



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 8924 660777, Fax: +91 8924 660759, Email ID : oil-info@eisai.co.in

hbc
human health care

Date: July 1, 2021.

To

The Environmental Engineer,
Regional Office, APPCB,
Madhavadhara,
Visakhapatnam-530009

Subject: Submission of CFO condition wise compliance-reg.

Reference: Consent Order No: APPCB/VSP/VSP/166/HO/CFO/2021 dated 23.04.2021

Dear Sir,

Herewith we are submitting; please find attached CFO condition wise compliance report.

Please acknowledge receipt.

Thanking you.

Yours Sincerely,

For Eisai Pharmaceuticals India Pvt.Limited.

Y. Tirupathi Reddy
Asst. General Manager-EHS

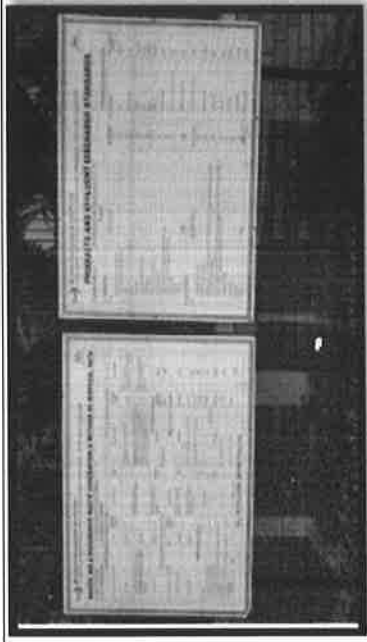


Encl.: As above

M/s. EISAI PHARMACEUTICALS INDIA PVT. LTD.,
CONSENT ORDER No: APPCB/VSP/VSP/166/HO/CFO/2021- dt: 23.04.21

SCHEDULE-A

S.No	Condition	Compliance status as on 01.07.2021
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.	So far we didn't face any disturbances in the industrial activities. If any upset conditions occur during industrial activities the management will intimate to the board.
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.	Analysis of waste water discharges or emissions is being carried out by third party agency for the parameters mentioned in this consent order. And we are submitting the monitoring data to the AP Pollution Control Board, Regional Office – Visakhapatnam every month. Latest reports are attached as per Annexure-1
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.	Complied by the industry We are following the rules and regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991. And we have obtained Public Liability Insurance.
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.	We have already placed sign board 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 exhibited



Noted.

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.

Yes.

6 The industry shall ensure that there shall not be any change in the process technology, source & composition of raw materials and scope of working without prior approval from the Board.

Complied

7 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.

We are already submitted Form-V Environmental Statement to the AP Pollution Control Board, Regional Office - Visakhapatnam for the financial year April 2019 to March 2020.

The management has obtained "Consent & Authorization Order APPCB/VSP/VSP/166/HO/CFO/2021- dt: 23.04.21

Consent & Authorization Order No:

APPCB/VSP/VSP/166/HO/CFO/2021

Date:23.04.2021

8 The applicant should make applications through Online for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules 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.

		Consent & Authorization Order copy attached as annexure-2 (Latest CFO copy) After expiry of the above consent order, application for renewal of consent order through online will be submitted 120 days before expiry date of this order, including fee & compliance of CFO conditions.
9	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.	Revised application will be submitted to the board if any changes in the industrial activities.
10	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.	Noted.
11	The industry shall be liable to pay Environmental Compensation / Other Environmental Taxes, if any environmental damage caused to the surroundings, as fixed by the Collector & District Magistrate or any other competent authority as per the Rules in vogue.	Noted.
12	The industry may explore the possibility of tapping the solar energy for their energy requirements.	We are using of Solar power.
13	The industry should educate the workers and nearby public of possible accidents and remedial measures.	Complied.

SCHEDULE-B

WATER:

S.No	Condition	Compliance																								
2	<p>The source of water is JNPC Supply. The following is the permitted water consumption:</p> <table border="1"><thead><tr><th data-bbox="504 1966 555 2101">S.No.</th><th data-bbox="504 1525 555 1966">Purpose</th><th data-bbox="504 1144 555 1525">Quantity (KLD)</th></tr></thead><tbody><tr><td data-bbox="555 1966 600 2101">1</td><td data-bbox="555 1525 600 1966">Process</td><td data-bbox="555 1144 600 1525">25.2</td></tr><tr><td data-bbox="600 1966 724 2101">2</td><td data-bbox="600 1525 724 1966">Washings including floor & reactor washings, QC, R&D water and scrubbing water</td><td data-bbox="600 1144 724 1525">81.1</td></tr><tr><td data-bbox="724 1966 810 2101">3</td><td data-bbox="724 1525 810 1966">Boiler, Cooling tower and other utilities</td><td data-bbox="724 1144 810 1525">322</td></tr><tr><td data-bbox="810 1966 855 2101">4</td><td data-bbox="810 1525 855 1966">Fire Hydrant</td><td data-bbox="810 1144 855 1525">1</td></tr><tr><td data-bbox="855 1966 900 2101">5</td><td data-bbox="855 1525 900 1966">Gardening</td><td data-bbox="855 1144 900 1525">190</td></tr><tr><td data-bbox="900 1966 944 2101">6</td><td data-bbox="900 1525 944 1966">Domestic</td><td data-bbox="900 1144 944 1525">70</td></tr><tr><td data-bbox="944 1966 976 2101">Total</td><td data-bbox="944 1525 976 1966"></td><td data-bbox="944 1144 976 1525">689.3 KLD</td></tr></tbody></table>	S.No.	Purpose	Quantity (KLD)	1	Process	25.2	2	Washings including floor & reactor washings, QC, R&D water and scrubbing water	81.1	3	Boiler, Cooling tower and other utilities	322	4	Fire Hydrant	1	5	Gardening	190	6	Domestic	70	Total		689.3 KLD	<p>Being complied The management is not using more than the stipulated quantities of water.</p>
S.No.	Purpose	Quantity (KLD)																								
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Total		689.3 KLD																								

3. 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
2	PH	6.50 – 8.50
	Temperature oC	< 45OC
	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.

4 The effluent discharged shall comply with the tolerance limits mentioned below as per MoEF notification dated 09.07.2009 prescribed for Pharmaceutical (Manufacturing and Formulation) industry

5 The industry shall maintain Electro Magnetic flow meters with totalisers for water used and effluent generation for HTDS & LTDS effluent The industry shall maintain web camera for flow meters for disposal of HTDS & LTDS effluent to CETP and data transmitted to CPCB and APPCB without interruption.

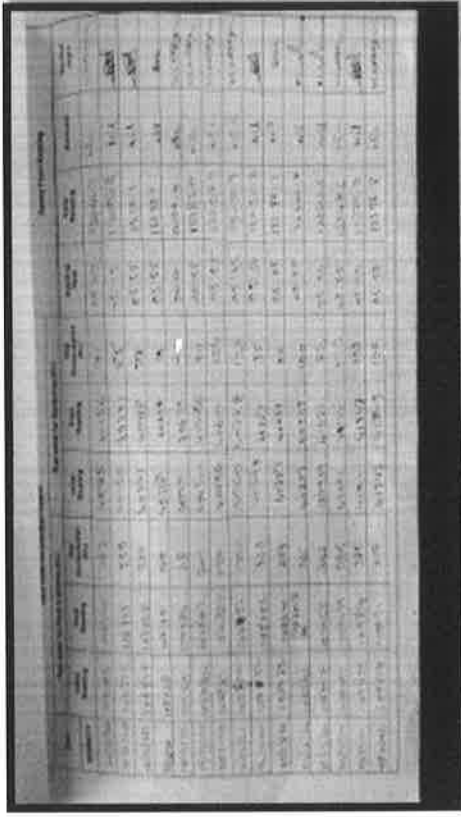
We have engaged third party agency for analysis of waste water discharges and all the parameters are well within the standard limits. Latest reports are attached as per Annexure-1

Complied by the industry

We have already provided digital flow meters with totalizers with necessary pipelines for assessing the quantity of water. And maintaining the records for readings and same will be made available

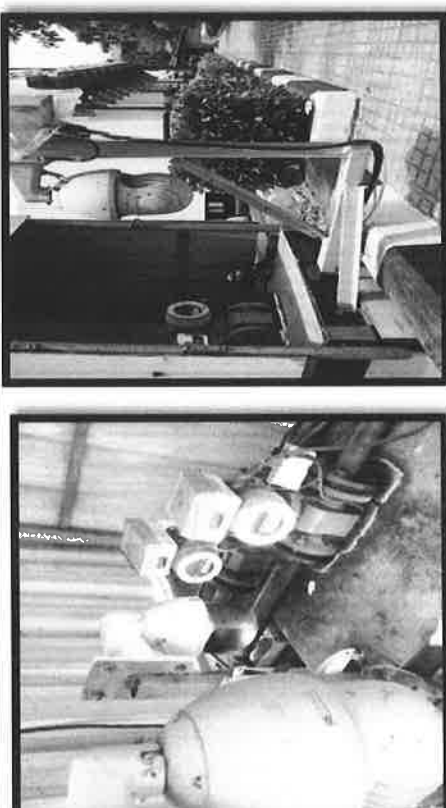
to the inspecting officers of the board at the time of inspection.

Photographs are given below.



The photograph shows a large, multi-column table with handwritten entries. The table is oriented vertically in the image. The columns are labeled at the top, but the text is small and difficult to read. The entries appear to be organized in rows, possibly representing different items or transactions. The handwriting is in dark ink on a light-colored paper.



