



ANDHRA PRADESH POLLUTION CONTROL BOARD
D.No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamalavari Street, Kasturibaipet, Vijayawada – 520010.

Website :www.appcb.ap.nic.in

CONSENT ORDER FOR ESTABLISHMENT & OPERATION

Order No. 299 /APPCB/CFE/RO-VSP/HO/2012

Dt:13.10.2019

Sub: APPCB – CFE - **M/s. Lupin Ltd., Plot No.130, JNPC, Parawada, Visakhapatnam** – Consent for Establishment 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 order dt. 31.10.2012 and amendment orders dt. 16.02.2013 & 09.10.2017.
2) Industry's application received through A.P. Single Desk Portal on 12.09.2019.
3) R.O's inspection report dt. 04.10.2019.
4) CFE Committee meeting held on 10.10.2019.
5) Industry's Ir. dt.10.10.2019

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 products with installed capacities as mentioned below, with an additional investment of Rs. 44.956 Crores.

As per CFE order dt. 31.10.2012 & amendment order dt. 16.02.2013:

S. No.	Products	Capacity (kg/day)
1	Abacavir Sulphate	13.9
2	Asenapine Maleate	5.6
3	Atazanavir Sulphate	13.9
4	Atorvastatin Calcium	33.3
5	Azithromycin Monohydrate	33.3
6	Clopidogrel Bisulfate	97.2
7	Darunavir Ethanolate	13.9
8	Desvenlafaxine Benzoate	13.9
9	Desvenlafaxine Succinate	13.9
10	Diacerein	5.6
11	Donepezil Hydrochloride	13.9
12	Dronedarone Hydrochloride	3.3
13	Duloxetine Hydrochloride	27.8
14	Efavirenz	8.3
15	Emtricitabine	27.8
16	Esomeprazole Magnesium	13.9
17	Febuxostat	3.3
18	Fesoterodine Fumarate	13.9
19	Fexofenadine Hydrochloride	8.3
20	Glipizide	5.6
21	lloperidone	3.3

22	Lansoprazole	13.9
23	Levetiracetam	16.7
24	Lopinavir	5.6
25	Mesalamine	41.7
26	Milnacipran	13.9
27	Pioglitazone Hydrochloride	13.9
28	Pitavastatin Calcium	13.9
29	Prasugrel Hydrochloride	5.6
30	Pregabalin	55.6
31	Rabeprazole Sodium	13.9
32	Raltegravir Potassium	13.9
33	Ranolazine	83.3
34	Ritonavir	5.6
35	Rufinamide	13.9
36	Sevelamer Carbonate	138.9
37	Simvastatin	27.8
38	Telmisartan	13.9
39	Tenofovir Disoproxil Fumarate	13.9
40	R & D Pilot Plant Trial Run Products (Bulk Drugs and Intermediates)	102.8
	Total	982.2 Kg/day

After Change of Product Mix:

S. No	Products	Proposed Quantity (kg/day)	No. of stages	Starting Raw Material	Quantity of SRM (kg/day)
1	Clopidogrel Bisulfate	1.4	2	(S)-N-(2-TE)-2-CPMEHCL	1.82
2	Darunavir Ethanolate	5.6	3	DNV-II	6.28
3	Dronedarone Hydrochloride	1.4	4	2-butyl-3-(4-hydroxybenzoyl)-5-nitrobofuran	1.2
4	Duloxetine Hydrochloride	5.6	2	S(-)MMAA	4.08
5	Emtricitabine	1.4	3	FCME (EMTRI-III)	3.79
6	Rabeprazole Sodium	2.1	3	Chloro compound	3.57
7	Raltegravir Potassium	2.8	2	RLT-II	5.61
8	Ranolazine	27.8	5	2,6,xylidine	14.74
9	Ritonavir	1.4	3	Crude BDH Succinate salt	1.6
10	Simvastatin	2.8	3	Lovastatin	6.11
11	Tenofovir Disoproxil Fumarate	55.6	1	TNF-III	48.31
12	Acotiamide Hydrochloride Hydrate	33.3	3	2,4,5-TMBA	26.95
13	Azilsartan Kamedoxomil	8.3	5	Cyanoester	22.69
14	Canagliflozin Hemihydrate	1.4	2	CNG-IV	2.65
15	Celecoxib	5.6	3	4-Methyl acetophenone	2.94
16	Choline Fenofibrate	8.3	2	4-Chlorophenyl 4-hydroxyphenyl ketone	6.77
17	Cysteamine Bitartrate	13.9	1	Cysteamine HCl	9.92

