



Eisai Pharmaceuticals India Pvt. Ltd.

CIN No: U24232AP2007PTC053247

Plot # 96,97,98,124 & 126, Ramky Pharma City (SEZ),

Parawada - 531 019, Visakhapatnam Dist., A.P., India. www.eisai.co.in

Ph: +91 8824 660777, +91 891 3047100 Fax: +91 8824 660759

Human Health Care

lke

To

Date: June 17,

2020

The Environmental Engineer,

AP Pollution Control Board,

Regional office,

Visakhapatnam.

Sub: Submission of CFE & CFO Six Monthly Compliance report for our Industry M/s. Eisai Pharmaceuticals India Pvt. Ltd., SEZ, Plot Nos. 96, 97, 98,124 & 126, Ramky PharmaCity, Parawada, Visakhapatnam-Reg.

Ref: 1) Consent Order for Establishment (Expansion) No: 166/APPCB/CFE/RO-VSP/HO/2013 Date: 13.02.2019.

2) Consent& Authorization Order No (CPF-cum-Expansion): APPCB/NSP/VSP/166/HO/CFO/2019- Date: 09.03.2019 valid up to 30.11.2022.

Respected Sir,

With reference to the above, we M/s. Eisai Pharmaceuticals India Pvt. Ltd., SEZ, Plot Nos. 96, 97, 98,124 & 126, Ramky Pharma City, Parawada, Visakhapatnam, Andhra Pradesh here with submit six monthly compliance report for Consent Order for Establishment (Expansion), Consent & Authorization Order No (CPF-cum-Expansion) obtained from AP Pollution Control Board respectively vide ref (1), (2) cited above for the period of 01st January 2020 to 30th June 2020 as on July 2020 in online website pcb.gov.in. Kindly acknowledge the same.

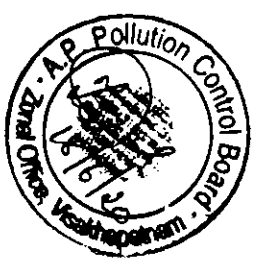
Thanks and Regards,

For M/s. Eisai Pharmaceuticals India Pvt. Ltd.,

PROXY

Mr. Tiruganathi Reddy EIL

Mr. Manager-ERHS



CC to the JCEE, AP Pollution Control Board, Zonal Office - Visakhapatnam.

HALF YEARLY COMPLIANCE REPORT
CONSENT FOR ESTABLISHMENT & CONSENT FOR OPERATION
COMPLIANCE REPORT

01st JANUARY 2020 TO 30th JUNE 2020

For

M/s. EISAI PHARMACEUTICALS INDIA PVT. LTD.,

Plot Nos.96, 97, 98,124 & 126,

Ramky Pharma City (SEZ),

Parawada, District Visakhapatnam - 531019

Andhra Pradesh-INDIA

PREPARED BY

SV ENVIRO LABS & CONSULTANTS

Environmental Engineers & Consultants in Pollution Control

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Recognized by MoEF&F and NABL



Signature
15/6/2020



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**COMPLIANCE OF CONSENT ORDER FOR
ESTABLISHMENT (EXPANSION)**

DATED: 13.02.2019

**COMPLIANCE FOR CONSENT ORDER FOR ESTABLISHMENT (EXPANSION)
M/s. EISAI PHARMACEUTICALS INDIA PVT. LTD.,
CONSENT ORDER No. 166/APP/CB/CFE/RO-VSP/HO/2013, dt: 13.02.2019**