		<p>Complied. Above ground LTDS and HTDS effluent storage tanks has been provided separately.</p>						
6	<p>The LTDS and HTDS effluents shall be stored in above ground level collection tanks separately.</p>	<p>Complied.</p>						
7	<p>Effluents shall not be discharged on land or any water bodies or aquifers or outside under any circumstances. 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.</p>	<p>Complied.</p>						
8	<p>The industry shall maintain proper manifest system for effluent transported to CETP and submit the details of quantity of High TDS and Low TDS effluents sent to CETP of Pharmacity every month to the RO, Visakhapatnam.</p>	<p>Complied, These details are being submitted to the APPCB, Regional Office every month.</p>						
9	<p>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.</p>	<p>Complied.</p>						
10	<p>The industry shall construct separate storm water drains and provide rain water harvesting structure. No effluents shall be discharged into the storm water drains.</p>	<p>Complied.</p>						
<p>Air pollution</p>								
11	<p>The emissions shall not contain constituents in excess of the prescribed limits mentioned below:</p>	<p>Complied.</p>						
	<table border="1"> <thead> <tr> <th data-bbox="1380 1008 1420 1120">Chimney No.</th> <th data-bbox="1380 1120 1420 1926">Parameter</th> <th data-bbox="1380 1926 1420 2184">Emission Standards</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Chimney No.	Parameter	Emission Standards				
Chimney No.	Parameter	Emission Standards						

	<table border="1"> <tr> <td data-bbox="209 1883 272 2092">1</td> <td data-bbox="209 1391 272 1883">Particulate Matter</td> <td data-bbox="209 1066 272 1391">100 mg/Nm³</td> </tr> <tr> <td data-bbox="272 1883 320 2092">3</td> <td data-bbox="272 1391 320 1883">HCl</td> <td data-bbox="272 1066 320 1391">35 mg/Nm³</td> </tr> <tr> <td></td> <td data-bbox="320 1391 368 1883">NH₃</td> <td data-bbox="320 1066 368 1391">30 mg/Nm³</td> </tr> <tr> <td></td> <td data-bbox="368 1391 416 1883">Sulphuric acid mist</td> <td data-bbox="368 1066 416 1391">50 mg/Nm³</td> </tr> <tr> <td></td> <td data-bbox="416 1391 475 1883">Chlorine</td> <td data-bbox="416 1066 475 1391">15 mg/Nm³</td> </tr> </table>	1	Particulate Matter	100 mg/Nm ³	3	HCl	35 mg/Nm ³		NH ₃	30 mg/Nm ³		Sulphuric acid mist	50 mg/Nm ³		Chlorine	15 mg/Nm ³	
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	Chlorine	15 mg/Nm ³															
12	<p>The industry shall comply with ambient air quality standards of PM₁₀ (Particulate Matter size less than 10 microns) - 100 micro gram/ m³; PM_{2.5} (Particulate Matter size less than 2.5 micro gram) - 60 mg/ m³; SO₂ - 80 micro gram/ m³; NO_x - 80 micro gram/m³, outside the factory premises at the periphery of the industry.</p> <p>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.</p> <p>Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A) Night time (10 PM to 6 AM) - 70 dB (A)</p>	Complied.															
13	<p>The industry shall comply with emission limits for DG sets of capacity up to 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.</p>	Complied.															
14	<p>The industry shall maintain dedicated multi stage scrubbers to the process vents to control the process emissions and other gaseous emissions. The industry shall maintain online pH monitoring system to the scrubbers provided to treat the process emissions. Scrubbed liquid shall be recycled as far as possible and finally shall be sent effluent storage tanks. The details of chemicals consumption used in the scrubber should be recorded and kept accessible for the inspection officials of the Board.</p>	Complied.															

15	<p>The evaporation losses in solvents shall be controlled by taking suitable measures, which include:</p> <ol style="list-style-type: none"> 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 	<p>Complied.</p> <p>Complied; Solvents are transferred by using pumps.</p> <p>Complied, Closed centrifuge is being used.</p> <p>The reactor vents connected with primary/ secondary condensers and condenser vents are connected to scrubber.</p> <p>All storage tanks have been provided with breather valve with nitrogen padding to avoid vapour emission.</p> <p>Complied.</p>
16	<p>The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.</p>	<p>Complied.</p>
17	<p>The industry shall not manufacture new products and not exceed the consented capacity without CFE/CFO of the Board.</p>	<p>Complied.</p>
18	<p>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</p>	<p>Complied.</p>
19	<p>The industry shall maintain sheds for storage of hazardous waste with dyke wall and leachate collection system.</p>	<p>Complied.</p>
20	<p>The industry should submit records on source of intermediates for each product-wise and the consolidated records and report the compliance to RO, Visakhapatnam</p>	<p>Complied.</p>
21	<p>The industry shall install and maintain hood on the top of the effluent storage tanks and vent connected to scrubber with online pH meter to avoid odour nuisance in the surroundings.</p>	<p>Complied.</p>

22	The industry shall provide separate energy meters for effluent Treatment Plant (ETP), and Air pollution Control equipment's to record energy consumed	Complied.
23	The industry shall maintain the following records and the same shall be made available to the inspecting officers of the Board: <ul style="list-style-type: none"> a. Daily production details (ER-1 Central Excise Returns). b. Quantity of effluent 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 	Complied.
24	Green belt of adequate width and density shall be maintained along the boundary of the industry with minimum area of 33% of total area.	Complied.
25	The industry shall maintain valid the PLI policy which includes Environmental Relief Fund (ERF) and submit copy to RO, Visakhapatnam on yearly base.	Complied.
26	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.	We do not have solvent recovery set up in our facility. All spent solvents are disposed to Authorized agency.
27	The industry shall provide multi gas sensors with alarm in production blocks and SRU	Provided.
28	The industry shall dispose the spent solvents / mixed spent solvents to APPCB authorized recyclers / recover within the premises.	Complied.
29	The industry shall comply with the following as per Standard Operating Procedures of CPCB prescribed for SRP(Captive utilization): <ul style="list-style-type: none"> I. The vent of the condenser shall be passed through VOC absorption media like activated carbon. II. Installation of online analyzer for VOC at the vent out let in time 	Not Applicable.

	<p>bound manner.</p> <p>III. Online emission monitoring system for VOC emission should be installed in stack attached to vent of the condenser and online emission data be connected to APPCB Server.</p>	
30	The industry shall submit quarterly compliance report for the Standard Operating Procedures of CPCB prescribed for SRP (Captive utilization) along with monitoring reports carried out by NABL accredited or EPA approved Laboratories.	Not Applicable.
31	The industry shall submit half-yearly compliance report for the schedule A,B& C conditions stipulated in CFO & HWA order audited through NABL / MoEF accredited laboratories.	Complied.
32	<p>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:</p> <ul style="list-style-type: none"> 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 	Complied.
33	The industry shall file & update the information in OCEMS - Industry Information Data Entry Software for Compliance Reporting Protocol in PART-II (Sections F & G) Every Quarter on 1st January, 1st April, 1st July and 1st October through this software system.	Complied.

34	The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.	Complied.
35	The industry shall submit AAQ monitoring reports conducted by authorized agency every month.	Complied, AAQM Reports are being submitted to the APPCB, Regional office every month.
36	The industry shall take all safety measures and provide firefighting equipment in the plant	Complied.
37	Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.	Complied.
38	The industry shall submit mock drill report carried out at least once in six months, as required under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989	Complied.
39	System of leak detection and repair of pump / pipeline shall be installed in the plant and immediate response team shall be identified for preventive maintenance.	Complied.
40	Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB shall be followed from time to time.	Noted.
Specific Conditions:		
41	The industry shall operate with valid NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional office, APPCB	Complied. Licence No.: 14698/VSP/MSB/2020, Date: 10/02/2021. Fire NOC Valid up to 16 th November-2023. Details are given in Annexure-3
42	The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned regional office, APPCB.	Complied. External Safety Audit conducted on 15 th & 16 th December-2020. External safety Audit report along with compliance report submitted to APPCB-RO-VSKP. Details are given in Annexure-4.

43	<p>The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity / flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (MSIHC) Rules, 1989 and identify major accident hazard chemicals, and the details shall be furnished to the Factories Department and the Regional office , APPCB time to time duly certifying the same by the industry. Further, the industry shall extend training to the working personnel while handling hazardous chemicals for the prevention of accidents and necessary antidotes to ensure safety, as per the MSIHC Rules, 1989.</p>	Complied.
44	<p>The industry shall submit Risk analysis and risk assessment covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.</p>	Complied.
45	<p>The industry shall carryout calibration of safety equipment and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office.</p>	Complied.
46	<p>The industry shall install fluorescent Wind Vane at the highest point in the industry premises</p>	Complied.
47	<p>VOC meters with real time data transmission facility through internet of things (IoT) shall be installed near the production blocks and near the chemical storage tanks and link to the servers of APPCB and CPCB, within 3 months.</p>	Complied.
SCHEDULE - C		
1	<p>The authorized person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.</p>	Agreed and Complied.

2	The authorization shall be produced for inspection at the request of an officer authorized by the State Pollution Control Board.	Complied.
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	Complied.
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;	Complied.
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".	Noted.
7	It is the duty of the authorised person to take prior permission of the State Pollution Control Board to close down the facility.	Yes.
8	An application for the renewal of an authorisation shall be made as laid down under these Rules.	Yes.
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.	Complied.
Specific Conditions:		
10	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.	Agreement with TSDF-Parawada and AFRF.

11	The industry shall comply with the provisions of HWM Rules, 2016 in terms of interstate transport of Hazardous Waste and manifest document prescribed Under Rule 18 and 19 of the HWM Rules, 2016.	Complied.
12	The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016	Complied.
13	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 buy:back basis	Complied.
14	The industry shall transport the hazardous waste to cement industries only through vehicle fitted with GPS tracking system	Agreed and Complied.
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.	Complied.
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	Complied.
17	Annual return shall be filed by June 30 th for the period ensuring 31 st March of the year.	Complied.

-&-



EISAI PHARMACEUTICALS INDIA PVT LTD.

hhe
human health care

Consent for Establishment (CFE)



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.pcb.ap.gov.in

CONSENT ORDER FOR ESTABLISHMENT

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

Dt:15.06.2021

Sub: APPCB – CFE - M/s. Eisai Pharmaceuticals India Pvt. Ltd, SEZ, Plot No.96, 97, 98, 124 & 126, JN Pharma City, Parawada, Visakhapatnam – Consent for Establishment 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.

Ref: 1) Industry's CFE(CPM) application received through A.P.OCMMS on 17.05.2021.
2) R.O's inspection report dt.27.05.2021.
3) CFE Committee meeting held on 03.06.2021.
4) RO mail dt.03.06.2021 regarding payment of balance fee by industry.

