



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

Order No. 166 /APPCB/CFE/RO-VSP/HO/2013

Dt: 22.06.2018

Sub: APPCB – CFE - **M/s. Eisai Pharmaceuticals India Pvt Ltd, SEZ, Plot Nos. 96, 97, 98, 124 & 126, JN Pharma City, Parawada, Visakhapatnam** – Consent for Establishment of the Board for **expansion** 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 expansion order dt. 10.06.2016.
2) Industry's application received through APOCMMS on 08.06.2016.
3) R.O's inspection report dt. 12.06.2018.
4) Industry's Ir. dt. 13.06.2018.
5) CFE Committee meeting held on 14.06.2018.

1. In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **expansion** within the existing premises to produce the products with installed capacities as mentioned below, without any additional investment.

As per CFE order dt. 01.10.2016:

Sl. No	Formulations (Million Units / Annum)	Quantity
1	Aricept (Donepezil Hydrochloride)	60.00
2	Myonal (Eperisone Hydrochloride)	300.00
3	DEC	400.00
4	Pariet	500.00
5	Warfarine	1200.00
6	Urief (Silodosin) (packing only)	20.00
7	Methycobal	190.00
8	Aricep 23 mg (packing only)	20.00
9	Teuri (packing only)	20.00
10	Merislon (Betahistine Mesilate) Tablets	20.00
11.	Zonegran (Zonisamide) Tablets	20.00
12.	Aricept M Forte	5.00
13.	Aricept M	5.00
	Total	2760.00
	Bulk Drugs (API) (Kg/day)	
14.	Donepezil Hydrochloride	5.55
15.	Eperisone Hydrochloride	55.55
16.	AKR(1-(3-chloro-5-(4-(4-chlorothiophen -2-yl)-cyclohexyl piperazin-1-yl) thiazol-2-ylcarbamoyl) pyridine-2-yl) piperidine-4-carboxylicacid, monomaleate)	2.78
17.	ESPA ((L-Lysine, compound with 4-[2-[(1R,2R)-2-(2,4-difluorophenyl)-1-methyl-2-[(phosphonoxy)methoxy]-3-(1H-1,2,4-triazol-1-yl)propyl]-4-thiazoly] benzonitrile and ethanol)	5.55
18.	Pranlukast Hydrate	132.00
19.	Rebamipide	98.70
20.	Epalrestat	13.70
	Total	305.51

The industry shall manufacture Formulations and any two API products at any given point of time with a maximum production capacity of API products are 305.51 Kg/day.

After expansion:

Sl. No	Formulations (Million Units/ Annum)	After Expansion	No. of stages	Starting raw material	Quantity Kg/day
1	Aricept (Donepezil Hydrochloride)	60.00	---	----	---
2	Myonal (Eperisone Hydrochloride)	300.00	---	----	---
3	DEC	400.00	---	----	---
4	Pariet	500.00	---	----	---
5	Warfarine	1200.00	---	----	---
6	Urief (Silodosin) (packing only)	20.00	---	----	---
7	Methycobal	190.00	---	----	---
8	Aricep 23 mg (packing only)	20.00	---	----	---
9	Teuri (packing only)	20.00	---	----	---
10	Merislon (Betahistine Mesilate) Tablets	20.00	---	----	---
11.	Zonegran (Zonisamide) Tablets	20.00	---	----	---
12.	Aricept M Forte	5.00	---	----	---
13.	Aricept M	5.00	---	----	---
	Total	2760.00			
	Bulk Drugs (API) (Kg/day)				
14.	Donepezil Hydrochloride	5.55	3	5,6 Dimethyl Indanone	67
15.	Eperisone Hydrochloride	55.55	2	Ethyl Benzene	1100
16.	AKR(1-(3-chloro-5-(4-(4-chlorothiophen -2-yl)-cyclohexylpiperazin-1-yl)thiazol-2-ylcarbamoyl)pyridine-2-yl) piperidine-4-carboxylicacid, monomaleate)	2.78	4	EPS130	45
17.	ESPA ((L-Lysine, compound with 4-[2-[(1R,2R)-2-(2,4-difluorophenyl)-1-methyl-2-[(phosphonoxy)methoxy]-3-(1H-1,2,4-triazol-1-yl)propyl]-4-thiazolyl] benzonitrile and ethanol)	18.00	3	KSM	40
18.	Pranlukast Hydrate	132.00	2	4- Bromo methyl-1,2-dihydro quinoline-2-one	250
19.	Rebamipide	98.70	2	(E)-2-methyl-3-phenylacrylaldehyde	60
20.	Epalrestat	13.70	2	N-(3.acetyl-2-hydroxyphenyl)-4- (4-phenyl butoxy) benzamide	400
21.	EPS140	17.00	1	EPS130	45
22.	Azilsartan	9.00	3	Ethylchloroformate	58
	Total	352.28			

- As per the application, the above activity is to be located within the existing industry premises located at Plot Nos. 96, 97, 98, 124 & 126, JN Pharma City, Parawada, Visakhapatnam in an area of 50.67 Acres.