18	Dapagliflozin premix	1.4	1	DPG-IV	2.78
19	Dolutegravir Sodium	41.7	4	Acetal compound	71.59
20	Efinaconazole	1.4	2	Diol triazole	1.85
21	Empagliflozin	1.4	1	EMG-IV	4.34
22	Ezetimibe	5.6	4	4 Fluoro aniline	5.42
23	Fenofibrate	55.6	2	4-Chlorophenyl 4-hydroxyphenyl ketone (Hydroxy Compound)	64.98
24	Imipramine Pamoate	1.4	3	Iminodibenzo	1.4
25	Isoniazid	27.8	2	4-Cyanopyridine	43.40
26	Lamivudine	13.9	3	Lami-2	129.90
27	Linezolid	6.9	3	FMA	8.77
28	Propranolol Hydrochloride	2.8	2	1-Naphthol	2.84
29	Pyrazinamide	591.7	1	2-Cyanopyrazine	552.96
30	Sacubitril Valsartan Trisodium Complex	2.8	4	Biphenyl acid	2.15
31	Sitagliptin Phosphate	1.4	2	BOC ACID	1.16
32	Tenofovir Alafenamide Fumarate	2.1	2	TNF-III	5.83
33	Zolpidem Tartarate	2.8	3	Nitrile compound	2.57
34	Ziprasidone Hydrochloride	6.9	4	PBT HCl	6.49
35	R & D Pilot Plant Trial Run Products (Bulk Drugs and Intermediates)	33.3			
	Total	979.20			

By-products

S. No	Name of the Product	Existing as per CFE 31.10.2012		Proposed	
		Name of the By-Product	Quantity kg/day	Name of the By-Product	Quantity kg/day
1	Festoferodine Fumarate	Aluminium Hydroxide	53.6	Product dropped	
2	Asenapine Maleate	Aluminium Hydroxide and Lithium Chloride	12.4	Product dropped	
3	Ezetimibe	---		R-DPP HCl Salt	1.24

- As per the application, the above activity is to be located within the existing industry premises located at Plot No.130, JNPC, Parawada, Visakhapatnam in an area of 27.715 Acres (112157.8 Sq. m).
- The industry was inspected by the Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 30.09.2019 and observed that the site is surrounded by

North : Plot No : 130 A
South : Road
East : Ramky service area
West : Road followed by reservoir

4. The Board, after careful scrutiny of the application, verification report of the Regional Officer and recommendation of the CFE committee hereby issues **CONSENT FOR ESTABLISHMENT AND OPERATION 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 upto 31.10.2021 i.e., till the validity of CFO & HWA order.**

Encl: Annexure.

**Bandla
Siva Sankar
Prasad**

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CHAIRMAN

To

**M/s. Lupin Ltd., (CPM)
Plot No.130,
JNPC, Parawada,
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iconservices.vizag@gmail.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 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, Parawada and the maximum permitted water consumption is as following:

S. No	Purpose	Qty. as per CFE order dt.31.10.2012 (KLD)	After Change of Product Mix (KLD)
1.	Process	122.00	74.08
2.	Water for R & D	20.00	15.00
3.	Washings	70.00	70.00
4.	Boiler makeup	167.00	167.00
5.	Cooling tower	388.00	388.00
6.	Scrubbers	10.00	10.00
7.	Domestic	68.00	68.00
8.	Gardening	180.00	180.00
	Total	1025.00	972.08