1. In the reference 1st cited, an application was submitted to the Board seeking Consent for Establishment (CFE) **Change of Product Mix** to produce the products with installed capacities as mentioned below, with an additional investment of Rs.0.01 Crore.

Existing as per CFE order dt.07.07.2020 :

S. No	Name of the Products and By-products	Quantity (TPM)	No. of Stages	Starting Raw Material	Quantity of Starting Raw Material (Kg/day)
Formulation (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 Silodosin 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.	Alfence (Lorcaserin Tab 10 mg)	5	---	---	---
Total : 2760 Million Units /Annum					
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)- cyclohexylpiperazin-1- yl)thiazol-2- ylcarbamoyl)piperidine- 4- carboxylic acid, monom aleate)	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-yl)propyl]-4- thiazolyl]benzotrile and ethanol)	40.00	3	KSM	40
19.	Pranlukast Hydrate	132.00	2	4-Bromo methyl- 1,2- dihydro quinolone- 2-one	250
20.	Rebamipide	98.70	2	(E) -2 methyl-3- phenylacry ladehyde	60
21.	Epalrestat	13.70	2	N-(3. Acetyl-2- hydroxyph enyl)-4-(4- phenyl butoxy) benzamide	400
22.	EPS140	17.00	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchloro formate	58
24.	R&D and API Pilot plant products	20.00	--	---	---

25.	COVA	10.00	5	KSM-1	10.00
26.	SRCA	10.00	6	KSM-1	10.00
Total		414.28			
		Kg/day			

After Change of Product Mix:

S. No.	Name of the Products	Quantity	No. of Stages	Starting Raw Material	Quantity of Starting Raw Material (kg/day)
Formulation (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 Silodosin 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.	Alfence (Lorcaserin Tab 10 mg)	5	---	---	---
Total		2760			
Bulk Drugs (API) (kg/day)					
15.	Donepezil Hydrochloride	2	3	5,6 Dimethyl Indanone	67
16.	Eperisone Hydrochloride	10	2	Ethyl Benzene	1100
17.	AKR (1-(3-chloro-5-(4-(4-chlorothiophen-2-yl)-cyclohexyl)piperazin-1-yl)thiazol-2-yl)carbamoyl)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-yl)propyl]-4-thiazolyl]benzotrile and ethanol)	40.00	3	KSM	40
19.	Pranlukast Hydrate	132.00	2	4-Bromo methyl-1,2-dihydro quinolone-2-one	250
20.	Rebamipide	44.60	2	(E) -2 methyl-3-phenylacryldehyde	60
21.	Epalrestat	13.70	2	N-(3-Acetyl-2-hydroxyphenyl)-4-(4-phenylbutoxy) benzamide	400
22.	EPS140	17.00	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchloroformate	58
24.	R & D and API Pilot plant products	20.00	--	—	—
25.	COVA	10.00	5	KSM-1	10.00
26.	SRCA	10.00	6	KSM-1	10.00
27.	AJM300	30.00	New		
28.	EZM030	5.00	New		
29.	HAND	15.00	New		
30.	RAM050	5.00	New		
31.	Edoxaban Tosylate	5.00	New		
	Total	371.08 kg/day			

2. As per the application, the above activity is to be located within the existing industry premises located at **SEZ, Plot No.96, 97, 98,124 & 126, JN Pharma City, Parawada, Visakhapatnam** in an area of 50.67 acres.

3. The industry was inspected by the Asst. Environmental Engineer, Regional Office, Visakhapatnam, A.P Pollution Control Board on 20.05.2021 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 and verification report of the Regional Officer, hereby issues **CONSENT FOR ESTABLISHMENT 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 7 years from the date of issue of the order**

Encl: Annexure.

Nambada
Venkata
Bhaskara Rao

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pseudonym=68b93d9669e19334217defc1e9a
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JOINT CHIEF ENVIRONMENTAL ENGINEER UH-1 (FAC)

To

M/s. Eisai Pharmaceuticals India Pvt. Ltd,
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada, Visakhapatnam
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 trail 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	Quantity as per CFE order dt.07.07.2020 (KLD)	Quantity after CFE (CPM) (KLD)
1.	Process	25.2	25.2
2.	Washings Including floor & rector washings, QC, R&D water and scrubbing water	81.1	81.1
3.	Boiler , cooling tower and other utilities	322	322
4.	Fire Hydrant	1	1
5.	Gardening	190	190
6.	Domestic	70	70
	Total	689.3 KLD	689.3 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	Quantity as per CFE order dt.07.07.2020 (KLD)			Quantity after CFE (CPM) (KLD)		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
1	Process water	13.57	0	13.57	13.57	0	13.57
2	Process & Washings-Formulations	0	81.5	81.5	0	81.5	81.5
3	Boiler blow down	0	192	192	0	192	192
4	Cooling tower blow down						
5	DM Plant/Softner Regeneration water, EDI reject, Ro , ACF reject, MGF Reject water	0	192	192	0	192	192
6	Domestic effluent	0	63	63	0	63	63
	Total	13.57	336.5	350.07	13.57	336.5	350.07

Treatment & disposal:

Source	Treatment	Mode of final disposal
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacy for further treatment
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 :

Existing as per CFE Order dt.07.07.2020:

S. No.	Details of Stack	Stack 1	Stack – 2, 3& 4
1	Attached to	Oil fired Boilers	D.G. Set
2	Capacity	2 X 3.0 TPH & 1 X 2.0 TPH	4 X 1500 KVA
3	Fuel	Oil	Diesel
4	Stack height	40 m common stack	8 m each
5	Control Equipment	--	Acoustic enclosures and silencers

After CPM: No changes in Air Emissions

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.
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, 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.

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.

Solid / Hazardous Waste:

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

S. No.	Name of the waste	Quantity as per CFE Order dt.07.07.2020	Quantity after CFE (CPM)	Mode of Disposal
1.	Used Oil / Waste Lubrication Oil	3000 LPA	3000 LPA	To authorized Re-processors / Recyclers / to the Cement industries for co-processing in the kiln.

2.	De-Toxified Containers & Liners	5 TPM	20TPM	To the authorized agencies/re-use/ recycle/TSDf, Parawada
3.	General waste (Like Thermo coal, Insulation waste, Contaminated Cotton waste, Centrifuge Bags, Used PPE's and other waste etc.,)	20 TPM	20TPM	Sent to authorized agencies/TSDf, Parawada
4.	Spent Catalyst	0.011 TPM	0.011 TPM	Recovery within the premises / to authorised agency for recovery / To M/s. Visakha Solvents, JNPC, Parawada
5.	Process Waste (including expired/defaced/rejected tablets, binder solutions, rejected or spilled APIs, Laboratory Wastes and utility wastes etc. and R&D Expired & rejected material)	16.38 TPM	16.38 TPM	To TSDf, Parawada for incineration (or) to the Cement industries/ AFRF.
6.	ETP Sludge	30 kg/day	30 kg/day	TSDf, Parawada for secured land filling.
7.	Spent Solvents	33.07 KLD	33.07 KLD	Recovery within the premises / to authorised agency for recovery / To M/s. Visakha Solvents, JNPC, Parawada
8.	E-waste	5TPM	5TPM	To Authorised collection centers
9.	Paper, cotton waste & packing materials i.e wood, carton & ropes etc.,	5TPM	5TPM	Sale to outside agencies/recyclers
10.	Metal scrap (MS,SS,GI & Aluminum)	50TPM	50TPM	
11.	Used Lead Acid Batteries	10 Nos. / annum	2 TPM ⁹	To dealers on buy back system
12.	Glass Bottles / Scrap	3TPM	3TPM	To the authorized agencies/re-use/ recycle/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 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 industry specific standards with respect to process emissions stipulated by the MoEF & CC, Gol, New Delhi from time to time."

S. No.	Details of process emissions	Emission Control system	Emission Standard
1	HCl	Multi stage water scrubbers and alkali scrubbers	35 mg/Nm ³
2	NH ₃		30 mg/Nm ³
3	Sulphuric acid mist		50 mg/Nm ³
4	Chlorine		15 mg/Nm ³

23. The industry shall display online data outside the main factory gate on quantity and nature of hazardous chemicals being used in the plant, water & air emissions and solid waste generated within the factory premises, as per Hon'ble Supreme Court order.
24. **The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.**
25. The industry shall submit a copy of the NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.
26. **The industry shall submit risk assessment report covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.**
27. The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity / flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (MSIHC) Rules, 1989 and the details shall be furnished to the Factories Department and to the Regional Office, APPCB on monthly basis duly certifying the same.
28. The industry shall identify major accident hazard chemicals & list out the hazardous chemicals endangered to human health & environment and the details shall be furnished to the Factories Department and to the Regional Office, APPCB time to time duly certifying the same by the industry. Further the industry shall extend training to the working personnels while handling hazardous chemicals for prevention of accidents and necessary antidotes to ensure the safety, as per the MSIHC Rules, 1989.

29. The industry shall carryout calibration of safety equipments and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office. The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
30. **The industry shall comply with the Technical suggestions at Chapter No. 7.3 & 7.4 for Hazardous Chemical handling industries by High Power Committee (HPC) of Govt. of Andhra Pradesh. The HPC report is available at www.ap.gov.in.**
31. The industry shall utilize DG power for captive consumption only & power shall not be supplied to grid and shall follow the amendments issued by MoEF & CC/CPCB from time to time on DG sets in respect of conditions & standards.
32. 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.
33. 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.
34. **The industry shall submit compliance to the conditions stipulated in the EC and CFE orders to the concerned Regional Officer of APPCB every six months and shall upload the same at APPCB website viz., [https://pcb.ap.gov.in/UI/Submission Compliance of EC CFE CFO Direction.aspx](https://pcb.ap.gov.in/UI/Submission%20Compliance%20of%20EC%20CFE%20CFO%20Direction.aspx).**
35. 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.
36. 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.
37. 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.

