00	---	6.00	6.00
4.	Boiler Blow down	---	4.00	4.00	---	4.00	4.00
5.	Softener & DM plant	---	4.00	4.00	---	4.00	4.00
6.	Domestic Effluent	---	14.00	14.00	---	14.00	14.00
	<b>Total</b>	<b>62.39</b>	<b>78.6</b>	<b>140.99</b>	<b>62.03</b>	<b>78.23</b>	<b>140.26</b>

**Treatment & disposal:**

<b>Source</b>	<b>Treatment</b>	<b>Mode of final disposal</b>
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacy for further treatment
LTDS	Pretreatment (Neutralization)	To CETP of M/s. Ramky Pharmacy for further treatment and disposal
Domestic waste water	---	The overflow of the Septic tank shall be sent to the CETP for further treatment.

6. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
7. The industry shall properly operate and maintain online real time monitoring system along with web camera facilities and shall ensure that it is connected to APPCCB / CPCB websites as per CPCB directions.
8. Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas. All pipe valves, sewers, drains shall be leak proof.
9. The LTDS and HTDS effluents shall be stored in above ground level collection tanks separately. Hoods shall be provided to the tanks and connect to the scrubber to mitigate emissions.
10. The industry shall provide tank in tank system for effluent collection at production blocks. Free board shall be maintained in the tanks to prevent spillages.
11. The industry shall construct rain water runoff tank for collection and storage of first flush storm water. The industry shall maintain dry condition outside drains in un-rainy season.

**Air:**

12. The Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution after Change of Product mix :

<b>S. No.</b>	<b>Details</b>	<b>Stack 1</b>	<b>Stacks 2,3</b>
a)	Attached to	Coal fired Boilers	D.G sets
b)	Capacity	1 x 3 TPH & 1 x 6 TPH	1 x 1500 KVA & 1 x 1250 KVA
c)	Fuel	Coal	Diesel
d)	Stack height	30m	7.7m & 7.1m above the roof
e)	Control Equipment:	Cyclone separator with common bag filter	Acoustic enclosures and silencers

13. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.
14. The industry shall properly operate and maintain the monitoring system to all the stacks / vents in the plant. Regular monitoring shall be carried out and report shall be submitted to the Regional officer.

15. The industry shall properly operate and maintain multi-stage scrubbers to the process vents to control the process emissions. The industry shall ensure that online pH measuring facility with auto recording system is connected to the scrubbers.
16. The industry shall provide multi-stage scrubbers to the process vents to control the process emissions. The industry shall provide online pH measuring facility with auto recording system to the scrubbers provided to treat the process emissions.
17. The industry shall properly operate and maintain VOC monitoring system with auto recording facility.
18. The industry shall implement adequate measures to control all fugitive emissions from the plant.
19. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, GoI vide notification No. GSR. 826 (E), dated. 16.11.2009 during construction and regular operational phase of the project at the periphery.  
The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time.
20. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
21. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
22. The evaporation losses in solvents shall be controlled by taking the following measures:
  - i. Chilled brine circulation shall be carried out to effectively reduce the solvent losses into the atmosphere.
  - ii. Transfer of solvents shall be done by using pumps instead of manual handling.
  - iii. Closed centrifuges shall be used to reduce solvent losses.
  - iv. All the solvent storage tanks shall be connected with vent condensers to prevent solvent vapours.
  - v. The reactor vents shall be connected with primary & secondary condensers to prevent escaping of solvent vapour emissions into atmosphere.

**Solid / Hazardous Waste:**

23. The industry shall comply with the following for disposal of Solid waste:

<b>S. No.</b>	<b>Name of the Hazardous Waste</b>	<b>Qty as per CFO order dt.26.10.2017</b>	<b>Qty after CFE (CPM)</b>	<b>Disposal option</b>
1.	Organic solid waste (Process organic residue & Distillation bottom residue)	9770.1 kg/day	9189 kg/day	To the authorized Cement industries for co-processing (or) TSDF, Parawada for incineration
2.	Inorganic solid waste (from process)	1714.76kg/day	2444.37 kg/day	To TSDF, Parawada for secured land filling.
3.	Stripper Distillation (SRU)	2000 kg/day	2000 kg/day	To the authorized Cement industries for co-processing (or) TSDF, Parawada for incineration
4.	Spent carbon	576.97 kg/day	428.52 kg/day	To the authorized



