

**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

CONSENT ORDER FOR ESTABLISHMENT**Order No. APPCB/VSP/VZN/91/CFE/HO/2012****25/02/2020**

Sub: APPCB – CFE - **M/s. Mylan Laboratories Limited (Unit-8), G. Chodavaram (V), Pusapatirega (M), Vizianagaram District** - Consent for Establishment (CFE) 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. EC order dt. 01.11.2006 issued by MoEF&CC, Gol. New Delhi
 2. Marine disposal order dt.12/09/2007, issued by MoEF, Gol, New Delhi
 3. CFE order dt. 8/8/18
 4. CFE Amendment order dt. 13/11/18
 5. CFE application received through APOCMMS on 28.01.2020..
 6. R.O's inspection report dt. 03.02.2020.
 7. CFE Committee meeting held on 12.02.2020
 8. Industry's lrs.dt12.02.2020 & 24.02.2020.

1. In the reference 5th cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **Change of Product Mix** to produce the products with installed capacities as mentioned below, with an additional investment of Rs. 0.1 Lakh.

S. No.	Name of the Products and By-products	Consented qty as per EC Order dt. 01/11/2006 (TPM)	As per CFE Order dt. 8/8/2018 & amendment Order dt. 13/11/2018 (Kg/day)	Quantity after change of product mix (Kg/day)
1	Tia Profenic Acid	3.0	---	---
2	Naproxen Sodium	50	3.33	3.33
3	Trazadone HCL	3.0	333.33	333.33
4	Allopurinol	8.0	166.67	166.67
5	Nabumetone	1.0	166.67	16.67
6	Efavirenz (EFD 1 NBC (Grignard Reagent)	15.0	1333.33	1033.33
7	Abacavir Sulfate	3.0	333.33	400.00
8	Nelfinavir Mesylate	5.0	---	---
9	Indinavir sulfate	3.0	---	---
10	Ciprofloxacin HCL	25.0	---	---
11	Cytosine Menthyl Ester (CME Intermediate)	16.6	400.0	400
12	Zidovidine	25.0		
13	Gabapentine	40.0	50.00	50
14	Cyclohexyl Ester (CXE)	---	333.33	333.33
15	Alendronate Sodium	---	50	50.0
16	Propafenon HCL	---	3.33	3.33

17	Fexofenadine HCL	---	3.33	3.33
18	Menthyl Glyoxylate Hudrate (MGH)	---	3.33	3.33
19	Emtricitabine	---	16.67	16.67
20	Lanthanum carbonate	---	73.33	233.33
21	Mirtazapine	---	3.33	3.33
22	Baclofen	---	10.0	10.0
23	Ritonavir	---	167.67	166.67
24	Atazanavir sulfate	---	136.67	166.67
25	Clozapine	---	83.33	183.33
26	Memantine HCL	---	40.0	40.0
27	Risedronate Sodium	---	50.0	50.0
28	Valsartan	---	833.33	733.33
29	Tenofovir	---	800.0	1350
30	Lopi Rito Premix	---	283.33	283.33
31	Quetiapine	---	3.33	3.33
32	Pentaprazole Sodium	---	33.33	300.00
33	Lansoprazole	---	3.33	33.33
34	Valacyclovir	---		
35	Acyclovir	---	400.0	166.67
36	Defrasirox	---	3.33	16.67
37	Varapamil	---	3.33	3.33
38	Lamivudine	---	866.67	66.67
39	Try Cyclic Ketone	---		
40	FCE	---	333.33	400.00
41	Sildenafil Citrate	---	166.67	333.33
42	Ambrisentan	---	3.33	3.33
43	Atorvastatin Calcium	---	306.67	400.00
44	Verenicline Tartrate	---	1.67	1.67
45	Sofosbuvir	---	186.67	186.67
46	Cobicistat	---	13.33	13.33
47	Pentaprazole Megnesium	---	100.0	140.0
48	Ledipasvir	---	33.33	33.33
49	Daclatasvir	---	33.33	33.33
50	Velpatasvir	---	33.33	33.33
51	Reltagravir	---	33.33	33.33
52	Dolutegravir	---	33.33	33.33
53	Linagliptin	---	3.33	3.33
54	Validation products	---	33.33	33.33
55	Citalopram Hydrobromide	2.50	---	---
56	Naproxen Intermediate (Acetyl Yara Yara)	50.0	---	---
		250.10 TPM (8336.67 Kg/day)	8305.0 Kg/day	8305.0 Kg/day

	Captive Power		2.5 MW	2.5 MW
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By-products:

S. No.	Name of the Products and By-products	As per CFE Order dt. 8/8/2018 & amendment Order dt. 13/11/2018 (Kg/day)	Quantity after change of product mix (Kg/day)
1	Zinc Salt	3570.61	2767.27
2	Magnesium Salt	385.33	298.63
3	Phosphate Salts	159.75	201.40
4	Phosphorous Oxy Chloride	15.23	15.23
5	Phosphate Salts	2618.2	159.75
6	Sodium bromide water*	--	14 KLD

***The industry shall send the Sodium Bromide Water – 14 KLD generated during manufacture of Tenofeir in stage-II as by-product to the authorized manufacturers of Bromine or Sodium Bromide.**

2. As per the application, the above activity is to be located in the existing industry premises at G. Chodavaram (V), Pusapatirega (M), Vizianagaram District.