Nambada
Venkata
Bhaskara Rao

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JOINT CHIEF ENVIRONMENTAL ENGINEER UH-1 (FAC)

To

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



EISAI PHARMACEUTICALS INDIA PVT LTD.

h/c
human health care

Consent for Establishment (CFE)



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

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

07/07/2020

Sub: APPCB – CFE - M/s. Eisai Pharmaceuticals India Pvt. Ltd, SEZ, Plot No.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. EC order dt.10.03.2005 for entire JNPC, Parawada, Visakhapatnam.
 2. CFE Expansion order dt.13.02.2019.
 3. Industry's application received through A.P.OCMMS on 13.05.2020 & 15.06.2020
 4. R.O's inspection report dt.06.07.2020.
 5. CFE Committee meeting held on 07.07.2020.

- In the reference 3rd cited, an application was submitted to the Board seeking
1. 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.21.61 Cr.

As per CFE (Exp) dated 13.02.2019:

File No.APPCB-11021/45/2018-TEC-CFE-APPCB

S. No.	Name of the Product	Quantity
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 (Silodosin)- 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.	Alfence (Lorcaserin Tab 10 mg)	5
	Total	2760

Bulk Drugs (API) (Kg/day)		
15.	Donepezil Hydrochloride	5.55
16.	Eperisone Hydrochloride	55.55
17.	AKR (1-(3-chloro-5-(4-(4-chlorothiophen-2-yl)- cyclohexylpiperazin-1-yl)thiazol-2-ylcarbamoyl)piperidine-4-carboxylic acid, monomaleate)	2.78
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-yl)propyl]-4-thiazolyl]benzotrile and ethanol)	18.00
19.	Pranlukast Hydrate	132.00
20.	Rebamipide	98.7
21.	Epalrestat	13.7
22.	EPS140	17
23.	Azilsartan	9.00

File No.APPCB-11021/45/2018-TEC-CFE-APPCB

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.

After expansion:

S. No	Name of the Products and By-products	Quantity (TPM)	No. of Stages	Starting Raw Material	Quantity of Starting Raw Material (Kg/day)
Formulation (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 Silodosin 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.	Alfence (Lorcaserin Tab 10 mg)	5	---	---	---
Total : 2760 Million Units /Annum					
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-	2.78	4	EPS130	45

	yl)thiazol-2-ylcarbamoyl)piperidine-4-carboxylic acid, monomaleate)				
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-yl)propyl]-4-thiazolyl]benzotrile and ethanol)	40.00	3	KSM	40
19.	Pranlukast Hydrate	132.00	2	4-Bromo methyl-1,2-dihydro quinolone-2-one	250
20.	Rebamipide	98.70	2	(E) -2 methyl-3-phenylacryldehyde	60
21.	Epalrestat	13.70	2	N-(3. Acetyl-2-hydroxyphenyl)-4-(4-phenyl butoxy) benzamide	400
22.	EPS140	17.00	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchloroformate	58
24.	R&D and API Pilot plant products	20.00	--	—	—
25.	COVA	10.00	5	KSM-1	10.00
26.	SRCA	10.00	6	KSM-1	10.00
Total		414.28			
		Kg/day			

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 05.06.2020 and observed that the site is surrounded by

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

**BATCHU SIVA PRASAD, JCEE(BSP), O/o JOINT CHIEF ENVIRONMENTAL
ENGINEER1-APPCB
JOINT CHIEF ENVIRONMENTAL ENGINEER**

To
M/s. Eisai Pharmaceuticals India Pv.t Ltd., (expn)
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada,
Visakhapatnam.
E-mail : 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:

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

S. No.	Purpose	Quantity as per CFE order dt. 13.02.2019	Quantity after Expansion (KLD)
1.	Process	18.3	25.2
2.	Washings Including floor & rector washings, QC, R&D water and scrubbing water	78	81.1
3.	Boiler , cooling tower and other utilities	322	322
4.	Fire Hydrant	1	1
5.	Gardening	190	190
6.	Domestic	50	70
	Total	659.3 KLD	689.3 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	Quantity as per CFE dt. 13.02.2019 (KLD)			Total after expansion (KLD)		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
1.	Process water	4.67	0	4.67	13.57	0	13.57
2.	Process & Washings	0	78.3	78.3	0	81.5	81.5
3.	Boiler blow down				---		
4.	Cooling tower blow down						
5.	DM Plant/Softner Regeneration water, EDI reject, Ro , ACF reject, MGF Reject water		192	192		192	192
6.	Domestic effluent	0	45	45	-	63	63
	Total	4.67	315.3	319.97 KLD	13.57	336.5	350.07 KLD

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:

S. No.	Details of Stack	Stack 1	Stack - 2, 3& 4
1	Attached to	Oil fired Boilers	D.G. Set
2	Capacity	2 X 3.0 TPH & 1 X 2.0 TPH	4 X 1500 KVA
3	Fuel	Oil	Diesel
4	Stack height	40 m common stack	8 m each
5	Control Equipment	--	Acoustic enclosures and silencers

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.
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, 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.

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.

Solid / Hazardous Waste:

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

S. No.	Name of the waste	Quantity as per CFE order dt.13.02.2019	Total after expansion	Mode of Disposal
1.	Used Oil / Waste Lubrication Oil	3000 Ltrs/Annum	3000 Ltrs/Annum	To authorized Re-processors / Recyclers / to the Cement industries to use as alternate fuel in the kiln.
2.	De- Toxified Containers &	—	5.00TPM	To the authorized

File No.APPCB-11021/45/2018-TEC-CFE-APPCB

	Liners			agencies/re-use/ recycle/TSDf, Parawada.
3.	Glass Bottles / Scrap	--	03.00TPM	
4.	General waste (Like Thermo coal, Insulation waste, Contaminated Cotton waste, Centrifuge Bags, Used PPE's and other waste etc.,)	----	20.00TPM	Sent to authorized agencies/TSDf, Parawada
5.	Used Lead Acid Batteries	10 Nos./annum	10 Nos./annum	To dealers on buy back system
6.	Spent Solvents	25.67 KLD	33.07KLD	Recovery within the premises / to authorised agency for recovery / To M/s. Visakha Solvents, JNPC, Parawada
7.	Spent Catalyst	0.011 TPM	0.011 TPM	To the Supplier for re-generation / TSDf Parawada.
8.	ETP Sludge	29 Kg/day	30.00 Kg/day	TSDf, Parawada for secured land filling.
9.	Process Waste (including expired/defaced/rejected tablets, binder solutions, rejected or spilled APIs, Laboratory Wastes and utility wastes etc. and R&D Expired & rejected material	10.00 TPM	16.38 TPM	To TSDf, Parawada for incineration (or) to the Cement industries/ AFRF.
10.	E-waste	----	05.00 TPM	To Authorised collection centers
11.	Paper, cotton waste & packing materials i.e wood, carton & ropes etc.,	----	05.00 TPM	Sale to outside agencies/recyclers
12.	Metal scrap (MS,SS,GI & Aluminum)	----	50.00 TPM	Sale to outside agencies/recyclers

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) 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:

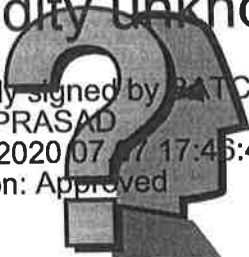
- 22. Existing green belt shall not be disturbed due to the proposed expansion. Thick green belt shall be maintained all along the boundary & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.
- 23. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Regional Office and Zonal Office of the Board.
- 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 attracts action under the provisions of relevant pollution control Acts.
- 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.
- 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.

**BATCHU SIVA PRASAD, JCEE(BSP), O/o JOINT CHIEF ENVIRONMENTAL
ENGINEER1-APPCB
JOINT CHIEF ENVIRONMENTAL ENGINEER**

**To
M/s. Eisai Pharmaceuticals India Pv.t Ltd., (expn)
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada,
Visakhapatnam.**

Validity unknown

Digitally signed by BATCHU
SIVA PRASAD
Date: 2020.07.07 17:45:40 IST
Reason: Approved





EISAI PHARMACEUTICALS INDIA PVT LTD.

hhe
human health care

Consent for Operation (CFO)



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/2021- 23/04/2021

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 District - 531 021
E-mail: t-y@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 - 13.57 KLD	13.57	The industry shall route the pretreated effluent through M/s. Andhra Pradesh Environment Corporation (APEMC) so as to send to MEE of CETP, JN Pharmacy for forced evaporation.
2.	LTDS effluents : Process & Washings - 81.5 KLD + Boiler blow down + Cooling tower blow down + DM Plant / Softner regeneration water, EDI reject, RO, ACT reject , MGF reject water - 192.0 KLD	273.5	The industry shall route the pretreated effluent through M/s. APEMC so as to send to CETP, JN Pharmacy.
3.	Domestic	63	The overflow of the septic tank shall be sent to the CETP for further treatment.

ii. Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow (m ³ /hr)
1.	Attached to 2 x3.0 TPH & 1x2.0 TPH Oil fired boilers	--
2.	Attached to 4x1500 KVA DG Sets	--
3.	Process Emissions	---

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 District 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	35.3 of Schedule - I	30 Kg/day	Shall be routed through M/s. APEMC so as to send to TSDF, Parawada, Visakhapatnam District for Secured land filling. (as Landfillable waste) / to send to pre-processors / authorized cement industries for co processing (as utilizable waste) / to TSDF for incineration (as incinerable waste)
2.	Process Waste (including expired/defaced/rejected tablets, binder solutions, rejected or spilled APIs, Laboratory Wastes and utility wastes etc. and R&D Expired & rejected material	28.4 of Schedule- 1	16.38 TPM	Shall be routed through M/s. APEMC so as to send to pre-processors/ authorized cement industries for co processing (as utilizable waste) / to TSDF for incineration (as incinerable waste)
3.	General waste (Like Thermo coal, Insulation waste, Contaminated Cotton waste, Centrifuge Bags, Used PPE's and other waste etc.,)		20.00 TPM	Shall be routed through M/s. APEMC so as to TSDF for incineration (as incinerable waste)

• HAZARDOUS WASTES WITH RECYCLING OPTION:

Sl.	Name of	Stream	Quantity	Method of disposal
-----	---------	--------	----------	--------------------

No	Hazardous Waste			
1.	Detoxified containers & liners	33.1 of Schedule -	5.00 TPM	Shall be routed through M/s. APEMCL so as to send to authorized agencies, after complete detoxification for re-use / recycle (as recyclable waste)
2.	Used oil / Waste lubrication oil	5.1 of Schedule -	3000 LPA	Shall be routed through M/s. APEMCL so as to send to authorized re-processors / recyclers (as recyclable waste) / to cement industries for co-processing (as utilizable waste)
3.	Spent solvents	28.6 of Schedule -	33.07 KLD	Recovery within the premises / shall be routed through M/s. APEMC so as to send to APPCB authorized SRS units / to cement industries for co-processing (as utilizable waste)
4.	Spent Catalyst	28.5 of Schedule -	0.011 TPM	Shall be routed through M/s. APEMC so as to send to the supplier for re-generation / recyclers (as recyclable waste)

• Other than Hazardous wastes:

Sl. No	Name of Hazardous Waste	Quantity	Method of disposal
1.	E-waste	5.0 TPM	Shall be routed through M/s. APEMC so as to send to authorized collection centers
2.	Paper Cotton Waste & Packing, materials i.e., Wood, Carton & ropes etc.,	5.0 TPM	Sale to outside agencies / recyclers
3.	Metal Scrap (MS, SS, GI & Aluminum)	50.00 TPM	
4.	Used Lead Acid Batteries	10 Nos/Annum	Shall be routed through M/s. APEMC so as to send to dealers on buy back system.
5.	Glass Bottles / Scrap	3.00 TPM	Shall be routed through M/s. APEMC so as to outside agencies / recyclers

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

Sl. No	Name of the Products and By-products	Quantity (TPM)	No of Stages	Starting Raw Material	Quantity of Starting Raw Material (Kg/day)
Formulation (Million Units /Annum)					
1.	Aricept (Donepezil	60	---	---	---

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	Hydrochloride)				
2.	Myonal/EPRY (Eperisone Hydrochloride)	300	---	---	---
3.	DEC	400	---	---	---
4.	Pariet	500	---	---	---
5.	Warfarine	1200	---	---	---
6.	Urief Silodosin Packing only	20	---	---	---
7.	Methycobal	190	---	---	---
8.	Aricep 23 mg (Packing only)	15	---	---	---
9.	Teuri Packing only	20	---	---	---
10.	Merislon (BetahistineMesilate) Tablets (Packing only)	20	---	---	---
11.	Zonegran (Zonisamide) Tablets (Packing only)	20	---	---	---
12.	Aricept M Forte	5	---	---	---
13.	Aricept M	5	---	---	---
14.	Alfence (Lorcaserin Tab 10 mg)	5	---	---	---
Total		2760 Million Units /Annum			
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)- cyclohexylpiperazin-1- yl)thiazol-2- ylcarbamoyl)piperidin e-4- carboxylicacid, monom aleate)	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-yl)propyl]-4- thiazolyl]benzotrile	40.00	3	KSM	40

	and ethanol)				
19.	Pranlukast Hydrate	132.00	2	4-Bromo methyl-1,2-dihydro quinolone-2-one	250
20.	Rebamipide	98.70	2	(E) -2 methyl-3-phenylacrylaldehd e	60
21.	Epalrestat	13.70	2	N-(3. Acetyl-2-hydroxyphenyl)-4-(4- phenyl butoxy) benzamide	400
22.	EPS140	17.00	1	EPS130	45
23.	Azilsartan	9.00	3	Ethylchloroformate	58
24.	R&D and API Pilot plant products	20.00	--	—	—
25.	COVA	10.00	5	KSM-1	10.00
26.	SRCA	10.00	6	KSM-1	10.00
Total		414.28			
		Kg/day			

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.**

DR.

B.MADHUSUDHANA RAO, JCEE(MSRB), O/o JOINT CHIEF ENVIRONMENTAL ENGINEER-4-APPCB

To

**M/s. Eisai Pharmaceuticals India Pvt. Ltd,
(After expansion)
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada,
Visakhapatnam District - 531 021**

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 industry shall ensure that there shall not be any change in the process technology, source & composition of raw materials and scope of working without prior approval from the Board.
 7. 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.
 8. The applicant should make applications through Online for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules 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.
 9. 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.
 10. 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.
 11. The industry shall be liable to pay Environmental Compensation / Other Environmental Taxes, if any environmental damage caused to the surroundings, as fixed by the Collector & District Magistrate or any other competent authority as per the Rules in vogue.
 12. The industry may explore the possibility of tapping the solar energy for their energy requirements.
 13. The industry should educate the workers and nearby public of possible accidents and remedial measures.

SCHEDULE-B

1. **The existing Consent order No. APPCB/VSP/VSP/166/CFO/HO/2018, dated 31.07.2018 & APPCB/VSP/VSP/166/ CFO/HO/2019, dated 09.03.2019 having validity up to 30.11.2022 will be cancelled from the date of receipt of this order.**

WATER POLLUTION:

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

S. No	Purpose	Quantity (KLD)
1.	Process	25.2
2.	Washings including floor & reactor washings, QC, R&D water and scrubbing water	81.1
3.	Boiler, cooling tower and other utilities	322
4.	Fire hydrant	1
5.	Gardening	190
6.	Domestic	70
TOTAL		689.3

3. 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.

- The effluent discharged shall comply with the tolerance limits mentioned below as per MoEF notification dated 09.07.2009 prescribed for Pharmaceutical (Manufacturing and Formulation) industry
- The industry shall maintain Electro Magnetic flow meters with totalisers for water used and effluent generation for HTDS & LTDS effluent. The industry shall maintain web camera for flow meters for disposal of HTDS & LTDS effluent to CETP and data transmitted to CPCB and APPCB without interruption.
- The LTDS and HTDS effluents shall be stored in above ground level collection tanks separately.
- Effluents shall not be discharged onland or any water bodies or aquifers or outside under any circumstances. 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.
8. The industry shall maintain proper manifest system for effluent transported to CETP and submit the details of quantity of High TDS and Low TDS effluents sent to CETP of Pharmacy every month to the RO, Visakhapatnam.
 9. 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.
 10. The industry shall construct separate storm water drains and provide rain water harvesting structure. No effluents shall be discharged into the storm water drains.

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
3	HCl	35 mg/Nm ³
	NH ₃	30 mg/Nm ³
	Sulphuric acid mist	50 mg/Nm ³
	Chlorine	15 mg/Nm ³

12. The industry shall comply with ambient air quality standards of PM₁₀ (Particulate Matter size less than 10 microns) - 100 micro gram/ m³; PM_{2.5} (Particulate Matter size less than 2.5 micro gram) - 60 mg/ m³; SO₂ - 80 micro gram/ m³; NO_x - 80 micro gram/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 maintain dedicated multi stage scrubbers to the process vents to control the process emissions and other gaseous emissions. The industry shall maintain online pH monitoring system to the scrubbers provided to treat the process emissions. Scrubbed liquid shall be recycled as far as possible and finally shall be sent effluent storage tanks. The details of chemicals consumption used in the scrubber should be recorded and kept accessible for the inspection officials of the Board.
15. 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.
16. The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.

GENERAL:

- 17. The industry shall not manufacture new products and not exceed the consented capacity without CFE/CFO of the Board.
- 18. 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.
- 19. The industry shall maintain sheds for storage of hazardous waste with dyke wall and leachate collection system.
- 20. The industry should submit records on source of intermediates for each product-wise and the consolidated records and report the compliance to RO, Visakhapatnam
- 21. The industry shall install and maintain hood on the top of the effluent storage tanks and vent connected to scrubber with online pH meter to avoid odour nuisance in the surroundings.
- 22. The industry shall provide separate energy meters for Effluent Treatment Plant (ETP), and Air pollution Control equipments to record energy consumed.
- 23. 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.
- 24. Green belt of adequate width and density shall be maintained along the boundary of the industry with minimum area of 33% of total area.
- 25. The industry shall maintain valid the PLI policy which includes Environmental Relief Fund (ERF) and submit copy to RO, Visakhapatnam on yearly base.
- 26. 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.
- 27. The industry shall provide multi gas sensors with alarm in production blocks and SRU.
- 28. The industry shall dispose the spent solvents / mixed spent solvents to APPCB authorized recyclers / recover within the premises.
- 29. The industry shall comply with the following as per Standard Operating Procedures of CPCB prescribed for SRP(Captive utilization):
 - i. The vent of the condenser shall be passed through VOC absorption media like activated carbon.
 - ii. Installation of online analyser for VOC at the vent out let in time bound manner
 - iii. Online emission monitoring system for VOC emission should be installed in

- stack attached to vent of the condenser and online emission data be connected to APPCB Server.
- 30.The industry shall submit quarterly compliance report for the Standard Operating Procedures of CPCB prescribed for SRP(Captive utilization) along with monitoring reports carried out by NABL accredited or EPA approved Laboratories
 - 31.The industry shall submit half-yearly compliance report for the schedule A,B& C conditions stipulated in CFO & HWA order audited through NABL / MoEF accredited laboratories.
 - 32.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.
 - 33.The industry shall file & update the information in OCEMS - Industry Information Data Entry Software for Compliance Reporting Protocol in PART-II (Sections F & G) Every Quarter on 1st January, 1st April, 1st July and 1st October through this software system.
 - 34.The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.
 - 35.The industry shall submit AAQ monitoring reports conducted by authorised agency every month.
 - 36.The industry shall take all safety measures and provide firefighting equipment in the plant.
 - 37.Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - 38.The industry shall submit mock drill report carried out at least once in six months, as required under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.
 - 39.System of leak detection and repair of pump / pipeline shall be installed in the plant and immediate response team shall be identified for preventive maintenance.
 - 40.Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB shall be followed from time to time.