SCHEDULE-A

S.No	Condition	Compliance
1	The proponent shall obtain Consents 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.	We have obtained "Consent & Authorization Order (Expansion)" under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 from AP Pollution Control Board. Consent & Authorization (Expansion) Order No: APPCB/VSP/VSP/166/HO/CF0/2018- Date: 31.07.2018. Consent & Authorization (Exp) Order attached as annexure. Consent & Authorization (CPM-cum-expansion) Order No: APPCB/VSP/VSP/166/HO/CF0/2019- Date: 09.03.2019 valid up to 30.11.2022. Consent & Authorization Order (CPM-cum-expansion) attached as annexure.
2	The applicant shall provide 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.	We have already provided energy meters for Air Pollution Control Equipments for recording energy consumption and we have already provided an alternative electric power source such as DG Sets for operating all pollution control systems. DG Set photographs are attached as annexure.
3	The industry shall construct separate storm water drains and provide rain water harvesting structures. No effluents shall be discharged into the storm water drains.	Storm Water drains are maintaining well, first 15 minutes storm water is being stored in a tank after checking its pH same will be transferred into LTDS tank. After 15 minutes storm water is being routed into Ramky Rain water harvesting Pits.

WATER:

S.No	Condition				Compliance																																
4	<p>The source of water is JN Pharamacity, Parawada and the maximum permitted water consumption is as following:</p> <table border="1" data-bbox="237 417 1238 992"> <thead> <tr> <th data-bbox="237 417 327 561">S.No</th> <th data-bbox="333 417 696 561">Purpose</th> <th data-bbox="703 417 965 561">Qty as per CFE (exp) dt. 22.06.2018 (KLD)</th> <th data-bbox="972 417 1238 561">After expansion (KLD)</th> </tr> </thead> <tbody> <tr> <td data-bbox="237 561 327 597">1</td> <td data-bbox="333 561 696 597">Process water</td> <td data-bbox="703 561 965 597">15.30</td> <td data-bbox="972 561 1238 597">18.30</td> </tr> <tr> <td data-bbox="237 597 327 777">2</td> <td data-bbox="333 597 696 777">Washings including floor & reactor washings, QC, R&D water and scrubbing water (washings - 32, others - 10)</td> <td data-bbox="703 597 965 777">61.00</td> <td data-bbox="972 597 1238 777">78.00</td> </tr> <tr> <td data-bbox="237 777 327 848">3</td> <td data-bbox="333 777 696 848">Boiler, Cooling tower and other utilities</td> <td data-bbox="703 777 965 848">322.00</td> <td data-bbox="972 777 1238 848">322.00</td> </tr> <tr> <td data-bbox="237 848 327 884">4</td> <td data-bbox="333 848 696 884">Fire Hydrant</td> <td data-bbox="703 848 965 884">1.00</td> <td data-bbox="972 848 1238 884">1.00</td> </tr> <tr> <td data-bbox="237 884 327 920">5</td> <td data-bbox="333 884 696 920">Gardening</td> <td data-bbox="703 884 965 920">190.00</td> <td data-bbox="972 884 1238 920">190.00</td> </tr> <tr> <td data-bbox="237 920 327 956">6</td> <td data-bbox="333 920 696 956">Domestic</td> <td data-bbox="703 920 965 956">40.00</td> <td data-bbox="972 920 1238 956">50.00</td> </tr> <tr> <td data-bbox="237 956 327 992"></td> <td data-bbox="333 956 696 992">Total</td> <td data-bbox="703 956 965 992">629.30</td> <td data-bbox="972 956 1238 992">659.30</td> </tr> </tbody> </table> <p data-bbox="237 997 1272 1063">As per the details the industry's average water consumption is 467.9 KLD during the period from July, 2018 to December, 2018.</p> <p data-bbox="237 1091 1272 1157">Separate meters with necessary pipe lines shall be provided for assessing the quantity of water used for each of the purposes mentioned above.</p>				S.No	Purpose	Qty as per CFE (exp) dt. 22.06.2018 (KLD)	After expansion (KLD)	1	Process water	15.30	18.30	2	Washings including floor & reactor washings, QC, R&D water and scrubbing water (washings - 32, others - 10)	61.00	78.00	3	Boiler, Cooling tower and other utilities	322.00	322.00	4	Fire Hydrant	1.00	1.00	5	Gardening	190.00	190.00	6	Domestic	40.00	50.00		Total	629.30	659.30	<p>We are not using more than the stipulated quantities. We have provided separate water meters with pipe lines for assessing the quantity of water used for each of the purpose.</p>
S.No	Purpose	Qty as per CFE (exp) dt. 22.06.2018 (KLD)	After expansion (KLD)																																		
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6	Domestic	40.00	50.00																																		
	Total	629.30	659.30																																		
5	<p>The maximum waste water generation shall not exceed the following:</p> <table border="1" data-bbox="237 1244 1261 1321"> <thead> <tr> <th data-bbox="237 1244 327 1321">S.No</th> <th data-bbox="333 1244 528 1321">Source</th> <th data-bbox="535 1244 891 1321">Qty as per CFE (exp) dt. 22.06.2018 (KLD)</th> <th data-bbox="898 1244 1261 1321">After expansion (KLD)</th> </tr> </thead> <tbody> </tbody> </table>				S.No	Source	Qty as per CFE (exp) dt. 22.06.2018 (KLD)	After expansion (KLD)	<p>We are maintaining waste water generation within the limits. We have engaged third party agency for analysis of waste water discharges from process and washings, after pretreatment through HTDS Effluent Treatment Plant, this</p>																												
S.No	Source	Qty as per CFE (exp) dt. 22.06.2018 (KLD)	After expansion (KLD)																																		

