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. 155 /APPCB/CFE/RO-VSP/HO/2014 **26/12/2019**

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. CFE CPM order dt. 28.02.2017 and Amendment order dt. 12.09.2017.
2. Industry's application received through A.P. OCMMS on 27.11.2019.
3. R.O's inspection report dt. 15.12.2019.

1. In the reference 3rd 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, without any additional investment.

As per CFE order dt. 28.02.2017 and Amendment order dt. 12.09.2017:

S. No.	Product	Quantity (kg/day)	No. of stages	Starting Raw Materials	Quantity (kg/day)
Group – 1					
1.	Effavirenz	333.33	3	MMAA	543.95
2.	Acyclovir	333.33	4	Guanine	283.33
3.	Valsartan	50.00	2	CMVEH	227.31
4.	Lamivudine	333.33	3	Cyclo Hexyl Ester	1414.38
5.	Valacyclovir	333.33	3	Acyclovir	260.42
6.	Celecoxib	100.00	3	4-Methyl acetophenone (4-MAP)	65.27
7.	Levofloxacin	133.33	3	Levo ethyl ester (LFX)	196.70
8.	Dolutegravir	133.33	3	Dolutegravir sodium DOS I	196.03
9.	Etoricoxib	33.33	3	Methyl-6methylnicotinate	5.11
10.	Esomeprazole	83.33	3	2-Chloromethyl - 4-methoxy-3,5-dimethyl pyridine HCl	150.50
	Total	**1866.64**			
Group – 2					
1	Tenofavir	100.00	3	Adenine	87.4
2	Zidovudine	1000.00	2	Beta Thymidine	1360.54
3	Setraline HCl	300.00	5	Tetralone	989.45
4	Emtricitabine	166.67	1	FCE	444.4
	Total	**1566.67**			

Campaign Products					
1	Piperaquine phosphate	33.33	3	4,7-Dichloro Quinoline	40.00
2	Sildenafil Citrate	150.00	1	Sildenafil Citrate (SDC) I EMP	69.95
3	Lumefantrine	333.33	3	LMN (2-Chloro-1-(2,7-dichloro-9H-Flourene-4-yl) ethanone	416.67
4	Dipyramidole	**400.00**	2	2,6dichloro 4-8di(piperidin-1-yl)pyrimido[5,4-d] pyrimidine	320.00
5	Pregabalin	66.67	3	3-Isobutyl pentane dionic acid dimethylester	66.67
6	Selvemer Carbonate	200.00	1	Sevelamer HCl	177.20
7	Selvemer HCl	200.00	1	Polyallyl amine HCl (50% solution)	463.50
8	Stavudine	10.00	4	β-Thymidine	34.38
9	Moxifloxacin	10.00	5	Moxifloxacin acid	13.89
10	Colesevelam HCl	200.00	1	Sevelamer HCl	102.41
11	Irbesertan	10.00	3	BMCP	15.0
12	FBN-I	33.33	2	Febantel (DM) I	22.0
13	BCI-II	25.00	2	Thiourea	5.3
14	Milnaciprone	100.00	4	POBH	0.3
15	Abacavir	50.00	3	AFC	86.8
16	Zofenopril	33.33	5	Trans-4-hydroxy L-proline	48.98
17	Naptopidol	66.67	3	1-Naphthol	78.35
18	Lamotrigine	100.00	4	2,3–Dichlorobenzoyl Chloride	282.67
19	Etravirine	100.00	7	Ethyl cyanoacetate	36.63
20	Pentaprozole Sodium	200.00	6	5 – Difluro Methoxy benzimidazole	101.00
21	Cyclo Serine	33.33	3	D-Serine	10.28
22	Pirferidone	10.00	4	2-Amino-5-methyl pyridine Or Amino Compound	86.02
23	Validation products	33.33			
Total		**400.00**			
Worst Load		**2267 kg/day**			

The industry shall produce products from either Group – 1 or Group – 2 along with one product from campaign products at any point of time with a maximum production capacity of 2267 kg/day.

By-products:

S.No.	Product name	Stage	By-product name	Quantity Kg/day
Group - 1				
1	Effavirenz	I	Sodium Acetate	634.68
2	Lamivudine	I	Potassium Ortho phosphate	1493.09
Group - 2				
1	Emtricitabine	I	DPHOP	721.67
2	Zidovudine	I	TEA salts	1536.70
		II	TTA salts	2983.00

The above byproducts shall be reused or disposed to authorized recyclers or disposed to TSDF.