				Cement industries for co-processing (or) TSDF, Parawada for incineration
5.	ETP Sludge	1000 kg/day	1000 kg/day	TSDF, Parawada for secured land filling.
6.	Off specified & Discarded raw materials, lab chemicals & products	50 kg/day	50 kg/day	To TSDF, Parawada (or) to the Cement industries for incineration.
7.	Spent mixed solvents (Coloured)	10,000 kg/day	10,000 kg/day	To authorized recovery units / Authorized cement plant for co-processing.
8.	Used Oil	2000 LPM	2000 LPM	To authorized Re-processors / Recyclers / to the Cement industries for co-processing in the kiln.
9.	Container & Container liners of Hazardous Waste & Chemicals	Containers – 5000 Nos. /Month & Liners – 10,000kg/month	Containers – 5000 Nos. /Month (or) 50 TPM & Liners – 10,000kg/month	To authorized agencies, after complete detoxification for re-use/ recycle.
10.	Recovered solvents (Distilled Colourless)	350 TPM	350 TPM	To Reuse / sale to authorized recyclers
11.	Thermo coal	50 kg/day	1000.00 kg/month	Sent to authorized agencies (or) TSDF, Parawada / Cement Industries
12.	Insulation waste	50 kg/day	50 kg/day	
13.	Glass wool	50 kg/day	50 kg/day	
14.	E – waste	5 TPM	5 TPM	Authorized collection center / recyclers / dismantler / disposal facility
15.	Paper, cotton waste & packing materials i.e., wood, carton, ropes etc	16 TPM	16 TPM	Sale to outside agencies / recyclers
16.	Ply wood boxes, tins	10 TPM	10 TPM	
17.	Metal scrap (MS, SS, GI, Aluminium)	25 TPM	25 TPM	
18.	Spent discarded resins	400 kg/month	400 kg/month	To TSDF, Parawada for secured land filling.
19.	Discarded Personal protective equipment	1000 kg/month	1000 kg/month	
20.	Discarded Thermocol	1000 kg/month	1000 kg/month	

21.	Discarded Tube Lights	50 kg/month	50.00 kg/month	To TSDF, Parawada (or) to the Cement industries for incineration.
22.	HEPA Filters / Oil filters	50 Nos. / annum	50 Nos. / annum	
23.	Discarded UF/RO membranes	30 Nos. / annum	30 Nos. / annum	
24.	Broken glassware, glass bottles, glass vials, etc	1.0 TPM	1.0 TPM	To authorized agencies, after complete detoxification for re-use/ recycle.
25.	PPFRP Waste	50 kg/day	50 kg/day	TSDF / Authorized recyclers / Cement Industry
26.	Waste paint materials	100 kg/month	100 kg/month	
27.	Coal Ash	8.33 TPD	8.33 TPD	To brick Manufacturers.
28.	Contaminated cotton rags	----	0.5 TPM	To dispose TSDF for incineration or AFRF / Cement Industries for Co-Processing /Authorized preprocessing Units
29.	Lead Acid Batteries	----	250 Nos./annum	To dealers on buy back system

24. The proponent shall place the chemical drums and / or any drums in a shed provided with concrete platform only. The Platform shall be provided with sufficient dyke wall and effluent collection system. The industry shall provide containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.

25. The following rules and regulations notified by the MoEF&CC, GoI shall be implemented.

- a) Regulation of Persistent Organic Pollutants Rules, 2018.
- b) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
- c) Plastic Waste Management Rules, 2016.
- d) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
- e) Fly Ash Notification, 2016.
- f) Batteries (Management & Handling) Rules, 2010.
- g) E-Waste (Management) Rules, 2016.
- h) Construction and Demolition waste Management Rules, 2016.
- i) Solid Waste Management Rules, 2016.
- j) The Public Liability Insurance Act, 1991 and its amendments thereof.

**Other Conditions:**

26. The industry shall comply with the following conditions as committed vide Ir. dt.12.08.2022:
  - The effluent generation shall not increase from the existing consented quantities.

