ANDHRA PRADESH POLLUTION CONTROL BOARD
PARYAVARAN BHAVAN, A - 3, INDUSTRIAL ESTATE,
SANATHNAGAR, HYDERABAD - 500 018

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CONSENT ORDER FOR ESTABLISHMENT & OPERATION

Order No. 250 /APPCB/CFE/RO-VSP/HO/2014 **Dt: 15.02.2019.**

Sub: PCB – CFE - **M/s. Mylan Laboratories Ltd., Unit – 10, SEZ, Plot No. 86, JNPC, Parawada, Visakhapatnam –** Consent for Establishment (CFE) & Consent for Operation (CFO) of the Board for **Change of Product Mix** under Sec.25/26 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 (Exp) Order No. 250/PCB/CFE/RO-VSP/HO/2014, dated 04.03.2016
2. Industry's CFE (CPM) application No.836715 received through APOCMMS on 22.01.2019.
3. R.O's inspection report dt. 29.01.2019.
4. CFE Committee meeting held on 08.02.2019.
5. RO's mail dt. 08.02.2019 regarding payment of CFE fee.

1. In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **Change of Product Mix** to produce the following products with installed capacities as mentioned below, with an additional investment of Rs. 13.28 Crores.

As per CFE expansion order dt. 04.03.2016:

S. No.	Products / Line of Activity	Quantity (Kg/day)
	Group 1: (Any 3 products at any point of time - 4000.01 kg/day)	
1.	**Tenofavir**	**1666.67**
2.	**Efavirenz**	**1666.67**
3.	Acyclovir	333.33
4.	Citalopram	233.33
5.	**Abacavir**	**666.67**
6.	Valacyclovir	233.33
	Group 2: (Any 2 products at any point of time – 466.67 kg/day)	
1.	**Gabapentine**	**266.67**
2.	Trazodone	100.00
3.	Lanthanum Carbonate	100.00
4.	Clozapine	83.33
5.	Carvedilol	133.33
6.	**Atazanavir**	**200.00**
	Group 3: (Any 2 products at any point of time - 600 kg/day)	
1.	**Valsartan**	**333.33**
2.	Ritanovir	166.67
3.	Escitalopram	66.67

4.	Montelukast	166.67
5.	Irbesartan	166.67
6.	Atorvastatin	166.67
7.	Levofloxacin	166.67
8.	**Lopinavir**	**266.67**
9.	Validation products	28.33 kg/day

Total production capacity of all groups at any point of time – 5066.68 kg/day.

After Change of Product Mix:

S. No	Products Name	Quantity kg /day	No's of Stages	Starting raw materials	Quantity kg /day
	Group-1(Any three)				
1	Tenofavir	**1666.67**	3	Adenine	1456.79
2	Efavirenz	**2000.00**	1	Amino Carbinol (EFD-1)	1836
3	Acyclovir	333.33	4	Guanine	381.60
4	Citalopram	333.33	5	1-Bromo-4-Flourobenzene	283.62
5	Abacavir	**633.33**	3	AFC Abacavir (ABC-I)	852.60
6	Valacyclovir	200.00	6	Guanine	245.47
	Sub-Total	**4300.00**			
Group-2 (Any two)					
1	Dolutegravir sodium	**333.33**	3	Dolutegravir sodium DOS I	489.51
2	Valsartan	**133.33**	2	CMVEH	227.34
3	Gabapentine	**133.33**	4	1,1-Cyclo hexane di-acetic anhydride (CHA-1)	431.06
4	Ritonavir	**166.67**	5	BDH hemi succinate (BDH as 100%)	143.16
5	Carvedilol	**166.67**	5	2-(2-Methoxyphenoxy) ethylamine hydrochloride (MPEA.HCl)	806.21
6	Atazanavir	**133.33**	2	Atazanavir Sulfate	183.89
	Sub-Total	**500.00**			

Group-3 (Any two)					
1	Trazodone	**100.00**	4	1,3 Chloro Phenyl Piperzine HCl	84.36
2	Lanthanum Carbonate	**100.00**	1	Lanthanum oxide	56.70
3	Clozapine	**83.33**	2	CODD	92.13
4	Escitaloprame	**166.67**	5	1-Bromo-4- Fluoro benzene	446.42
5	Montelukast	**100.00**	4	MKS -I	492.29
6	Irbesartan	**100.00**	3	1-Bromo-4- Fluoro benzene	150
7	Atorvastatin	**100.00**	2	FBA	68.85
8	Levofloxacin	**100.00**	3	Levo ethyl ester	100.06
9	Lopinavir	**100.00**	2	2,6 - Dimethyl phenoxy acetyl Chloide (DPC)	42.29
10	Validation Product	**66.67**	--	---	---
	Sub-Total	**266.67**			
	Total	**5066.67**			

