

**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 AND OPERATION**Order No.300 /APPCB/CFE/RO-VSP/HO/2012****20/03/2020**

Sub: APPCB – CFE - **M/s. Srikar Laboratories Pvt. Ltd., Plot No.32 A, JNPC, Parawada, Visakhapatnam** – Consent for Establishment and Operation 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.

1. CFE CPM order dt. 31.08.2019.
- Ref: 2. Industry's application received through A.P. OCMMS dt. 24.02.2020.
3. R.O's inspection report dt. 13.03.2020.
4. CFE Committee meeting held on 17.03.2020.
5. Industry's mail dt. 19.03.2020.

- In the reference 2nd cited, an application was submitted to the Board seeking Consent for
1. Establishment (CFE) and Consent for Operation (CFO) for **Change of Product Mix** within the existing premises to produce the products with installed capacities as mentioned below, with an additional investment of Rs. 3.77 Crores.

As per CFE CPM order dt. 31.08.2019

S. No.	Name of the Product	Quantity (Kg/day)
1	Atorvastatin Calcium	166.7
2	Diltiazem Hydrochloride	76.67
3	Domperidone	123.33
4	Donepezil Hydrochloride	100.0
5	Ezetimibe	100.0
6	Fluconazole	100.0
7	Ketorolac Tromethamine	33.3
8	Loperamide Hydrochloride	66.67
9	Loratadine	100.0
10	Losartan Potassium	200.0
11	Pantoprazole Sodium	266.67
12	Rosuvastatin Calcium	66.7
13	Ritonavir	100.0
14	Sodium Methoxide	1666.7
15	Dimethyl- {2-[2,3-dibromo-5-(phenyl carbonyl)-1H-pyrrol-1-yl] ethyl} propanedioate	100.0
16	Fexofenadine Hydrochloride	150.0
17	Diacetate	166.7
18	N-Benzyl tert-butylamine	166.7
19	1-(3-carboxypyridyl-2)-2-phenyl-4-methyl piperazine	100.0
20	Itraconazole	50.0

21	Enalapril Maleate	66.7
22	4-Phenyl-2-aminobutane (Labetalol Intermediate)	166.7
23	5-Bromoacetyo Salicylamide (Labetalol Intermediate)	166.7
24	4-N-BOC-amino piperidine	30.0
25	Telmisartan	33.33
26	Acyclovir	333.33
27	Fenofibrate	166.67
28	Valacyclovir Hydrochloride	166.67
29	Levetiracetam	333.33
30	Validation Products	33.3
31	Polyphenylene oxide	200.0
32	2-Ethyl-2-Nitrobenzene-1-Sulfonamide	33.33

The industry shall manufacture any 4 Products at any given point of time with production capacity 2600.0 Kg/day.

By-products

S. No.	Name of the By-Product	Quantity (Kg/day)	By-Product from
1	Aluminium Chloride Solution	1148.0	Fexofenadine Hydrochloride

After Change of Product Mix:

S. No.	Name of the Product	Qty (Kg/day)	No. of Stages	Name of the Starting Raw material	Qty (Kg/day)
	Existing Products				
1.	Atorvastatin Calcium	166.7	6	Tert-butyl-2-[(4R,6S)-6-(cyanomethyl)-2,2-dimethyl-1,3-dioxan-4-yl]acetate	111.7
2.	Diltiazem Hydrochloride	76.67	5	p-Anisaldehyde	103.5
3.	Domperidone	123.33	3	Ethyl-4-[(2-amino-4-chlorophenyl) amino] piperidine-1-carboxylate	234.3
4.	Donepezil Hydrochloride	100.0	5	Ethyl Isonipecotate	75.0
5.	Ezetimibe	100.0	6	4-(4-fluorobenzoyl) butyric Acid	81.5
6.	Fluconazole	100.0	2	2,4-difluoro-1H-1-yl-1,2,4-triazoleacetophenone	95.0
7.	Ketorolac Tromethamine	33.3	6	Benzoyl chloride	30.0
8.	Loperamide Hydrochloride	66.67	8	2,2'-diphenyl-4-bromo butyronitrile	104.0
9.	Loratadine	100.0	2	8-Chloro-11-(1-methyl piperidin-4-yl)-6,11-dihydro-	131.0

