





ANDHRA PRADESH POLLUTION CONTROL BOARD  
D.No.33-26-14D/2, Near Sunrise Hospital, Pushpa Hotel Centre,  
Chalamalavari Street, Kasturibaipet, Vijayawada - 520 010  
Phone. No.0866-2463200, Website : www.appcb.ap.nic.in

**RED CATEGORY  
CONSENT & AUTHORIZATION ORDER**

**Consent Order No : APPCB/VSP/VSP/166/HO/CFO/2019- 09/03/2019**

CONSENT is hereby granted for Operation under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation under Rule 6 of the Hazardous & Other Wastes (Management and Transboundary, Movement) Rules, 2016 and the rules and orders made there under (hereinafter referred to as 'the Acts', 'the Rules') to:

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

(Hereinafter referred to as 'the Applicant') authorizing to operate the industrial plant to discharge the effluents from the outlets and the quantity of emissions per hour from the chimneys as detailed below:

**i. Outlets for discharge of effluents:**

Outlet No.	Outlet Description	Max Daily Discharge (KLD)	Point of Disposal
1	Domestic	9 KLD	To the CETP of Pharmacity for treatment and disposal

There shall not any additional waste water generation due to Change of product mix cum expansion activity.

**ii) Emissions from chimneys:**

There shall not any additional emissions due to Change of product mix cum expansion activity.

**iii) HAZARDOUS WASTE AUTHORISATION (FORM - II) [See Rule 6 (2)]:**

M/s. Eisai Pharmaceuticals India Pvt Ltd, SEZ, Plot No.96, 97, 98, 124 & 126, JN Pharma City, Parawada, Visakhapatnam is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

**• HAZARDOUS WASTES WITH DISPOSAL OPTION:**

S.No	Name of the Hazardous Waste	Stream	Quantity of Hazardous Waste	Method of disposal
1.	R &D Expired & Rejected material	28.4 of Schedule- I	200 Kgs/day	Coastal Waste Management Project, Parawada.

This consent order is valid for manufacture the following products along with quantities indicated only:

Sl. No.	Formulations (Million Units/ Annum)	Quantity as per CFO order dated 31.07.2018	Expansion cum CPM	Total after expansion
1.	Aricept (Donepezil Hydrochloride)	60.00	--	60.00
2.	Myonal (Eperisone Hydrochloride)	300.00	--	300.00
3.	DEC	400.00	--	400.00
4.	Pariet	500.00	--	500.00
5.	Warfarine	1200.00	--	1200.00
6.	Urief (Silodosin) (packing only)	20.00	--	20.00
7.	Methycobal	190.00	--	190.00
8.	Aricep 23 mg (packing only)	20.00	-5	15.00
9.	Teuri (packing only)	20.00	--	20.00
10.	Merislon (Betahistine Mesilate) Tablets	20.00	--	20.00
11.	Zonegran (Zonisamide) Tablets	20.00	--	20.00
12.	Aricept M Forte	5.00	--	5.00
13.	Aricept M	5.00	--	5.00
14.	Alfence (Lorcaserin Tab 10 mg)	---	5	5.00
	Total	<b>2760.00</b>		<b>2760.00</b>
	<b>Bulk Drugs (API) (Kg/day)</b>			
15.	Donepezil Hydrochloride	5.55	--	5.55
16.	Eperisone Hydrochloride	55.55	--	55.55
17.	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	--	2.78
18.	ESPA ((L-Lysine, compound with 4-[2-[(1R,2R)-2-(2,4-difluorophenyl)-1-methyl-2-[(phosphonoxy)methoxy]-3-(1H-	18.00	--	18.00

	1,2,4-triazol-1-yl)propyl]-4-thiazoly] benzonitrile and ethanol)			
19.	Pranlukast Hydrate	132.00	--	132.00
20.	Rebamipide	98.70	--	98.70
21.	Epalrestat	13.70	--	13.70
22.	EPS140	17.00	--	17.00
23.	Azilsartan	9.00	--	9.00
24.	R & D and API Pilot Plant Products	---	20.00	20.00
	<b>Total</b>	<b>352.28</b>		<b>372.28</b>

This order is subject to the provisions of 'the Acts' and the Rules' and orders made thereunder and further subject to the terms and conditions incorporated in the schedule A, B & C enclosed to this order.