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	---	The overflow of the Septic tank shall

Treatment & Disposal:

	Total	4.67	286.30	290.97	4.67	315.30	319.97
1	Process water	4.67	---	4.67	4.67	---	4.67
2	Process & Washings	---	58.30	58.30	---	78.30	78.30
3	Boiler blow down	---	192.00	192.00	---	192.00	192.00
4	Cooling tower blow down						
5	DM Plant/Softener Regeneration water, EDI reject, RO reject, ACE reject, OF reject, MGF Reject						
6	Domestic effluent	---	36.00	36.00	---	45.0	45.0
	TOTAL	HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL

treated waste water is being sent To M/s. Ramky Pharmacy for forced evaporation and pretreatment through LTDS Effluent Treatment Plant, this treated waste water is being sent to CETP of M/s. Ramky Pharmacy for further treatment and disposal. And we are not discharging any waste water outside the industry premises.
 HTDS Effluent Pretreatment Plant and LTDS Effluent Pretreatment Plant Photographs are attached as annexure.

	waste water		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.			We are not discharging any waste water outside the industry premises.
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.			We have complied. Web Cameras available as well as directly connected to APPCB
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.			We have complied with the conditions as directed by the board.

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 (exp) dt. 22.06.2018.			We have complied with the conditions.
	S.No	Details of stack	Stack 1	Stack -4
	a)	Attached to	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
	After expansion:			
	S.No	Details of stack	Stack 1	Stack -4
	a)	Attached to	Boilers	D.G. Set

b)	Capacity	2 x 3.0TPH & 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

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.	We have provided a sampling port with removable dummy.
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.	Presently, we are regularly carrying out monitoring by third party agency. And we are submitting monitoring every month to the EE, AP Pollution Control Board, Regional Office - Visakhapatnam. Monitoring reports are attached as annexure.
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.	We are properly operating and maintaining multistage scrubbers to the process vents for controlling the emissions from the process. Scrubber Photograph is attached as annexure.
13	The industry shall properly operate and maintain VOC Monitoring system with auto recording facility.	We are operating and maintaining VOC sensor system. VOC Sensor Photograph is attached as annexure.
14	The industry shall implement adequate measures to control all fugitive emissions from the plant.	For reducing fugitive emissions, process area connected to scrubber.
15	The proponent shall ensure compliance of National Ambient Air quality standards notified by MoEF, Govt vide notification no.GSR.826 (E), dated. 16.11.2009 during construction and regular operational phase of the project	We have engaged third party agency for monitoring of Ambient Air Quality and Noise Levels, all the parameters are within standards as directed by the board.