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

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

Sl. No	Source	Qty. as per CFE order dated 31.10.2012 (KLD)			After Change of Product Mix (KLD)		
		HTDS	LTDS	Total	HTDS	LTDS	Total
1.	Process	84.00	47.00	131.00	44.50	32.30	76.80
2.	Scrubber	9.00	---	9.00	9.00	---	9.00
3.	Washings	---	66.50	66.50	---	66.50	66.50
4.	Research & Development	20.00	---	20.00	15.00	---	15.00
5.	Boiler blow down	---	6.00	6.00	---	6.00	6.00
6.	DM Plant	7.00	---	7.00	7.00	---	7.00
7.	Cooling Tower blow down	---	97.00	97.00	---	97.00	97.00
8.	Domestic	---	60.80	60.80	---	60.80	60.80
	Total	120.00	277.30	397.30	75.50	262.60	338.10

Treatment & disposal:

Source	Treatment	Mode of final disposal
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacy for forced evaporation.
LTDS	Pretreatment (Neutralization)	To CETP of M/s. Ramky Pharmacy for further treatment and disposal
Domestic waste water	---	Taken into LTDS tank and sent to the CETP for further treatment.(As per Lr.dt.10.10.2019).

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 Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution after Change of Product Mix: (as per Lr.dt.10.10.2019)

Sl. No.	Details	Stack 1		Stack – 2
1.	Attached to	Boiler		D.G sets
2.	Capacity	3 X 4.0 TPH	1 X 2 TPH Boiler (Standby)	4 X 1500 KVA
3.	Fuel	Furnace oil		Diesel
4.	Stack height	Common stack of height 37 m		8 m. each (above roof)
5.	Control Equipment	---		Silencers & 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 / Hazardous Waste:

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

S. No	Name of waste	Qty. as per CFE order dt. 31.10.2012 & 16.02.2013	After Change of Product Mix (as per lr. dt.10.10.2019)	Method of disposal
1.	Process residue & wastes (Inorganic)	1302 kg/day	50.16 kg/day	To TSDF for secured land fill
2.	Organic residue (TPD)	5251 kg/day	869.54 kg/day	To the authorized Cement industries for co-processing (or) TSDF, Parawada for incineration
3.	Spent Carbon	122 TPA	58.5 TPA	

4.	Spent Solvents	6958 kg/day	4201.10 kg/day	Recovery within the premises / to authorised agency for recovery.
5.	Spent Catalyst	33 TPA	11.50 TPA	To the Supplier for recovery.
6.	Used/spent oil	15 TPA	15 TPA	To authorized Re-processors / Recyclers / to the Cement industries for co-processing in the kiln.
7.	Glass Bottles / Scrap	-	As and when generated	To authorized agencies, after complete detoxification for re-use/ recycle.
8.	Used Lead Acid Batteries	12 Nos./year	500 Nos./ Year	To dealers on buy back system
9.	Insulation Waste	-	As and when generated	To authorized agencies (or) TSDf, Parawada / Cement Industries
10.	Chemical sludge / Tank Bottom sludge from cleaning activities	220 TPA	200 TPA	To TSDf / Sent for co-processing in cement plants / Authorized agencies involved in waste mixing and sending mixed waste for co-processing to cement plants.
11.	Date expired/ off specification product	17.5 TPA	17.50 TPA	To TSDf / Sent for co-processing in cement plants / Authorized agencies involved in waste mixing and sending mixed waste for co-processing to cement plants.
12.	Empty barrels/ containers / liners/ PPEs / Filters contaminated with hazardous wastes / chemicals	15,000 Nos. of containers & 30 TPA of polythene liners	15,000 Nos. of containers (160 TPA) & 30 TPA of polythene liners/ used PPEs/ Filters	To authorized agencies, after complete detoxification for re-use/ recycle.

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) 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:

- 21. Existing green belt shall not be disturbed due to the proposed Change of Product Mix. Thick green belt shall be maintained 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.
- 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.

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CHAIRMAN

To

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