After change of product mix:

S. No	Name of the products	Production capacity (kg/day)	No's of Stages	Starting raw materials	Quantity (kg/day)
Group-1					
1	Setraline HCl	100	5	Tetralone	263.48
2	Levofloxacin	300.00	3	Levo ethyl ester (LFX)	176.60
3	Zidovudine	733.00	2	Beta Thymidine	1184.27
4	Sevelamer Carbonate	400.00	1	Sevelamer HCl	354.40
5	Abacavir	467.00	3	AFC	810.54
	Total	**2000**			
Group-2					
1	Dolutegravir	333.33	3	Dolutegravir sodium DOS I	489.57
2	Celecoxib	600	3	4-Methyl acetophenone (4-MAP)	391.70
3	Etoricoxib	133.33	3	Methyl-6methylnicotinate	20.31
4	Lamivudine	400.00	3	Cyclo Hexyl Ester	771.42
5	Emtricitabine	195	1	FCE	520.00
	Total	**1661.66**			
Campaign products					
1	Lamotrigine	100.00	4	2,3–Dichlorobenzoyl Chloride	282.67
2	Tenofavir	200	3	Adenine	174.80
3	Valacyclovir	267	3	Acyclovir	313.77
4	Esomeprazole	85	3	2-Chloromethyl - 4-methoxy-3,5-dimethyl pyridine HCl	153.51
5	Piperaquine phosphate	200	3	4,7-Dichloro Quinoline	240.00
6	Sildenafil Citrate	207	3	Sildenafil Citrate (SDC) I	96.52

				EMP	
7	Lumefantrine	200	3	LMN (2-Chloro-1- (2,7-dichloro-9H- Flourene-4-yl) ethanone	250.05
8	Sevelamer HCl	154	1	Polyallyl amine HCl (50% solution)	356.89
9	Moxifloxacin	10	5	Moxifloxacin acid	13.88
10	Colesevelam HCl	50	1	Sevelamer HCl	25.60
11	FBN-I	66.67	2	Febantel (DM) I	44.02
12	BCI-II	66.67	2	Thiourea	14.19
13	Milnaciprone	100	4	POBH	61.27
14	Etravirine	200	7	Ethyl cyanoacetate	73.26
15	Pantoaprozole Sodium	267	3	5-Difluro Methoxy benzimidazole	134.84
16	Pirferidone	96	4	2-Amino-5-methyl pyridine Or Amino Compound	123.87
17	Dipyramidole	267	2	2,6dichloro 4-8di(piperidin-1-yl)pyrimido[5,4-d] pyrimidine	404.55
18	Efavirenz	166.67	3	MMAA	272.00
19	Mirtazapine	150	1	Mirtazapine Acid	185.08
20	Tadalafil	170.5	4	D-Tryptophan	358.05
21	Pretomanid	150	2	Benzyloxy propyl pivalate (PRT-III)	232.50
22	Chlorthalidone	160	3	3-(4'-Chlorophenyl) Phthalimide (CHL-III)	144.00
23	Validation products	33.33			
	Any one product	**267**			
	Group-1 OR Group-2 along with one product from campaign products	**2267**			

The industry shall manufacture products from either Group-1 OR Group-2 along with one product from campaign products at any given point of time with a maximum production capacity of 2267 kg/day.

Byproducts:

S.No	Products name	Stage	By products Name	Quantity (kg/day)
Group-1				
1	Zidovudine	I	TEA salts	1126.40
		II	TTA salts	2186.54
2	Setraline HCl	II	Trans isomer	23.70
		III	Cis isomer	102.78
	Total			**3439.42**
Group-2				
1	Lamivudine	I	Potassium orthophosphate salts	**1791.71**
2	**Emtricitabine**	I	DPHOP	**844.35**
	Total			**2636.06**
Campaign products				
1	Tenofovir	II	Spent sodium bromide and acetate salts	**1790.00**
2	Pretomanid	I	Potassium bromide	**34.05**
3	Efavirenz	I	Sodium acetate	317.35
	Any one product			**1790.0**
	Group-1 OR Group-2 along with one product from campaign products			**5229.42**

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 Environmental Engineer & Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 12.12.2019 and observed that the site is surrounded by

North : Road followed by Tadi (V) at a distance about 100 m
South : M/s. Admiron Life Sciences,
East : Industrial Plot,
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 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 Ltd., Unit – 9, (CPM)
Plot No. 5, JNPC, Parawada,
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srinivas.gangavarapu@mylan.in

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 trail runs.