3. The industry was inspected by the Environmental Engineer & Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 12.06.2018 and observed that the site is surrounded by

North : Road followed by industrial plot of M/s. Ramky SEZ
South : SEZ Road
East : Granules Omnichem
West : SEZ Road

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 FOR EXPANSION** 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 a period of 7 years from the date of issue.**

Encl: Annexure.

MEMBER SECRETARY

To

**M/s. Eisai Pharmaceuticals India Pvt Ltd, SEZ,
Plot Nos. 96, 97, 98, 124 & 126,
JN Pharma City, Parawada,
Visakhapatnam.
r-b@eisai.co.in, g-anand@eisai.co.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 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:

1. The source of water is JN Pharmacy, Parawada and the maximum permitted water consumption is as following:

As per CFE (Exp) Order dated 10.06.2016

S. No.	Purpose	Quantity (KLD)
1	Process water	66.00
2	Washings including floor & reactor washings, QC, R&D water and scrubbing water (washings - 32, others - 10)	
3	Boiler, Cooling tower and other utilities	483.00
4	Fire Hydrant	
5	Gardening	
6	Domestic	40.00
	Total	589.00

After expansion:

S. No.	Purpose	Quantity (KLD)
1.	Industrial cooling, boiler feed.	322.00
2.	Domestic & gardening purposes.	230.00
3.	Processing, whereby water gets polluted and pollutants are easily bio- degradable.	---
4.	Processing, whereby water gets polluted and the pollutants are not easily bio-degradable.	77.30
	Total	629.30

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

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

S. No.	Source	Quantity as per CFE (Exp) Order dated 10.06.2016 (KLD)			Quantity after expansion (KLD)		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
01.	Process water	3.36	----	3.36	4.67	---	4.67
02.	Process & Washings	----	55.00	55.00	---	58.30	58.30
03.	Boiler Blow down	----	192.00	192.00	---	192.00	192.00
04.	Cooling tower blow down						
05.	DM Plant/ Softener Regeneration water, EDI reject, RO reject, ACE reject, OF Reject, MGF Reject						
06.	Domestic effluent	----	36.00	36.00	---	36.00	36.00
	Total	3.36	283.00	286.36	4.67	286.30	290.97

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.

3. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
4. 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:

5. The Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution after expansion:

Sl. No	Details of Stack	Stack 1	Stack – 4
a)	Attached to	Oil fired Boilers	D.G. Set
b)	Capacity	2 X 3.0 TPH & 1 X 2.0 TPH	3 X 1500 KVA
c)	Fuel	Oil	Diesel
d)	Stack height	40 m common stack	8 m each
e)	Control Equipment	----	Acoustic enclosures

6. 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.
7. The industry shall provide 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.
8. The industry shall provide 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.
9. The industry shall provide VOC monitoring system with auto recording facility.
10. The industry shall implement adequate measures to control all fugitive emissions from the plant.
11. 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.
12. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.

13. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
14. 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:

15. The industry shall comply with the following for disposal of Solid wastes:

Sl. No.	Solid Waste generated from	Existing	After expansion	Method of Disposal
1.	ETP Sludge	29 Kg/day	29 Kg/day	To TSDF, Parawada for secured land fill
2.	Spent Catalyst	0.011 TPM	0.011 TPM	Returned back to manufacturers for recovery / TSDF Parawada
3.	Process waste (including expired/ defaced/ rejected tablets, binder solutions, rejected or spilled APIs, Laboratory wastes and utilities wastes etc.	10.0 TPM	10.0 TPM	Coastal Waste Management Project, Parawada.
4.	Spent Solvents	60.0 TPM	25.67 KLD	To M/s. Visakha Solvents, JNPC, Parawada
5.	Waste Oil	2000 Lts/Annum	2000 Lts/Annum	To authorized Re-processors / Recyclers
6.	Used lead acid batteries	10 Nos./ year	10 Nos./ year	To Vendors authorized recyclers

16. 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.
17. 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:

18. Green belt shall be developed 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.

19. 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.
20. 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.
21. 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.
22. 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.

MEMBER SECRETARY

To

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Visakhapatnam.
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