				5H-benzo [5,6] cyclohepta [1,2-b] pyridine-11-ol	
10.	Losartan Potassium	200.0	4	Tolylbenzotrile	120.0
11.	Pantoprazole Sodium	266.67	2	2-Chloromethyl-3,4-dimethoxy pyridine hydrochloride	173.3
12.	Rosuvastatin Calcium	66.7	3	Triphenyl-[4-(4-fluorophenyl)-6-isopropyl-2-[(2-N-methyl-N-methylsulfonyl) amino] pyrimidin-5-yl-methyl phosphine bromide	149.3
13.	Ritonavir	100.0	2	(2S,3S,5S)-2-Amino-3-hydroxy-5-t-butyl oxycarbonyl amino-1,6-diphenyl hexane succinate	125.0
14.	Sodium Methoxide	1666.7	1	Methanol	2469.1
15.	Dimethyl- {2-[2,3-dibromo-5- (phenyl carbonyl)-1H-pyrrol-1-yl] ethyl} propanedioate	100.0	3	Benzoyl chloride	47.4
16.	Fexofenadine Hydrochloride	150.0	9	Methallyl chloride	52.5
17.	Diacetate	166.7	1	Para- Hydroxyacetophenone	131.0
18.	N-Benzyl tert-butylamine	166.7	1	Benzyl chloride	147.1
19.	1-(3-carboxypyridyl-2)-2-phenyl-4-methyl piperazine	100.0	1	1-Methyl-3-phenyl piperazine	74.1
20.	Itraconazole	50.0	10	1-(4-Methoxy phenyl) piperazine	36.3
21.	Enalapril Maleate	66.7	2	(S, S)-N-(1-Ethoxycarbonyl-3-phenylpropyl) alanine	53.3
22.	4-Phenyl-2-aminobutane (Labetalol Intermediate)	166.7	1	Benzyl Acetone	175.4
23.	5-Bromoacetyo Salicylamide (Labetalol Intermediate)	166.7	1	5-Acetyl Salicylamide	143.0
24.	4-N-BOC-amino piperidine	30.0	1	Ethyl-4-aminopiperidine-1-carboxylate	33.3
25.	Telmisartan	33.33	11	3-Methyl-4-amino benzoic Acid	43.3

26.	Acyclovir	333.33	8	Guanidine Nitrate	433.3
27.	Fenofibrate	166.67	2	4-Chloro-4'-hydroxybenzophenone	119.2
28.	Valacyclovir Hydrochloride	166.67	2	N-Benzyloxy carbonyl-L-Valine	183.0
29.	Levetiracetam	333.33	6	2-bromo butyric Acid	833.3
30.	Validation Products	33.3	-	-	-
31.	Polyphenylene oxide	200.0	1	2,6-Dimethylphenol in Toluene (50%)	528.0
32.	2-Ethyl-2-Nitrobenzene-1-Sulfonamide	33.33	1	2-Nitrobenzenesulfonyl Chloride	40.0
	Proposed Products				
33.	6-Methyl pyran-2,4-dione (6- MPD)	66.67	1	3-Acetyl-6-Methyl-2H-Pyran-2,4 (3H)-dione (Dehydro acetic acid)	135.0
34.	(S)-2-Amino-N-(1-Hydroxy-3-Methylbutan-2-yl)-3-Methylbenzamide (EBH)	3.33	3	L-Valine	4.2
35.	N-(2-Hydroxyethyl) Succinimide	2.5	1	Succinic anhydride	2.5
36.	2-(2-(2,2,2 TrifluoroEthoxy) Phenoxy) Ethyl Methane sulphonate (TPM)	16.67	4	Catechol	25.0
	Total (Maximum of any 4 Products)	2600.0			

The industry shall manufacture any 4 products at any point of time with a max production capacity of 2600 Kg/day.

By-products

S. No.	Name of the By-Product	Quantity (Kg/day)	By-product from
1.	Aluminium Chloride Solution	1148.0	Fexofenadine Hydrochloride

2. As per the application, the above activity is to be located within the existing industry premises located at **Plot No.32 A, JNPC, Parawada, Visakhapatnam** in an area of 3.81 Acres.

3. The industry was inspected by the Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 13.03.2020 and observed that the site is surrounded by

North : M/s. Minerva Flavours
South : Road followed by M/s. Gland Pharma
East : M/s. Kanoria Chemicals
West : Road

4. The Board, after careful scrutiny of the application and verification report of the Regional Officer, hereby issues **CONSENT FOR ESTABLISHMENT AND CONSENT FOR 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 30.06.2023 (i.e., validity of CFO order dt. 31.12.2019).**

Encl: Annexure.