This combined order of consent & Hazardous Waste Authorization shall be valid for a period ending with the 30<sup>th</sup> day of November, 2022.

Bandla Siva  
Sankar Prasad

Digitally signed by Bandla Siva Sankar Prasad  
DN: cn=Banda Siva Sankar Prasad, postalCode=520010,  
2.5.4.20=c040c01b17f6f398976702e0cb9e479454f1  
3c09821c03bc47734986555b35, st=Andhra  
Pradesh  
Date: 2019.03.11 10:50:58 +05'30'

**BANDLA SIVA SANKARA PRASAD  
CHAIRMAN**

To  
M/s. Eisai Pharmaceuticals India Pvt Ltd,  
SEZ, Plot No.96, 97, 98, 124 & 126,  
JN Pharma City, Parawada, Visakhapatnam

Copy to :

1. The JCEE, Zonal Office, Visakhapatnam for information and necessary action.
2. The Environmental Engineer, Regional Office, Visakhapatnam for information and necessary action.

#### **SCHEDULE-A**

1. Any up-set condition in any industrial plant / activity of the industry, which result in, increased effluent / emission discharge and/ or violation of standards stipulated in this order shall be informed to this Board, under intimation to the Collector and District Magistrate and take immediate action to bring down the discharge / emission below the limits.
2. The industry should carryout analysis of waste water discharges or emissions through chimneys for the parameters mentioned in this order on quarterly basis and submit to the Board.
3. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 should be followed as applicable.
4. The industry should put up two sign boards (6x4 ft. each) at publicly visible places at the main gate indicating the products, effluent discharge standards, air emission standards, hazardous waste quantities and validity of CFO and exhibit the CFO

- order at a prominent place in the factory premises.
5. Notwithstanding anything contained in this consent order, the Board hereby reserves the right and powers to review / revoke any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
  6. The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No.14 of E(P) Rules, 1986 & amendments thereof.
  7. The applicant should make applications through Online for renewal of Consent (under Water and Air Acts) and Authorization under H&OW (M&TM) Rules, 2016 at least 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts and detailed compliance of CFO conditions for obtaining Consent & HW Authorization of the Board. The industry should immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions. Any change in the management shall be informed to the Board. The person authorized should not let out the premises / lend / sell / transfer their industrial premises without obtaining prior permission of the State Pollution Control Board.
  8. 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 Appellate authority constituted under Section 28 of the Water(Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air(Prevention and Control of Pollution) Act, 1981.

#### SCHEDULE-B

##### **WATER POLLUTION:**

1. The LTDS effluents sent to CETP, Pharmacity shall not contain constituents in excess of the tolerance limits mentioned below, as per their MoU with M/s Ramky Pharma City.

Outlet	Parameter	Concentration in mg/l
1	pH	6.50 - 8.50
	Temperature °C	< 45 <sup>0</sup> C
	TDS	12,000 mg/l
	TSS	600 mg/l
	BOD	3,000 mg/l
	COD	8,000 mg/l
	Oil and Grease	20 mg/l
	Chromium Hexavalent (as Cr+6)	2 mg/l
	Chromium ( total ) (as Cr)	2 mg/l
	Ammonical Nitrogen (as N)	30 mg/l
	Cyanide (as CN)	0.20 mg/l
	Lead (as Pb)	1 mg/l
	Nickel (as Ni)	3 mg/l
	Zinc (as Zn)	15 mg/l
	Arsenic (as As)	0.20 mg/l
Mercury (as Hg)	0.01 mg/l	

The industry shall segregate the HTDS and LTDS effluent streams and the effluents which are not meeting the above standards shall be treated as HTDS effluents and

shall be sent CETP of Pharmacy for evaporation.