Special conditions:

- 41.The industry shall operate with valid NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.
- 42.The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at

- concerned Regional Office, APPCB.
- 43.The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity / flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (MSIHC) Rules, 1989 and identify major accident hazard chemicals, and the details shall be furnished to the Factories Department and the Regional Office, APPCB time to time duly certifying the same by the industry. Further, the industry shall extend training to the working personnel while handling hazardous chemicals for the prevention of accidents and necessary antidotes to ensure safety, as per the MSIHC Rules, 1989.
 - 44.The industry shall submit Risk analysis and risk assessment covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.
 - 45.The industry shall carryout calibration of safety equipment and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office.
 - 46.The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
 - 47.VOC meters with real time data transmission facility through internet of things (IoT) shall be installed near the production blocks and near the chemical storage tanks and link to the servers of APPCB and CPCB, within 3 months.

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. 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.
11. The industry shall comply with the provisions of HWM Rules, 2016 in terms of interstate transport of Hazardous Waste and manifest document prescribed Under Rule 18 and 19 of the HWM Rules, 2016.
12. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.
13. 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.
14. The industry shall transport the hazardous waste to cement industries only through vehicle fitted with GPS tracking system.
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.
17. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.

The industry shall submit Half yearly compliance reports to all the stipulated conditions in Environmental Clearance (EC), Consent for Establishment (CFE) and Consent for Operation (CFO) through website i.e., <https://pcb.ap.gov.in> by 1st of January and 1st July of every year. The first half yearly compliance reports shall be furnished by the industry and second half yearly compliance reports shall be the audited through MoEF&CC recognized and National Accreditation Board for Laboratory Testing (NABL) accredited third party.

DR. B.MADHUSUDHANA RAO, JCEE(MSRB), O/o JOINT CHIEF ENVIRONMENTAL ENGINEER4-APPCB

**To
M/s. Eisai Pharmaceuticals India Pvt. Ltd,
(After expansion)
SEZ, Plot No.96, 97, 98, 124 & 126,
JN Pharma City, Parawada,
Visakhapatnam District - 531 021**



EISAI PHARMACEUTICALS INDIA PVT LTD.

h/c
human health care

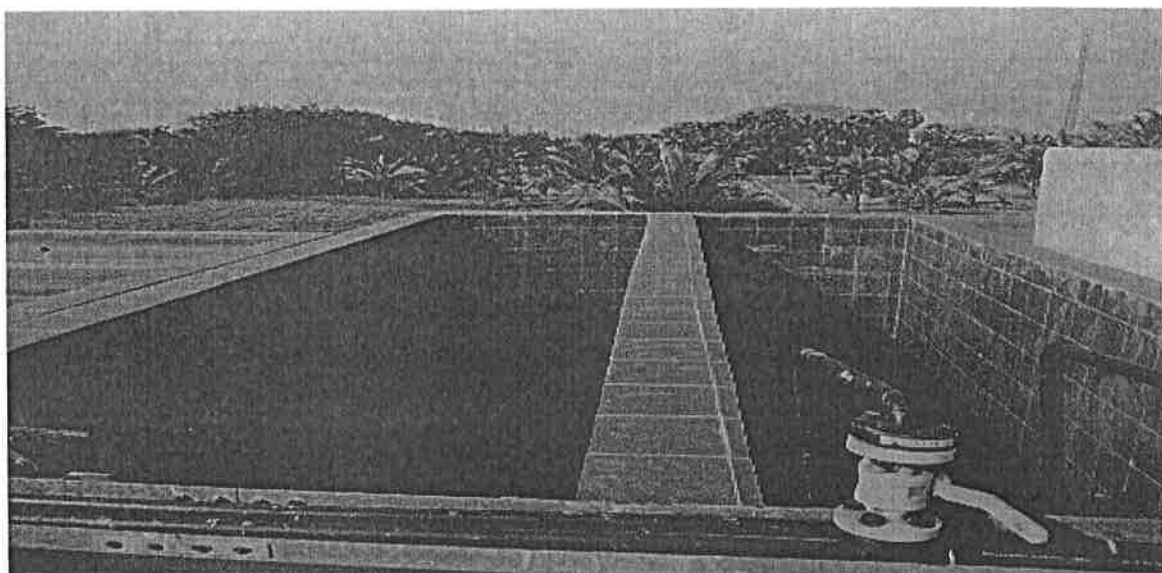
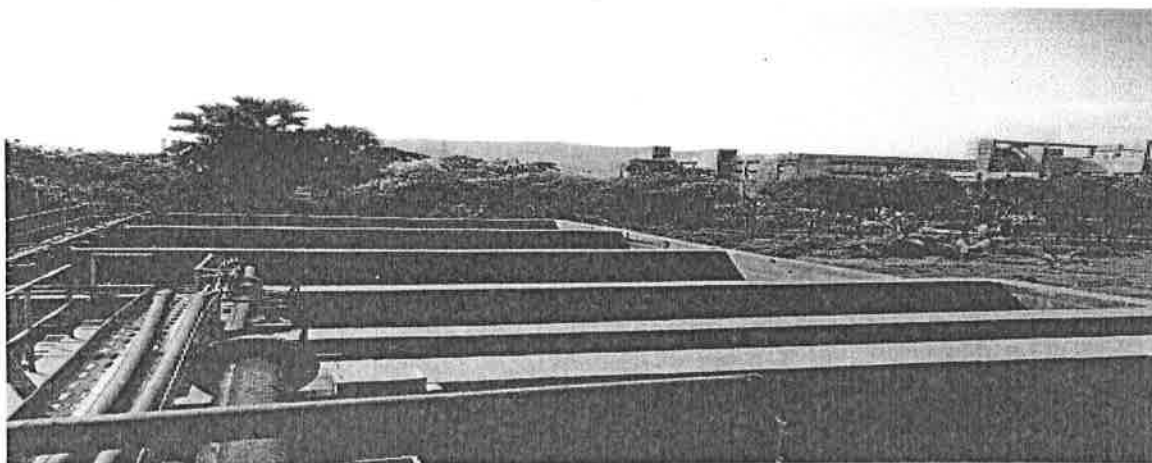
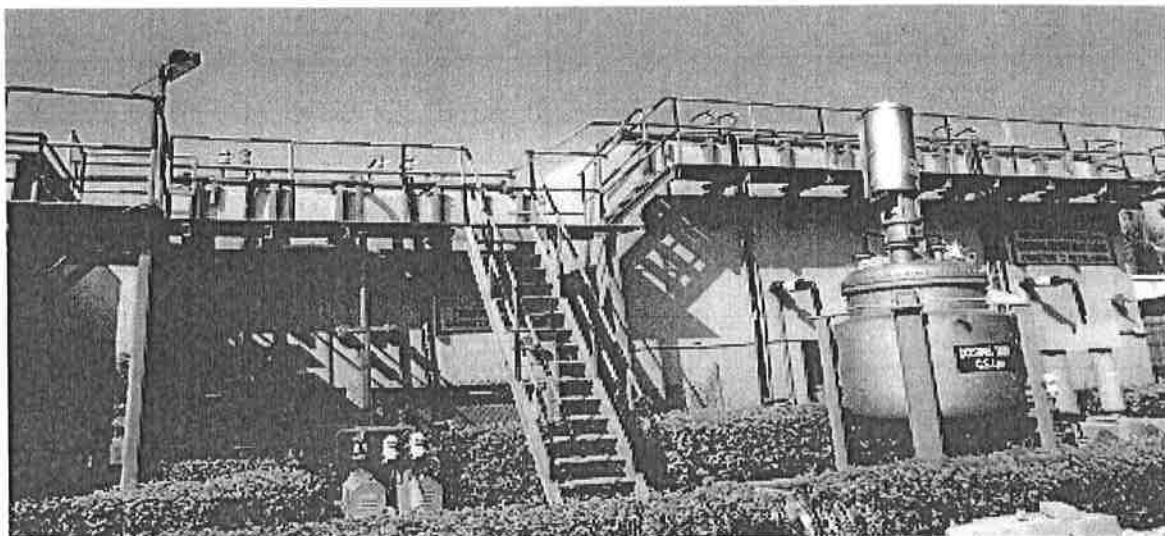
Above Ground ETP Photos (LTDS and HTDS)