3. The above site was inspected by the Environmental Engineer and Asst. Environmental Engineer, Regional Office, Vizianagaram, A.P Pollution Control Board on 31.01.2020 and observed that the site is surrounded by

North NH-5 Road
South Agricultural lands
East Approach road to Kovada (V)
West Agricultural lands

4. The Board, after careful scrutiny of the application, verification report of Regional Officer and recommendations of the CFE Committee, 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 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

**VIVEK YADAV IAS, MS(VY), O/o MEMBER SECRETARY-APPCB
MEMBER SECRETARY**

To

**M/s. Mylan Laboratories Limited
(Unit-VIII), G. Chodavaram (V)
Pusapatirega (M),
Vizianagaram District.
E-Mail: srinivasa.anumula@mylan.in**

Copy to: 1. The JCEE, Z.O: Visakhapatnam for information and necessary action.
2. The EE, R.O: Vizianagaram 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 and provide rain water harvesting structures. No effluents shall be discharged in to the storm water drains.

Water:

4.	The source of water is Ground Water and Tankers and the maximum permitted water consumption is as following:
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S. No.	Purpose	Consented quantity as per EC dt. 01/11/06	Quantity after change of product mix (KLD) as per Ir.dt.24.02.2020
1)	Process & Washings	970 m ³ /day	470.0
2)	Cooling tower Makeup		150.0
3)	Boiler Feed		245.0
4)	DM Plant regeneration		30.0
5)	Softener Washings		10.0
6)	Domestic		50.0
7)	Gardening		15.0
	Total	970 m³/day	970.0 KLD

The industry shall restrict the quantity of water consumption to 970 KLD as per the EC order dt. 01.11.2006.

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:

S. No.	Source	Consented quantity as per EC order dt. 01/11/06	Quantity after change of product mix (KLD) as per Ir.dt.24.02.2020
1	High TDS Process and Wash Effluents	700m ³ /day	309.0

2	Low TDS Effluents		239.0
3	Boiler Blow down, Cooling tower bleed off, DM plant & softener		110.0
4	Domestic		42.0
	Total	700m³/day	700.0 KLD
4	Raw Water (Fresh Water) RO Rejects		263.0
	Total:		963.0 KLD

The industry shall restrict the waste water generation to 700 KLD as per the EC order dt. 01.11.2006.

Treatment & disposal:

Out let – as per CFE order dt.08.08.2018:

S. No.	Description	Treatment	Mode of disposal
1	High TDS Process and wash effluents.	Pre-treatment, Stripper, MEE (200 KLD + 250 KLD) Followed by ATFD (25 KLD + 30 KLD)	<ul style="list-style-type: none"> MEE condensate shall be fed to Biological ETP. MEE Salts shall be disposed to TSDF.
2	Low TDS effluents.	Biological ETPs (350 KLD + 200 KLD + 150 KLD) followed by primary RO (550 KLD + 150 KLD) followed by secondary RO (400 KLD + 250 KLD).	<ul style="list-style-type: none"> ROs permeate shall be recycled and RO Rejects shall be fed to MEE system (200 KLD + 250 KLD).
3	Boiler blow down, Cooling tower bleed off, DM Plant & Softener effluents.	Biological ETP.	<ul style="list-style-type: none"> About 90 KLD of permeate to be recycled to utilities. 20 KLD of rejects to MEE.
4	Fresh water RO rejects		To Sea through marine outfall under the supervision of marine out fall team after confirmation of analysis of sample from lab.

- The ZLD system consisting of stripper, MEE, ATFD system with condenser and Biological ETP, RO plant shall be properly operated. All the units of the ZLD system shall be impervious to prevent ground water pollution. The units of ZLD system shall be above the ground level.

Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.

- The industry shall provide magnetic flow meters with totalisers at the inlet and outlet of Stripper, MEE and RO and ETP.
- The industry shall properly maintain online real time monitoring system along with web camera facilities as per the directions of CPCB. The industry shall connect them to APPCB / CPCB websites as per CPCB directions.

9. 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.
10. The industry shall carryout monitoring of marine outfall pipeline, as committed in the CFE Committee meeting held on 12.02.2020.

Air:

11. The Air pollution Control equipment shall be installed along with the commissioning of the activity and shall comply with the following for controlling air pollution after Change of Product Mix:

S. No.	Details of Stack	Stack 1	Stack 2	Stack 3	Stack 4	Stack 5
a)	Attached to:	Boiler	Boiler	Boiler	Boiler	Thermic fluid heater
b)	Capacity	20 TPH	5 TPH	4 TPH	2 TPH (Standby)	3 x 2.0 lakh K.cal/hr (one Thermic fluid heater is standby)
c)	Name of the Fuel :	Coal	Coal	Coal	Coal	Diesel
d)	Stack height above ground (m.)	40 m	30 m	30 m	30 m	20 m
e)	Air Pollution Control Equipment:	Cyclone separator followed by ESP	Bag filters	Bag filters	Bag filters	----

