



ANDHRA PRADESH POLLUTION CONTROL BOARD

D.No.33-26-14D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamalavari Street, Kasturibaipet, Vijayawada - 520 010

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Member Secretary

RED CATEGORY

CONSENT & AUTHORIZATION ORDER BY REGISTERED POST WITH ACKNOWLEDGEMENT DUE

Consent Order No : APPCB/VSP/VSP/166/HO/CFO/2018-

31/07/2018

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,
(After 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	HTDS effluents Process	4.67	After pre-treatment, shall be sent to the CETP of Pharmacity for evaporation

2.	LTDS effluents: Process & washes – 58.30 KLD + Boiler blow down, Cooling tower blow down, DM Plant /Softener Regeneration water, EDI reject, RO reject, ACE reject, OF Reject, MGF Reject –192.00 KLD + Domestic – 36.0 KLD	286.30	After pre-treatment, shall be sent to the CETP of Pharmacy for further treatment and disposal
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ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow (m ³ /hr)
1.	Attached to 2 x 3 TPH & 1x2 TPH Oil fired boilers	--
2.	Attached to 3x1500 KVA DG sets	--

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.	ETP Sludge	34.3 of Schedule - I	29 Kg/day	Shall be sent to TSDF, Parawada for secured landfill.
2.	Process waste (including expired/defaced/ rejected tablets, binder solutions, rejected or spilled APIs, Laboratory wastes and utilities wastes etc.)	28.4 of Schedule - I	10.0 TPM	Shall be sent to TSDF, Parawada
3.	Spent Solvents	28.5 of Schedule - I	25.67 KLD	To M/s. Visakha Solvents, JNPC, Parawada

• HAZARDOUS WASTES WITH RECYCLING OPTION:

S.No	Name of the Hazardous Waste	Stream	Quantity of Hazardous Waste	Method of disposal
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1.	Waste oil	5.1 of Schedule - I	2000 Lts/annum	To Authorised Reprocessors/ Recyclers.
2.	Spent Catalyst	28.2 of schedule-1	0.011 TPM	Shall return back to manufacturers for recovery / TSDf Parawada

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

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)-cyclohexyl)piperazin-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			

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 30th day of November, 2022.

VIVEK YADAV IAS
MEMBER SECRETARY

To
M/s. Eisai Pharmaceuticals India Pvt Ltd,
(After expansion)
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 **JCEE, Unit-II, APPCB, Vijayawada** for information.
3. 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. Not withstanding 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

1. The industry shall handover the original Auto renewal Consent order dated 28.08.2017 to the RO, Visakhapatnam after receipt of this order which was valid upto 30.11.2022. The same stands cancelled from the date of issue of this order.

WATER POLLUTION:

2. Floor washings shall be admitted into effluent collection system only and shall not be allowed to find their way into storm water drains or open areas. Effluents shall not be discharged onland or any water bodies or aquifers under any circumstances.
3. The industry shall maintain dry condition in drains in non-rainy season. The industry shall construct rainwater runoff tank for collection and storage of first flush storm water and the contaminated storm water.
4. The LTDS effluents sent to CETP, Pharmacy 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
2	pH	6.50 - 8.50
	Temperature °C	< 45 ⁰ 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.

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

S. No.	Purpose	Quantity (KLD)
1	Process water	15.30
2	Washings including floor & reactor washings, QC, R&D water and scrubbing water (washings - 32, others - 10)	61.00
3	Boiler, Cooling tower and other utilities	322.00
4	Fire Hydrant	1.00
5	Gardening	190.00
6	Domestic	40.00
	Total	629.30

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

6. The industry shall maintain HDPE tanks in the effluent collection tank (both locations at block and common collection point). The effluent shall be connected to the HDPE tanks and from the HDPE tanks, effluent shall be pumped to the ETP. Free space shall be maintained around the HDPE tanks to observe leakages if any.
7. The industry shall construct above ground tanks / tank in tank facility for collection of effluents from production block with in time bound program.
8. The industry shall submit the details of quantity of High TDS and Low TDS effluents sent to CETP of Pharmacy every month to the RO, Visakhapatnam.
9. The industry shall maintain proper manifest system for effluent transported to CETP. They shall submit monthly reports to the E.E., RO-Visakhapatnam.
10. 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.