By- Products:

Sl. No	Name of the product	Name of the By-Product	Quantity Kg/Day
1	Tenofovir	Chloro Methyl Isopropyl Carbonate	4167.00
		Sodium sulfate	2000.00
		Sodium Bromide MLs	12495.00
2	Valacyclovir	1.3 Dicyclohexl Urea	313
3	Escitalopram	Ammonium Phosphate	110
4	Citalopram	Sodium phosphate	112
		Ammonium Phosphate	2692
5	Atzanavir	Phosphate Salts	265
6	Lopinavir	Sodium salts	1420

2. As per the application, the above activity is to be located in the existing premises at SEZ, Plot No. 86, JNPC, Parawada, Visakhapatnam in an area of 27.09 Acres.

3. The above site was inspected by the Environmental Engineer & Asst. Environmental Engineer-1, Regional Office, Visakhapatnam, A.P Pollution Control Board on 25.01.2019 and observed that the site is surrounded by

North **:** JNPC, Internal Road

South **:** JNPC, Internal Road

East **:** JNPC, Internal Road

West **:** JNPC, SEZ Compound Wall & R & B Road

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 & CONSENT FOR OPERATION for Change of Product Mix** to the activity under Section 25/26 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 upto 31.03.2021 i.e., upto the validity of CFO & HWA order.**

Encl: Annexure

CHAIRMAN

To
M/s. Mylan Laboratories Ltd.,
Unit – 10, SEZ, Plot No. 86,
JNPC, Parawada,
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saikiran.dannana@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 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.

2. 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:

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

S. No	Purpose	Qty. as per CFE (expn) Order dt. 04.03.2016	After Change of Product Mix
1.	Manufacturing Process	256.00	256.00
2.	Process Washings (equipment wash, floor wash etc..)	25.00	25.00
3.	Boiler through RO plant	300.00	300.00
4.	Cooling Towers	500.00	500.00
5.	DM , softener & Vacuum systems	20.00	20.00
6.	Laboratories	12.00	12.00
7.	Domestic (Canteen & Sanitation)	30.00	30.00
8.	Gardening	50.00	50.00
9.	Detoxification	10.00	10.00
	Total	**1203 KLD**	**1203 KLD**

4. The maximum waste water generation after Change of Product Mix shall not exceed the following:

Sl. No.	Source	Qty. as per CFE (expn) Order dt. 04.03.2016 (KLD)			After Change of Product Mix (KLD)		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
1.	Process effluents	130.00	208.00	338.00	130.00	208.00	338.00
2.	Washings (Equipment wash, floors wash etc.)	----	25.00	25.00	----	25.00	25.00
3.	Laboratories	----	12.00	12.00	----	12.00	12.00
4.	Boiler blow down	----	30.00	30.00	----	30.00	30.00
5.	Cooling tower blow down	----	65.00	65.00	----	65.00	65.00
6.	DM , softener & Vacuum systems	----	20.00	20.00	----	20.00	20.00
7.	Detoxification effluent	----	10.00	10.00	----	10.00	10.00
8.	Domestic	----	30.00	30.00	----	30.00	30.00
	Total	**130.00**	**400.00**	**530.00**	**130.00**	**400.00**	**530.00**

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.

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

6. 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.

7. 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:

8. The proponent shall comply with the following for controlling air pollution after Change of Product Mix.

As per CFE expansion order dt. 04.03.2016:

S No	Details of Stack	Stack – 1	Stack –2	Stack –3	Stack – 4 to 9
1.	Attached to	Coal fired boiler	Coal fired boiler	Coal fired boiler	DG Set – 4 Nos.
2.	Capacity	1 X 12 TPH	1 X 8 TPH	1 X 4 TPH	1500 KVA, 500 KVA & 4 X 2000 KVA
3.	Fuel	Coal	Coal	Coal	Diesel
4.	Stack height	42 m (above GL)	36 m (above GL)	36 m (above GL)	8 m, 5 m, 2 x 9 m above roof level
5.	Control Equipment	ESP	Bag filter & MDC	Bag filter & MDC	Acoustic enclosures.