S. No	Details of Stack	Stack 6, 7, 8 & 9	Stack 10, 11, 12 & 36	Stack 13	Stack 14 & 35	Stack 15-34
a)	Attached to:	DG Sets	DG Sets	DG Sets	DG Sets	Process emissions
b)	Capacity	4 x 1500 KVA	4 x 1250 KVA (One DG set standby)	1 x 1010 KVA	2 x 500 KVA	---
c)	Name of the Fuel :	HSD	HSD	HSD	HSD	---
d)	Stack height above ground (m.)	4 x 15.0 m each	4 x 13.0 m each	12.5 m	2 x 10.5 m each	10 m
e)	Air Pollution Control Equipment:	Acoustic Enclosures Silencers & Mufflers	Acoustic Enclosures Silencers & Mufflers	Acoustic Enclosures Silencers & Mufflers	Acoustic Enclosures Silencers & Mufflers	Wet Scrubbers

12. 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.
13. The industry shall properly maintain and operate 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.
14. The industry shall properly maintain and operate 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.
15. The industry shall properly maintain and operate VOC monitoring system with auto recording facility.
16. The industry shall implement adequate measures to control all fugitive emissions from the plant.
17. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, Gol 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.
18. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
19. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.

20. 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 Waste:

21. The industry shall comply with the following for disposal of Solid wastes after Change of Product Mix as per Annexure II of Ir.dt. 12.02.2020:

S. No.	Type of waste	As per CFE (CPM) Order dt 08.08.2018 (TPM)	After Change of product mix (TPM)	Mode of Disposal
1	Process Organic Residue	97.65	100.83	To the authorized Cement industries for being used as alternate fuel in the kiln (or) TSDF, Parawada for incineration
2	Spent Carbon	19.0	19.38	To the authorized Cement industries for being used as alternate fuel in the kiln (or) TSDF, Parawada for incineration
3	Process Inorganic Salts & Distillation Bottom Residue	65.39	61.73	To TSDF, Parawada for secured land filling / Cement plants for co-processing.
4	Off Specified & Discarded Raw Materials, Lab Chemicals & Products	2.0	2.0	To TSDF, Parawada (or) to the Cement industries for incineration.
5	Spent Solvents (Coloured)	300.0	300.0	To TSDF, Parawada (or) to the Cement industries for incineration.
6	Stripper VOCs	300	300	To TSDF Parawada for Incineration / Cement Industries for Co-Processing
7	ETP Sludge	250.0	250.0	TSDF, Parawada for secured land filling.
8	Evaporation Salts	450.06	449.47	To TSDF, Parawada for secured land filling

Hazardous Waste with Recycling:

S. No.	Type of waste	As per CFE (CPM) Order dt 08.08.2018 & CFE amendment order dt. 13.11.2018	After Change of product mix	Mode of Disposal
9	Used Oil / Waste Lubricating Oil	3.0 TPM	3.0 TPM	Used as lubricant within the premises / to authorized Re-processors / Recyclers / to the Cement industries to use as alternate fuel in the kiln.
10	Mixed Solvents / Recovered Solvents (Colourless)	3000 TPM	3000 TPM	To authorized recovery units / Authorized cement plant for co-processing.
11	Detoxified Containers (Drums / Carboys / Containers)	2000 Nos./month	4000 Nos./month	After detoxification, they shall be disposed to the outside authorized agencies.
12	Detoxified liners	5000 Kg/month	10,000 Kg/month	To authorized agencies, after complete detoxification for re-use/ recycle.

Non-Hazardous:

S. No.	Type of waste	As per CFE (CPM) Order dt 08.08.2018 (TPM)	After Change of product mix (TPM)	Mode of Disposal
1	Coal Ash	500	500.0	CWMP Parawada / Brick Manufactures
2	Metal Scrap	100	100.0	To be Sold out to recyclers
3	Discarded PPE	1	1.0	CWMP, Parawada/authorized Cement Industries for Co-Processing
4	Industrial Garbage	15.0	25.0	
5	Non-Hazardous Domestic / Laboratory Solid Waste etc.,)	1	1.0	CWMP, Parawada authorized E-Waste recyclers
6	Discarded Bulbs, Tube Lights etc.	0.5	0.5	
7	Paper, Cotton Waste, Packing Waste, Ply wood wooden boxes, carton	5.0	5.0	Sale/CWMP Parawada /Cement Industries for Co-Processing.
8	E-Waste	2	2.0	To Authorized recycler

9	Thermocol waste	1.0	2.0	TSD / Cement Industry / Authorized recyclers
10	Insulation waste (glass wool)	2.0	2.0	

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.

23. The following rules and regulations notified by the MoE&F, 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:

24. Green belt shall be maintained properly 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.
25. 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.
26. 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.
27. 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.

28. 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.

**VIVEK YADAV IAS, MS(VY), O/o MEMBER SECRETARY-APPCB
MEMBER SECRETARY**

**To
M/s. Mylan Laboratories Limited
(Unit-VIII), G. Chodavaram (V)
Pusapatirega (M),
Vizianagaram District.
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