AIR POLLUTION:

11. The emissions shall not contain constituents in excess of the prescribed limits mentioned below:

Chimney No.	Parameter	Emission Standards
1	Particulate Matter	100 mg/Nm ³

12. The industry shall comply with ambient air quality standards of PM10 (Particulate Matter size less than 10µm) - 100 µg/ m³; PM2.5 (Particulate Matter size less than 2.5 µm) - 60 µg/ m³; SO₂ - 80 µg/ m³; NO_x - 80 µg/m³, outside the factory premises at the periphery of the industry.
Standards for other parameters as mentioned in the National Ambient Air Quality Standards CPCB Notification No.B-29016/20/90/PCI-I, dated 18.11.2009.
Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A)
Night time (10 PM to 6 AM) - 70 dB (A)
13. The industry shall comply with emission limits for DG sets of capacity upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Act Rules. In case of DG sets of capacity more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.
14. The industry shall provide hood on the top of the effluent storage tank and vents connected to the double stage scrubber to control odour nuisance.
15. Scrubber solution shall be recycled as far as possible and finally sent to CETP of Pharmacy for further treatment.
16. The evaporation losses in solvents shall be controlled by taking suitable measures, which include:
 - i. Chilled brine circulation to effectively reduce the solvent losses into the atmosphere.
 - ii. Transfer of solvents by using pumps and closed conveyance instead of manual handling.
 - iii. Closed centrifuges be used due to which solvent losses are reduced drastically.
 - iv. The reactor vents connected with primary & secondary condensers to catch the solvent vapours.
 - v. All the solvent storage tanks are connected with vent condensers to prevent solvent vapours.
19. The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.

GENERAL:

20. The industry shall integrate the Flow meters and web camera with CPCB RTDMS within 1 week.
21. The industry shall installed and maintain Electro Magnetic flow meters with totalisers for water and effluent quantity measurements for different streams of effluents and different categories of water usage stipulated in this order within 1 week.
22. The industry shall comply with CPCB directions dated 05.02.2014 / 02.03.2015 and guidelines issued regarding online monitoring systems issued from time to time. The online monitoring system shall be calibrated periodically as per equipment suppliers manual / CPCB guidelines.
23. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.
24. The industry shall evaluate the performance of solvent recovery system for each stream-wise and shall furnish plan of action to maintain the efficiency of solvent recovery more than 95% for each stream wise.
25. The industry shall not manufacture any product, other than those mentioned in this order
26. The drums containing chemicals / solvents shall be stored under a roof on

- elevated platform with a provision to collect leakages / spillages in the collection pit.
27. The industry shall maintain the following records and the same shall be made available to the inspecting officers of the Board:
 - a. Daily production details (ER-1 Central Excise Returns).
 - b. Quantity of Effluents generated, treated, recycled/reused and disposed to CETP.
 - c. Log Books for pollution control systems.
 - d. Characteristics of effluents and emissions.
 - e. Hazardous/non hazardous solid waste generated and disposed.
 - f. Inspection book.
 - g. Manifest copies of effluents / hazardous waste.
 29. The industry shall submit AAQ monitoring reports conducted by authorised agency every month.
 30. The industry shall comply with the conditions stipulated in the CFE (Expansion) order dated 22.06.2018.
 31. Green belt of adequate width and density shall be maintained along the boundary of the industry with minimum area of 33% of total area.
 32. Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB shall be followed from time to time.

SCHEDULE - C

[See rule 6(2)]

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

1. All the rules and regulations notified by Ministry of Environment and Forests, Government of India under the E(P) Act, 1986 in respect of management, handling, transportation and storage of the Hazardous wastes should be followed.
2. The industry shall not store hazardous waste for more than 90 days as per the Hazardous & Other Wastes (Management & Transboundary Movement) Rules, 2016 and amendments thereof.
3. 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.
4. 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.
5. The industry shall maintain proper records for Hazardous & 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 6 (5) of the Hazardous & Other Wastes (Management & Transboundary Movement) Rules, 2016 and amendments thereof.
6. 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.

VIVEK YADAV IAS

MEMBER SECRETARY

To
M/s. Eisai Pharmaceuticals India Pvt Ltd,
(After expansion)
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REDUCE REUSE RECYCLE