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

To

**M/s. Srikar Laboratories Pvt. Ltd. (CPM),
Plot No.32 A, JNPC, Parawada,
Visakhapatnam.
e.mail: srikarlaboratories@yahoo.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:

S. No.	Purpose	As per CFE (CPM) dt. 31.08.2019 (KLD)	After CPM (KLD)
1.	Process	47.0	47.00
2.	Washings (Reactor, Containers and floor moping)	4.00	4.00
3.	Boiler makeup	40.00	40.00
4.	Cooling tower makeup	25.00	25.00
5.	DM Plant regeneration	1.00	1.00
6.	Research & Development, Q.C.	1.00	1.00
7.	Scrubber	1.50	1.50
8.	Domestic	2.50	2.50
9.	Gardening	10.00	10.00
	Total	132.0 KLD	132.0 KLD

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	As per CFE (CPM) dt. 31.08.2019 (KLD)			After CPM (KLD)		
		HTDS	LTDS	Total	HTDS	LTDS	Total
1.	Process	19.00	38.40	57.40	19.00	38.40	57.40
2.	Washings	0.00	4.00	4.00	0.00	4.00	4.00
3.	Boiler blow down	0.00	5.00	5.00	0.00	5.00	5.00
4.	Cooling Tower	0.00	2.50	2.50	0.00	2.50	2.50
5.	DM Plant regeneration	0.00	1.00	1.00	0.00	1.00	1.00
6.	R & D, Q.C.	0.00	1.00	1.00	0.00	1.00	1.00
7.	Scrubber	0.00	1.50	1.50	0.00	1.50	1.50
8.	Domestic	0.00	2.00	2.00	0.00	2.00	2.00
	Total	19.00	55.40	74.40	19.00	55.40	74.40

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:	--	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 expansion:

As per CFE(CPM) dt.31.08.2019

Sl. No.	Details of Stack	Stack 1	Stack – 2	Stack 3
a)	Attached to	Boiler	Thermic Fluid Heating System	D.G. Set
b)	Capacity	3.0 TPH	2 Lakh K. Cal	1 x 380 KVA
c)	Fuel form	Coal	HSD	Diesel
d)	Stack height: Above the ground (m.)	30 m	10 m	10 m
e)	Details of Air Pollution Control Equipment	Dust collector and bag filter	----	Acoustic enclosure with silencer

After change of product mix: No change

10. A sampling port with removable dummy of not less than 15 cm diameter shall be maintained 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, 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.

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.

Coal and ash shall be stand under shed.

Solid / Hazardous Waste:

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

S. No.	Type of waste	Quantity as per CFE (CPM) dt. 31.08.2019	After CPM	Mode of Disposal
1.	Organic residue	1.28 TPD	1.28 TPD	To the authorized Cement industries for co-processing (or) TSDf, Parawada for incineration

2.	Inorganic solid waste	0.29 TPD	0.29 TPD	To TSDF, Parawada for secured land filling.
3.	Spent Carbon	0.25 TPD	0.25 TPD	To the authorized Cement industries for co-processing (or) TSDF, Parawada for incineration
4.	ETP Sludge	0.50 TPD	0.50 TPD	TSDF, Parawada for secured land filling.
5.	Waste Oils & Grease	250 LPM	250 LPM	To authorized Re-processors / Recyclers / to the Cement industries for co-processing in the kiln.
6.	a. Detoxified Container / Liners drums b. HDPE Carboys c. Fiber Drums d. PP Bags	300 Nos./month 600 Nos./month 2000 Nos./month 1500 Kg/month	300 Nos./month 600 Nos./month 2000 Nos./month 1500 Kg/month	To outside agencies, after complete detoxification for re-use/ recycle.
7.	Spent Mixed unrecovered solvents	1.5 KLD	1.5 KLD	To authorized recovery units / Authorized cement plant for co-processing.

Non-Hazardous Solid Waste

S. No.	Type of waste	Quantity as per CFE (CPM) dt. 31.08.2019	After CPM	Mode of Disposal
1.	Used Lead acid batteries	8 Nos./ year	8 Nos./ year	Send back to suppliers on buy back basis.
2.	Boiler Ash	10.4 TPD	10.4 TPD	Brick Manufactures
3.	Insulation Waste	1 TPM	1 TPM	Sent To TSDF
4.	E-Waste	10 Kg/day	10 Kg/day	Authorized collection centres recyclers/ Dismantlers/ Disposal facility
5.	Metal Scrap (MS, SS, GI & Aluminium)	2 TPM	2 TPM	Sale to outside agencies / recyclers
6.	Discarded Personal Protective equipment (PPE's)	0.2 TPM	0.2 TPM	Sent to TSDF
7.	Empty glass bottles	100 Nos./month	100 Nos./month	Send to Authorized parties for Recycle

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. **The industry shall comply with the following conditions, within one month. Otherwise, the CFE & CFO order will be revoked.**
- a. **The industry shall install hood on the effluents storage tanks and vent connected to the scrubber within one month.**
 - b. **The industry shall take immediate steps to obtain Responsible Care Certification as per Task Force directions dt. 23.03.2016.**
23. Existing green belt shall not be disturbed due to the proposed expansion. 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.
24. 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.
25. 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.
26. 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.

27. 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. Srikar Laboratories Pvt. Ltd.,
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Visakhapatnam
e.mail: srikarlaboratories@yahoo.com**