	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.	Monitoring reports are attached as annexure.										
16	The proponent shall not use or generate odour causing substances such as Mercaptans or cause odour nuisance in the surroundings.	We are not generating odour nuisance to 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.	We do not have solvent recovery set up in our facility. All spent solvents are disposed to common distillation plant which is established and operated by the SEZ developer (Ramky).										
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/driers shall be used to reduce solvent losses. iv. All the solvent storage tanks shall be conducted with vent condensers to prevent solvent vapours. v. The reactor vents shall be conducted with primary & secondary condensers to prevent escaping of solvent vapour emissions into atmosphere.	we have complied with the following measures for controlling the evaporation losses in solvents: i. We have complied. ii. Solvents are transferred by using pumps. iii. We are using closed centrifuge. iv. We have provided all storage tanks with breather valve with nitrogen padding to avoid vapour emission. v. The reactor vents connected with primary / secondary condensers and condensers vents are connected to scrubber.										
Solid / Hazardous Waste:												
19	The industry shall comply with the following for disposal of solid wastes:	We have complied with the conditions as per the directions of the board.										
	<table border="1"> <thead> <tr> <th>S.No.</th> <th>Name of solid waste</th> <th>As per CFE order dt. 22.06.2018</th> <th>After Exp</th> <th>Method of disposal</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	S.No.	Name of solid waste	As per CFE order dt. 22.06.2018	After Exp	Method of disposal						
S.No.	Name of solid waste	As per CFE order dt. 22.06.2018	After Exp	Method of disposal								

	1.	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.
	2.	ETP Sludge	29 kg/day	29 kg/day	TSDF, Parawada for secured land filling.
	3	Spent Solvents	25.67 KLD	25.67 KLD	Recovery within the premises / to authorized agency for recovery / to M.s, Visakha Solvents, NPC, Parawada.
	4	Spent Catalyst	0.011 TPM	0.011 TPM	To the Supplier for re-generation / TSDF Parawada
	5	Used Oil / Waste Lubrication Oil	2000 Lts/Annum	3000 Lts/Annum	Used as Lubricant

					within the premises / to authorized Re-processors / Recyclers/ to the cement industries to use as alternate fuel in the kiln.	
	6	Used lead acid batteries	10 No's/ Year	10 No's/ Year	To dealers on buy back system.	
	7	R&D Expired & Rejected material	----	200 Kg/day	To TSDF, Parawada.	
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 lines shall be detoxified at the specified covered platform with dyke walls and the wash water shall be routed to Low TDS Collection tank.					We have complied.
21	<p>The following rule and regulations notified by the MOE&F, GOI shall be implemented.</p> <p>a) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.</p> <p>b) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.</p> <p>c) Fly ash notification, 2016</p> <p>d) Batteries (Management & Handling) Rules 2010.</p> <p>e) E-waste (Management & Handling) Rules, 2016</p>					We have complied the rules and regulations notified by the MoEF & Gol.

		f) Construction and demolition waste management Rules,2016	
Other Conditions:			
22	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.	We have already developed green belt along the periphery of the industry. Green belt photographs are attached as annexure.	
23	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.	Not applicable.	
24	Concealing the factual data or submission of false information/fabricated data and failure to comply with any of the conditions mentioned in this order and attract action under the provisions of relevant pollution control Acts	Complied & Agreed.	
25	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.	We have complied & Agreed.	
26	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.	Agreed.	

ANNEXURE-1

(CONSENT ORDER FOR ESTABLISHMENT

(EXPANSION)) DATED: 22.06.2018



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 lr. 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	Merision (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-yl) carbamoyl) pyridine-2-yl) piperidine-4-carboxylic acid, 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-thiazolyl] 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	Merison (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)-cyclohexyl)piperazin-1-yl)thiazol-2-yl)carbamoyl)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			

2. 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 Omnicheem
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	40.00
6	Domestic	
	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 Capacity	Oil fired Boilers 2 X 30 TPH & 1 X 2.0 TPH	D.G. Set 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, Govt 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, Gol 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.