2. The source of water is JNPC Supply. The following is the permitted water consumption:

S. No.	Purpose	Quantity (KLD)
1	Process water	3.0
2	Washings including floor & reactor washings, QC, R&D water and scrubbing water	17.00
3	Domestic	10.00
	<b>Total</b>	<b>30.0</b>

3. Digital flow meters with totalizers with necessary pipelines shall be provided so as to assess the water used for different purposes within 1 month and maintain them properly and also maintain the records of the readings.

**GENERAL:**

4. The industry shall comply with the Regulation of Persistent Organic Pollutants Rules, 2018 notified by the MoEF&CC Notification vide G.S.R. 207 (E) dated 30.05.2018. As per the notification, the following 7 chemicals are prohibited to manufacturer, trade, use, import and export:

- i. Chlordecone,
- ii. Hexabromobiphenyl,
- iii. Hexabromodiphenyl ether and heptabromodiphenyl ether (commercial octa-BDE),
- iv. Tetrabromodiphenyl ether and pentabromodiphenyl ether (commercial penta-BDE),
- v. Pentachlorobenzene,
- vi. Hexabromocyclododecane and
- vii. Hexachlorobutadine.

5. The industry shall comply with all conditions stipulated in Schedule B of the CFO order No. APPCB/VSP/VSP/166/CFO/HO/2018, dated 31.07.2018.

**SCHEDULE - C**

***[See rule 6(2)]***

**[CONDITIONS OF AUTHORISATION FOR OCCUPIER OR OPERATOR HANDLING HAZARDOUS WASTES]**

1. The authorised person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
2. The authorisation shall be produced for inspection at the request of an officer authorised by the State Pollution Control Board.
3. The person authorised shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorisation.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. The person authorised shall implement Emergency Response Procedure (ERP) for which this authorisation is being granted considering all site specific possible scenarios such as spillages, leakages, fire etc. and their possible impacts and also carry out mock drill in this regard at regular interval of time;
6. The person authorised shall comply with the provisions outlined in the Central Pollution Control Board guidelines on "Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty".
7. It is the duty of the authorised person to take prior permission of the State Pollution Control Board to close down the facility.
8. An application for the renewal of an authorisation shall be made as laid down under

these Rules.

9. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.

**Specific Conditions:**

10. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.
11. The industry shall enter an agreement with the Cement industries for disposal of incinerable waste or shall dispose to Alternative Fuel Raw material facility (AFRF) OR to TSDf for co-incineration.
12. The industry shall transport the hazardous waste to cement industries through GPS vehicle.
13. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.
14. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal to the manufacturers / dealers on buyback basis.
15. The industry shall maintain 7 copy manifest system for transportation of waste generated and a copy shall be submitted to concerned Regional Office of APPCB. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter should carry a Transport Emergency (TREM) Card.
16. The industry shall maintain proper records for Hazardous and Other Wastes stated in Authorisation in Form-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc., and file annual returns in Form-4 as per Rule 20 (2) of the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.

The industry shall submit the condition wise compliance report of the conditions stipulated in Schedule A, B & C of this Order on half yearly basis to Board Office, Vijayawada and concerned Regional Office.

Bandla Siva  
Sankar Prasad

Digitally signed by Bandla Siva Sankar Prasad  
DN: cn=IN, o=APPCB, ou=EFS and T Head Office,  
cm=Bandla Siva Sankar Prasad,  
postalCode=520010,  
2.5.4.20=c040c01bf76f398976702e0c0b9b47945  
4f18e98b21c03bc477349d6555b35, st=Andhra  
Pradesh  
Date: 2019.03.11 10:51:35 +05'30'

**BANDLA SIVA SANKARA PRASAD**  
**CHAIRMAN**

To  
M/s. Eisai Pharmaceuticals India Pvt Ltd,  
SEZ, Plot No.96, 97, 98, 124 & 126,  
JN Pharma City, Parawada, Visakhapatnam