After Change of Product Mix:

S No	Details of Stack	Stack – 1	Stack –2	Stack – 3
1.	Attached to	Coal fired boiler	Coal fired boiler	DG Set – 4 Nos.
2.	Capacity	1 X 12 TPH	1 X 4 TPH	1500 KVA, 500 KVA & 4 X 2000 KVA
3.	Fuel	Coal	Coal	Diesel
4.	Stack height	42 m (above GL)	36 m (above GL)	8 m, 5 m, 2 x 9 m above roof level
5.	Control Equipment	ESP	Bag filter & MDC	Acoustic enclosures.

9. 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.

10. 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.

11. 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.

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

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

14. 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.

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

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

17. 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:

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

S.No.	Name of the waste	Existing	After CPM	Mode of disposal
1.	Process Inorganic Waste	3580 Kg/day	3580 Kg/day	TSDF, Parawada, Visakhapatnam District for secured land filling.
2.	ETP Sludge	1500 Kg/day	1500 Kg/day	
3.	Stripper Distillate	2000 Kg/day	2000 Kg/day	TSDF, Parawada, Visakhapatnam District for incineration OR AFRF / Authorised cement plants for co-processing.
4.	Process Organic Waste (includes distillation residue)	14717 Kg/day	14694Kg/day	
5.	Spent Carbon	2176 Kg/day	2199 Kg/day	
6.	Spent Mixed Solvents (colored)	25000 Kg/day	25000 Kg/day	
7.	Off specification & discarded products / raw materials/ intermediates / lab chemicals	150 Kg/day	250 Kg/day	TSDF, Parawada, Visakhapatnam District
8.	Pharma dust from clean rooms, Pharma rooms, AHUs, Bag filters and floor sweeping	10 Kg/day	100 Kg/day	
9.	Spill contaminant waste	50 Kg/day	50 Kg/day	

10.	Spill discarded resins	50 Kg/day	100 Kg/day	
11.	Used oil	4000 Lts/m	4000 Lts/m	APPCB Authorized recyclers.
12.	Container and container liners.	3000 Nos/month 20000 Kg/month	3000 Nos/month 20000 Kg/month	After complete detoxification, it shall be disposed off to outside agencies / to TSDF for detoxification.
13.	Thermo coal waste	5000 Kg/ month	5000 Kg/ month	TSDF, Parawada, Visakhapatnam District
14.	Insulation waste	5000 Kg/ month	5000 Kg/ month	
15.	Off specified & discarded raw material, lab chemicals & products	250 Kg/day	250 Kg/day	
16.	Discarded personal protective equipment	200 Kg/day	200 Kg/day	
17.	HEPA filters / oil filters	75 Nos./ month	500 Kgs/ month	
18.	Filtration bags	300 Nos / month	1500 Kgs / month	
19.	Laboratory vials	500 kg/month	500 kg/month	
20.	Empty glass bottles	1000 Nos/ month	500 Kgs/ month	Shall be disposed to outside agencies after detoxification
21.	Spent Mixed Solvents / Recovered Solvents (colorless)	60 KLD	60 KLD	APPCB Authorised solvent recovery units/ solvent recovery within the premises.
22.	Lead Acid Batteries	100 Nos.	100 Nos.	Authorized recyclers / to dealers on buy back system.
23.	Used tube lights	100 Nos. / month	100 Nos. / month	Authorized collection centers/ recyclers / dismantler / disposal facility
24.	E – waste	5000 Kg/year	5000 Kg/year	
25.	Paper, cotton waste & packing material i.e., wood, carton, ropes etc.,	10 TPM	10 TPM	Sale to outside agencies / recyclers
26.	Ply wood boxes, tins	10 TPM	10 TPM	
27.	Metal scrap (MS, SS, GI, Aluminum)	25 TPM	25 TPM	
28.	Glass bottles waste	50 Kg / month	50 Kg / month	
29.	Coal Ash	750 TPM	750 TPM	TSDF to use as stabilizing agent / Brick manufacturers

19. 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.

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

    a) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
    b) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.
    c) Fly Ash Notification, 2016.
    d) Batteries (Management & Handling) Rules, 2010.
    e) E-Waste (Management) Rules, 2016.
    f) Construction and Demolition waste Management Rules, 2016.

Other Conditions:

21. Existing green belt shall not be disturbed due to the proposed Change of Product Mix. Thick green belt shall be developed and maintained all along the boundary, either side of the internal roads & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.

22. 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.

23. 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.

24. 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.

25. 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.

CHAIRMAN

To

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