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**

MEMBER SECRETARY

ANNEXURE-2
(CONSENT ORDER FOR ESTABLISHMENT
(EXPANSION)) DATED: 13.02.2019



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: 13.02.2019

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. 22.06.2018.
 - 2) Industry's application received through A.P. OCMMS on 10.01.2019.
 - 3) R.O's inspection report dt. 19.01.2019.
 - 4) CFE Committee meeting held on 08.02.2019.

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, with an additional project cost of Rs. 28 Crores.

As per CFE (EXP) dated 22.06.2018:

Sl. No	Formulations (Million Units / Annum)	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
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)	2.78

	piperidine-4-carboxylic acid, monomaleate)		
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	
18.	Pranlukast Hydrate	132.00	
19.	Rebamipide	98.70	
20.	Epalrestat	13.70	
21.	EPS140	17.00	
22.	Azilsartan	9.00	
	Total	352.28	

After expansion:

Sl. No.	Name of the Product	Quantity	No. of stages	Starting raw material	Quantity kg/day
Formulations (Million Units/ Annum)					
1.	Aricept (Donepezil Hydrochloride)	60	---	---	---
2.	Myonal/EPRY (Eperisone Hydrochloride)	300	---	---	---
3.	DEC	400	---	---	---
4.	Pariet	500	---	---	---
5.	Warfarine	1200	---	---	---
6.	Urief (Sildenafil) - Packing only	20	---	---	---
7.	Methycobal	190	---	---	---
8.	Aricep 23 mg (Packing only)	15	---	---	---
9.	Teuri (Packing only)	20	---	---	---
10.	Merislon (Betahistine Mesilate) Tablets (Packing only)	20	---	---	---
11.	Zonegran (Zonisamide) Tablets (Packing only)	20	---	---	---
12.	Aricept M Forte	5	---	---	---
13.	Aricept M	5	---	---	---
14.	Aifence (Lorcaserin Tab 10 mg)	5	---	---	---
	Total	2760			
	Bulk Drugs (API) (Kg/day)				
15.	Donepezil Hydrochloride	5.55	3	5,6 Dimethyl Indanone	67
16.	Eperisone Hydrochloride	55.55	2	Ethyl Benzene	1100
17.	AKR (1-(3-chloro-5-(4-(4-chlorothiophen-2-yl)- cyclohexyl)piperazin-1-yl)thiazol-2-ylcarbamoyl)piperidine-4-carboxylic acid, monomaleate)	2.78	4	EPS130	45

18.	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- ylopropyl]-4- thiazolyl]benzotrile and ethanol)	18.00	3	KSM	40
19.	Pranlukast Hydrate	132.00	2	4- Bromo methyl- 1,2- dihydro quinoline -2- one	250
20.	Rebamipide	98.7	2	(E)-2- methyl-3- phenylac rylaldehy de	60
21.	Epalrestat	13.7	2	N- (3.acetyl- 2- hydroxyp henyl)-4- (4-phenyl butoxy) benzami de	400
22.	EPS140	17	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchlo roformate	58
24.	R&D and API Pilot Plant Products	20.00	---	---	---
		372.28 kg/day			

Total drug formulations of 2760.00 Million units / annum and Bulk Drugs of 372.28 kg/day.

- 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.
- The industry was inspected by the Environmental Engineer & Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 19.01.2019 and observed that the site is surrounded by

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

4. The Board, after careful scrutiny of the application and 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.**

Encl: Annexure.

Bandla Siva Digitally signed by
Bandla Siva Sankar
Sankar
Prasad
Date: 2019.02.13
16:53:18 +05'30'
CHAIRMAN

To

M/s. Eisai Pharmaceuticals India Pvt Ltd., (expn)
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada,
Visakhapatnam,
r-b@eisai.co.in, g-anand@eisai.co.in,
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