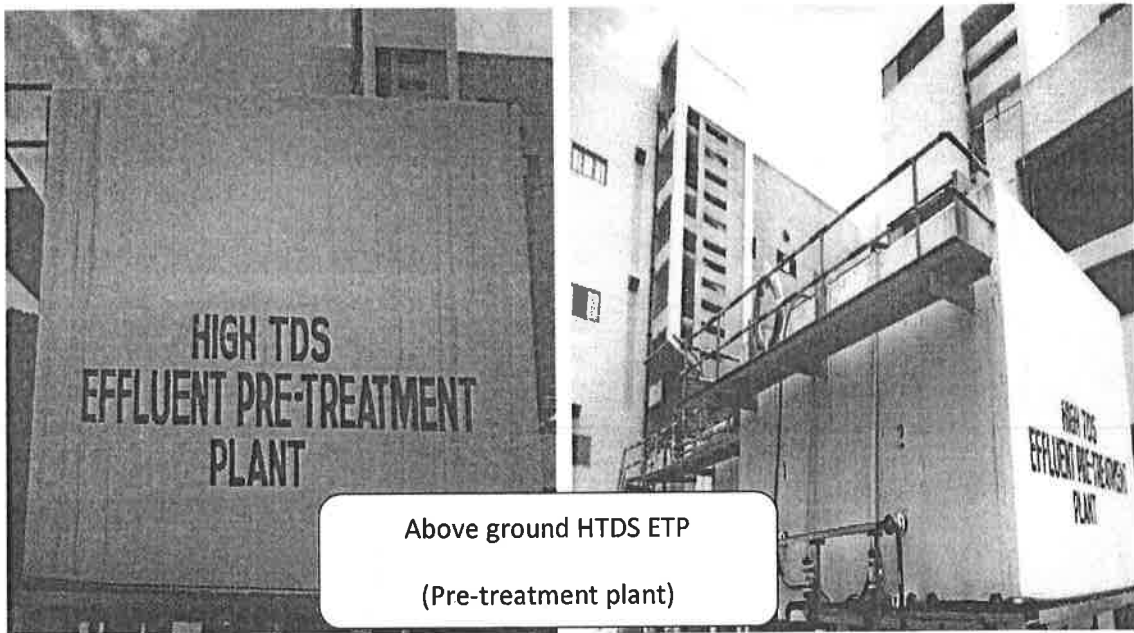
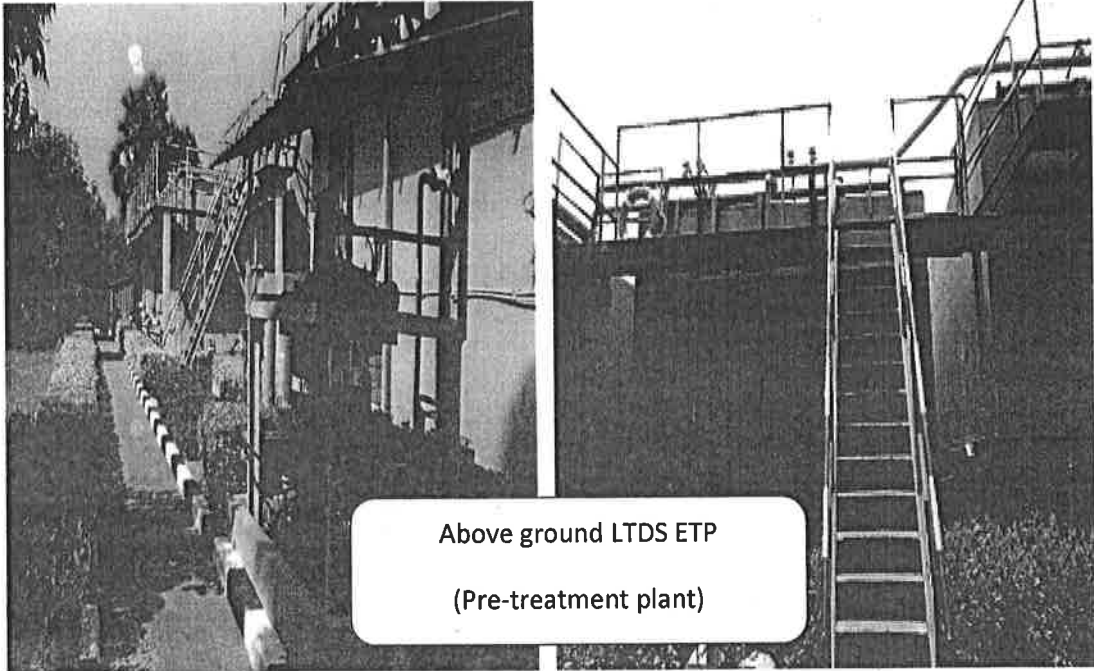
ABOVE GROUND ETP (LTDS & HTDS)

hkc
human health care

❖ Above ground ETP with acid proof tiles:



(Above Ground LTDS & HTDS Tanks)





EISAI PHARMACEUTICALS INDIA PVT LTD.

h/c
human health care

Latest Analysis Reports



ISO 9001, 14001 & 45001
CERTIFIED COMPANY

LAWN ENVIRO ASSOCIATES

[Engineers & Consultants in Pollution Control]
Recognised by Ministry of Environment Forest & Climate Change (MoEF & CC), GOI, New Delhi
& Laboratory Accredited by NABL

TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

AMBIENT AIR QUALITY DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Location	Top of the Gate-II Security Building	API Manufacturing Bldg East Side	Top of the R & D Building	LIMIT	PROTOCOL
1. Date of sampling	: 20-5-2021	20-5-2021	20-5-2021	--	---
2. Total time of monitoring	: 24 hr	24 hr	24 hr	--	---
3. Average flow rate (cum/m)	: 1.06	1.12	1.10	--	---
4. Particulate Matter Concentration ($\mu\text{g}/\text{m}^3$)-PM ₁₀	: 71	78	64	100	IS:5182 (Part-23); 2017
5. Particulate Matter Concentration ($\mu\text{g}/\text{m}^3$)-PM _{2.5}	: 24	30	22	60	IS:5182 (Part-24); 2019
6. Sulphur Dioxide (SO ₂) Concentration ($\mu\text{g}/\text{m}^3$)	: 11	09	07	80	IS:5182 (Part-2); 2018
7. Nitrogen Dioxide (NO ₂) Concentration ($\mu\text{g}/\text{m}^3$)	: 23	26	19	80	IS:5182 (Part-6); 2017


AUTHORISED SIGNATORY

1. RESPIRABLE DUST SAMPLER MODEL / SL.NO. RDS 9000 / 040139
2. RESPIRABLE DUST SAMPLER MODEL / SL.NO. RDS 9000 / 040140
3. RESPIRABLE DUST SAMPLER MODEL / SL.NO. RDS 9000 / 050239



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particular : Stack attached to the Diesel Fired Boiler – 02
Date of Sampling : 20-5-2021

PROTOCOL

1. Stack diameter (m) :	0.60	--
2. Stack cross sectional area (sq m) :	0.282	--
3. Flue gas temperature (°C) :	148	IS-11255 (Part-3); 2018
4. Exit velocity of flue gases (m/sec) :	7.10	IS-11255 (Part-3); 2018
5. Flow rate (cum/hr) :	7,208	IS-11255 (Part-3); 2018

	EMISSION DATA	LIMIT	
6. Suspended particulate matter Concentration (mg/N m ³) :	70	<100	IS-11255 (Part-1); 2019
7. Sulphur dioxide Concentration (mg/N m ³) :	112	---	IS-11255 (Part-2); 2019
8. Oxides of nitrogen Concentration (mg/N m ³) :	176	---	IS-11255 (Part-7); 2017


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES..

Head Office : "LAWN HOUSE", #184-C, Vengalrao Nagar, Hyderabad - 500 038. (T.S.) INDIA. Tel : 040-66730925. 66730926. Fax : 040-66730926
Branch Office : H.No.18/2, Ground Floor, Phase-1, Vuda Nagar, Rajiv Nagar Road, Kurmannapalem, Visakhapatnam - 530046 (A.P.) Tel : +91-9030029925
E-mail : lawnenviro@yahoo.co.in. Website : www.lawnenviro.com



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LAWN ENVIRO ASSOCIATES

[Engineers & Consultants in Pollution Control]

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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021


STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

	*I	*II	*III	*IV	PROTOCOL
1. Date of sampling	: 20-5-2021	20-5-2021	20-5-2021	20-5-2021	---
2. Stack diameter (m)	: 0.25	0.25	0.25	0.25	---
3. Stack cross sectional area (sq m)	: 0.049	0.049	0.049	0.049	---
4. Flue gas temperature (°C)	: 279	276	285	271	IS-11255 (Part-3); 2018
5. Exit velocity of flue gases (m/sec)	: 16.20	16.72	15.80	16.53	IS-11255 (Part-3); 2018
6. Flow rate (cum/hr)	: 2,858	2,949	2,787	2,916	IS-11255 (Part-3); 2018

	EMISSION DATA				LIMIT	
7. Suspended particulate matter Concentration (mg/N m ³)	: 68	64	61	67	<115	IS-11255 (Part-1); 2019
8. Sulphur dioxide Concentration (mg/N m ³)	: 142	156	147	163	---	IS-11255 (Part-2); 2019
9. Oxides of nitrogen Concentration (mg/N m ³)	: 289	280	291	286	---	IS-11255 (Part-7); 2017

Note: *I Stack attached to the 1500 KVA D.G. Set-I
*II Stack attached to the 1500 KVA D.G. Set-II
*III Stack attached to the 1500 KVA D.G. Set-III
*IV Stack attached to the 1500 KVA D.G. Set-IV


AUTHORISED SIGNATORY

STACK MONITORING KI : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.

Head Office : "LAWN HOUSE", #184-C, Ve.igalrao Nagar, Hyderabad - 500 038. (T.S.) INDIA. Tel : 040-66730925, 66730926, Fax : 040-66730926
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E-mail : lawnenviro@yahoo.co.in, Website : www.lawnenviro.com



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

	*I	*II	PROTOCOL
1. Date of sampling	: 21-5-2021	21-5-2021	--
2. Stack diameter (m)	: 0.36	0.36	--
3. Stack cross sectional area (sq m)	: 0.101	0.101	--
4. Flue gas temperature (°C)	: 39	44	IS-11255 (Part-3); 2018
5. Exit velocity of flue gases (m/sec)	: 10.82	10.05	IS-11255 (Part-3); 2018
6. Flow rate (cum/hr)	: 3,934	3,654	IS-11255 (Part-3); 2018
	EMISSION DATA		LIMIT
7. Acid Mist Concentration (mg/N m ³)	: 08	13	<35 ASTM

Note: *I Stack attached to the Scrubber (Chemistry Lab-01A)

*II Stack attached to the Scrubber (Chemistry Lab-01B)


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

	*I	*II	PROTOCOL
1. Date of sampling	: 21-5-2021	21-5-2021	--
2. Stack diameter (m)	: 0.36	0.36	--
3. Stack cross sectional area (sq m)	: 0.101	0.101	--
4. Flue gas temperature (°C)	: 40	43	IS-11255 (Part-3); 2018
5. Exit velocity of flue gases (m/sec)	: 9.94	10.46	IS-11255 (Part-3); 2018
6. Flow rate (cum/hr)	: 3,614	3,803	IS-11255 (Part-3); 2018

EMISSION DATA

LIMIT

7. Acid Mist Concentration (mg/N m ³)	: 09	11	<35	ASTM
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Note: *I Stack attached to the Scrubber (Chemistry Lab-02A)

*II Stack attached to the Scrubber (Chemistry Lab-02B)


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/Sl. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particular : Stack attached to the Scrubber (GE Lab)
Date of Sampling : 21-5-2021

PROTOCOL

1. Stack diameter (m) :	0.30	--
2. Stack cross sectional area (sq m) :	0.070	--
3. Flue gas temperature (°C) :	40	IS-11255 (Part-3); 2018
4. Exit velocity of flue gases (m/sec) :	9.72	IS-11255 (Part-3); 2018
5. Flow rate (cum/hr) :	2,449	IS-11255 (Part-3); 2018