- The SS reactor vents shall be connected to the scrubbers .
- The Vent condensers to all the solvent storage tanks shall be provided.
- The industry shall comply with the check list and SOP of CPCB w.r.t. Solvent recovery system - the vent of the condenser shall be passed through absorption media like Activated Carbon.
- The industry shall explore the possibility of obtaining individual PLI for the industry.
- The industry shall develop and maintain green belt not less than 33% of the total area in the premises.

27. "The industry shall comply with the industry specific standards with respect to emissions tank farm vents stipulated by the MoEF & CC, GoI, New Delhi vide Notification GSR541(E), dt.06.08.2021."

<b>S. No.</b>	<b>Details of process emissions</b>	<b>Emission Control system</b>	<b>Emission Standard</b>
1.	HCl	Multi stage water scrubbers and alkali scrubbers in series.	35 mg/Nm <sup>3</sup>
2.	NH <sub>3</sub>		30 mg/Nm <sup>3</sup>
3.	Chlorine		15 mg/Nm <sup>3</sup>
4.	Benzene		5 mg/Nm <sup>3</sup>
5.	Toluene		100 mg/Nm <sup>3</sup>
6.	Acetonitrile		1000 mg/Nm <sup>3</sup>
7.	Dichloromethane		200 mg/Nm <sup>3</sup>
8.	Xylene		100 mg/Nm <sup>3</sup>
9.	Acetone		2000 mg/Nm <sup>3</sup>

28. The industry shall display online data outside the main factory gate on quantity and nature of hazardous chemicals being used in the plant, water & air emissions and solid waste generated within the factory premises, as per Hon'ble Supreme Court order.

29. **The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.**

30. **The industry shall submit a copy of the NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.**

31. **The industry shall submit risk assessment report covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.**

32. **The industry shall obtain PESO clearance & policy under PLI Act before applying for CFO of the Board.**
33. The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity / flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (MSIHC) Rules, 1989 and the details shall be furnished to the Factories Department and to the Regional Office, APPCB on monthly basis duly certifying the same.
34. The industry shall identify major accident hazard chemicals & list out the hazardous chemicals endangered to human health & environment and the details shall be furnished to the Factories Department and to the Regional Office, APPCB time to time duly certifying the same by the industry. Further the industry shall extend training to the working personnels while handling hazardous chemicals for prevention of accidents and necessary antidotes to ensure the safety, as per the MSIHC Rules, 1989.
35. The industry shall carryout calibration of safety equipments and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office. The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
36. **The industry shall comply with the Technical suggestions at Chapter No. 7.3 & 7.4 for Hazardous Chemical handling industries by High Power Committee (HPC) of Govt. of Andhra Pradesh. The HPC report is available at [www.ap.gov.in](http://www.ap.gov.in).**
37. The industry shall utilize DG power for captive consumption only & power shall not be supplied to grid and shall follow the amendments issued by MoEF & CC/CPCB from time to time on DG sets in respect of conditions & standards.
38. Green belt shall be developed all along the boundary & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.
39. **The industry shall submit compliance to the conditions stipulated in the EC and CFE orders to the concerned Regional Officer of APPCB every six months and shall upload the same at APPCB website viz., [https://pcb.ap.gov.in/UI/Submission\\_Compliance\\_of\\_EC\\_CFE\\_CFO\\_Direction.aspx](https://pcb.ap.gov.in/UI/Submission_Compliance_of_EC_CFE_CFO_Direction.aspx).**
40. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Regional Office and Zonal Office of the Board.
41. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order attracts action under the provisions of relevant pollution control Acts.
42. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec. 27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21(4) of Air (Prevention and Control

of Pollution) Act, 1981 to revoke the order, to review any or all the conditions imposed herein and to make such modifications as deemed fit and stipulate any additional conditions.

43. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules, 1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

**VIJAY KUMAR GSRKR IAS, MEMBER  
SECY(GSRKRVK), O/o MEMBER SECRETARY-  
APPCB**

**To  
M/s. Mylan Laboratories Ltd., Unit – 9 (CPM)  
Plot No. 5, JNPC, Parawada,  
Visakhapatnam District  
(Presently Anakapalli District)**

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