2. The applicant shall properly operate and maintain 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 JN Pharmacity, Parawada and the maximum permitted water consumption is as following:

Sl. No	Purpose	Quantity as per CFE (CPM) order dt. 28.02.2017 (KLD)	Quantity after change of product mix (KLD)
1.	Process & Washings	87.57	85.2
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
	Total	**488.88**	**486.52**

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:

Sl. No.	Source	Quantity as per CFE (CPM) order dt. 28.02.2017 (KLD)			Quantity after change of product mix (KLD)		
		HTDS	LTDS	Total	HTDS	LTDS	Total
1.	Process Effluents	62.5	46.0	108.5	62.39	45.60	107.99
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
	Total	**62.5**	**79.0**	**141.5**	**62.39**	**78.6**	**140.99**

Treatment & disposal:

Source	Treatment	Mode of final disposal
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacity for forced evaporation.
LTDS	Pretreatment (Neutralization)	To CETP of M/s. Ramky Pharmacity 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 APPCB / 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.

Air:

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

Sl. No	Details of Stack	Stack 1	Stack 2	Stack 3to 5
a)	Attached to	Boilers – 2 Nos.	Thermic Fluid Heater	DG Sets – 3 Nos.
b)	Capacity of Boiler	1 X 3 TPH & 1 X 6 TPH	2 lakh K.cal/hr	1 x 500; 1 X 1500 KVA & 1 X 1250 KVA
c)	Fuel	Coal	HSD	HSD
d)	Stack height: Above the ground	30 m common stack	20.	4.5 m, 7.75 m and 7.1 m
e)	Details of Air Pollution Control Equipment:	Bag filters - 2 Nos.	---	Acoustic enclosures with silencers

10. 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.

11. 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.

12. 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.

13. The industry shall properly operate and maintain VOC monitoring system with auto recording facility.

14. The industry shall implement adequate measures to control all fugitive emissions from the plant.

15. 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.

16. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.

17. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.

18. 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:

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

Sl. No.	Type of waste	Quantity as per CFE order dt. 28.02.2017	Quantity after Change of Product Mix	Disposal options
1.	Organic solid waste	9122 kg/day	9770.1 kg/day	To Authorized cement plants for co-processing / TSDF, Parawada, Visakhapatnam for incineration.
2.	Inorganic solid waste (from process)	1601 kg/day	1714.76 kg/day	
3.	Stripper Distillation (SRU)	2000 kg/day	2000 kg/day	

4.	Spent carbon	1342.5 kg/day	576.97 kg/day	To Authorized cement plants for co-processing / TSDF, Parawada, Visakhapatnam for incineration.
5.	ETP Sludge	500 kg/day	1000 kg/day	To TSDF, Parawada for secured land filling.
6.	Off specified & Discarded raw materials, lab chemicals & products	25 kg/day	50 kg/day	To TSDF for incineration / Cement industry for co-processing.
7.	Spent mixed solvents (Coloured)	10,000 kg/day	10,000 kg/day	To TSDF for incineration / Cement industry for co-processing.
8.	Used Oil	2000 LPM	2000 LPM	To Authorized recyclers
9.	Container & Container liners of Hazardous Waste & Chemicals	Containers – 2000 Nos. /Month & Liners – 5000 kg/Month	Containers – 5000 Nos. /Month & Liners – 10000 kg/Month	Detoxified containers shall be sent to outside agencies. Container liners shall be sent to M/s. Coastal Waste Management Project (M/s. Ramky CETP facility) only.
10.	Recovered solvents (Distilled Colourless)	35 TPM	350 TPM	To Reuse / sale to authorized recyclers.
	OTHER SOLID WASTE			
11.	Thermo coal	50 kg/day	50 kg/day	To TSDF
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	To authorized collection center / recyclers / dismantler / disposal facility
15.	Paper, cotton waste & packing materials i.e., wood, carton, ropes etc	10 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 for land fill
19.	Discarded Personal	1000 kg/month	1000 kg/month	

	protective equipment			
20.	Discarded Thermocool	1000 kg/month	1000 kg/month	To TSDF
21.	Discarded Tube Lights	50 kg/month	50 kg/month	
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	To TSDF for encapsulation, Parawada, Visakhapatnam
25.	PPFRP Waste	--	50 kg/day	To TSDF for incineration.
26.	Waste paint materials	--	100 kg/month	
27.	Coal Ash	250 TPM	250 TPM	To TSDF to use as a stabilizing agent / brick manufacturers

20. 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.

21. 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:

22. **If the capacity of CETP, JNPC is not sufficient in future, then the additional capacity of the products issued in this order, that generate the excess quantity of HTDS effluent, than the quantity permitted based on the area of the industry, shall be withdrawn.**

23. **The industry shall submit compliance to the conditions stipulated CFE order 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

24. Existing green belt shall not be disturbed due to the proposed Change of Product Mix. **Thick green belt in an additional area of 1 acre with tall growing trees and good canopy shall be developed within a month so that 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 Ltd., Unit – 9, (CPM)
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Signature Not Verified

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