	EMISSION DATA	LIMIT	
6. Acidmist Concentration (mg/N m ³) :	10	<35	ASTM


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.,



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particular : Stack attached to the API Manufacturing Block – 2 (SCB – 1)
Date of Sampling : 21-5-2021

PROTOCOL

1. Stack diameter (m)	: 0.21	--
2. Stack cross sectional area (sq m)	: 0.0346	--
3. Flue gas temperature (°C)	: 41	IS-11255 (Part-3); 2018
4. Exit velocity of flue gases (m/sec)	: 5.86	IS-11255 (Part-3); 2018
5. Flow rate (cum/hr)	: 730	IS-11255 (Part-3); 2018

	EMISSION DATA	LIMIT	
6. Acidmist Concentration (mg/N m ³)	: 12	<35	ASTM


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.,



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particular : Stack attached to the Scrubber – Warehouse - 03
Date of Sampling : 22-5-2021

PROTOCOL

1. Stack diameter (m)	:	0.30	--
2. Stack cross sectional area (sq m)	:	0.070	--
3. Flue gas temperature (°C)	:	38	IS-11255 (Part-3); 2018
4. Exit velocity of flue gases (m/sec)	:	4.78	IS-11255 (Part-3); 2018
5. Flow rate (cum/hr)	:	1,205	IS-11255 (Part-3); 2018

EMISSION DATA

LIMIT

6. Acidmist Concentration (mg/N m ³)	:	06	<35	ASTM
--------------------------------------------------	---	----	-----	------


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.,



ISO 9001, 14001 & 45001
CERTIFIED COMPANY

LAWN ENVIRO ASSOCIATES

[Engineers & Consultants in Pollution Control]

Recognised by Ministry of Environment Forest & Climate Change (MoEF & CC), GOI, New Delhi
& Laboratory Accredited by NABL

TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

	*I	*II	*III	PROTOCOL
1. Date of sampling	: 22-5-2021	22-5-2021	22-5-2021	--
2. Stack diameter (m)	: 0.81	0.71	0.61	--
3. Stack cross sectional area (sq m)	: 0.515	0.396	0.292	--
4. Flue gas temperature (°C)	: 43	42	39	IS-11255 (Part-3); 2018
5. Exit velocity of flue gases (m/sec)	: 6.70	6.42	6.91	IS-11255 (Part-3); 2018
6. Flow rate (cum/hr)	: 12,422	9,152	7,264	IS-11255 (Part-3); 2018

	EMISSION DATA			LIMIT	
7. Acid Mist Concentration (mg/N m ³)	: 08	10	06	<35	ASTM

Note: *I Stack attached to the R&D Process Lab Scrubber-1
*II Stack attached to the R&D Kilo Lab Scrubber-2
*III Stack attached to the R&D Wet Lab Scrubber


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particular : Stack attached to the HCL Scrubber – API Pilot Plant Scrubber-01
Date of Sampling : 21-5-2021

PROTOCOL

1. Stack diameter (m)	: 0.11	--
2. Stack cross sectional area (sq m)	: 0.0095	--
3. Flue gas temperature (°C)	: 44	IS-11255 (Part-3); 2018
4. Exit velocity of flue gases (m/sec)	: 5.59	IS-11255 (Part-3); 2018
5. Flow rate (cum/hr)	: 191	IS-11255 (Part-3); 2018

	EMISSION DATA	LIMIT	
6. Acid Mist Concentration (mg/N m ³)	: 10	<35	ASTM


AUTHORISED SIGNATORY

STACK MONITORING KI : MODEL NO: APM-160/SI. No. 13-DTC-2012. Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.,



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particular : Stack attached to the HCL Scrubber – API Pilot Plant Scrubber-03
Date of Sampling : 22-5-2021

PROTOCOL

1. Stack diameter (m)	: 0.11	--
2. Stack cross sectional area (sq m)	: 0.0095	--
3. Flue gas temperature (°C)	: 40	IS-11255 (Part-3); 2018
4. Exit velocity of flue gases (m/sec)	: 5.48	IS-11255 (Part-3); 2018
5. Flow rate (cum/hr)	: 187	IS-11255 (Part-3); 2018

	EMISSION DATA	LIMIT	
6. Acid Mist Concentration (mg/N m ³)	: 06	<35	ASTM


AUTHORISED SIGNATORY

STACK MONITORING KI : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.,



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

STACK MONITORING DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

	*I	*II	PROTOCOL
1. Date of sampling	: 22-5-2021	21-5-2021	--
2. Stack diameter (m)	: 0.11	0.20	--
3. Stack cross sectional area (sq m)	: 0.0095	0.0314	--
4. Flue gas temperature (°C)	: 46	42	IS-11255 (Part-3); 2018
5. Exit velocity of flue gases (m/sec)	: 5.19	5.06	IS-11255 (Part-3); 2018
6. Flow rate (cum/hr)	: 177	572	IS-11255 (Part-3); 2018
	EMISSION DATA		LIMIT
7. Acid Mist Concentration (mg/N m ³)	: 10	08	<35 ASTM

Note: *I Stack attached to the Scrubber – API Manufacturing Block – 1 SCB – 1 (U-301)

*II Stack attached to the Scrubber – API Manufacturing Block – 1 SCB – 2 (U-302)


AUTHORISED SIGNATORY

STACK MONITORING KIT : MODEL NO: APM-160/SI. No. 13-DTC-2012, Calibrated on 03-4-2021, Due on 02-4-2022
M/s. LATA ENVIROTECH SERVICES.,



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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

WASTE WATER ANALYSIS

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Sample Particulars : Pre-Treated Effluent - (Before lifting to CETP) – M/s. Ramky Pharma City
Date of Collection : 20-5-2021
Date of Analysis : 21-5-2021
PROTOCOL : A.P.H.A 23rd Edition

		Limits prescribed by CETP
1. pH	: 7.20	6.5 – 8.5
2. Temperature °C	: 33	45
3. Total dissolved solids	: 1,520	12,000
4. Total suspended solids	: 241	600
5. Biochemical Oxygen Demand (3 days at 27° C)	: 783	3,000
6. Chemical Oxygen demand	: 1,965	8,000
7. Oil & Grease	: 2.50	20
8. Chromium Hexavalent as Cr+6	: 0.07	2.0
9. Chromium (Total) as Cr	: 0.10	2.0
10. Ammonical Nitrogen as N	: 25	30
11. Cyanide as CN	: <0.01	0.20
12. Lead as Pb	: 0.06	1.0
13. Nickel as Ni	: 0.10	3.0
14. Zinc as Zn	: 0.75	15
15. Arsenic as As	: <0.01	0.20
16. Mercury as Hg	: <0.001	0.01

Note: All values except pH are expressed in mg/L.


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TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

AMBIENT NOISE LEVEL DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Location	Levels in dB(A) Leq.	
	Day time	Night time
1. Near Energy Center :	53.70	48.20
2. Near Gate - II :	62.40	57.60
3. Near Gate - I :	59.10	54.30
4. Infront of Formulations :	67.80	62.80

- Note:
1. Noise levels are monitored on 20-5-2021.
 2. Instrument make - Kusam KM 928, SL.No. 110504136, Calibrated on 03-09-2020, Due On 02-09-2021.
 3. Day time is reckoned in between 6.0 am and 10.0 pm; Limit 75 dB (A).
 4. Night time is reckoned in between 10.0 pm and 6.0 am; Limit 70 dB (A).


AUTHORISED SIGNATORY



EISAI PHARMACEUTICALS INDIA PVT LTD.

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Latest Analysis Reports-AAQM



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& Laboratory Accredited by NABL

TEST REPORT

REF.NO: LAWN/EISAI/2021

Date: 29-5-2021

AMBIENT AIR QUALITY DATA

Name of the Industry & Address : **M/s. EISAI PHARMACEUTICALS INDIA PVT.LTD.,**
Plot Nos.96, 97, 98,124 & 126, Ramky Pharma City (SEZ),
Parawada, Visakhapatnam (Dist) – 531019. A.P.

Location	Top of the Gate-II Security Building	API Manufacturing Bldg East Side	Top of the R & D Building	LIMIT	PROTOCOL
1. Date of sampling	: 20-5-2021	20-5-2021	20-5-2021	--	---
2. Total time of monitoring	: 24 hr	24 hr	24 hr	--	---
3. Average flow rate (cum/m)	: 1.06	1.12	1.10	--	---
4. Particulate Matter Concentration ($\mu\text{g}/\text{m}^3$)-PM ₁₀	: 71	78	64	100	IS:5182 (Part-23); 2017
5. Particulate Matter Concentration ($\mu\text{g}/\text{m}^3$)-PM _{2.5}	: 24	30	22	60	IS:5182 (Part-24); 2019
6. Sulphur Dioxide (SO ₂) Concentration ($\mu\text{g}/\text{m}^3$)	: 11	09	07	80	IS:5182 (Part-2); 2018
7. Nitrogen Dioxide (NO ₂) Concentration ($\mu\text{g}/\text{m}^3$)	: 23	26	19	80	IS:5182 (Part-6); 2017


AUTHORISED SIGNATORY

1. RESPIRABLE DUST SAMPLER MODEL / SL.NO. RDS 9000 / 040139
2. RESPIRABLE DUST SAMPLER MODEL / SL.NO. RDS 9000 / 040140
3. RESPIRABLE DUST SAMPLER MODEL / SL.NO. RDS 9000 / 050239



EISAI PHARMACEUTICALS INDIA PVT LTD.

hbc
human health care

Fire NOC

Government of Andhra Pradesh
A.P. State Disaster Response and Fire Services Department
Annual Periodical Renewal Fire Certificate

From:
 Director
 State Disaster Response & Fire Services
 Andhra Pradesh, Vijayawada.

To:
 The Commissioner of Industries
 Mutyalampadu, Vijayawada.

File No: 14698/VSP/MSB/2020, Date:10/02/2021

Occupancy NoC RC Number: 4731/B1/2013, Dated:17-11-2013

Sub: Andhra Pradesh State Disaster Response and Fire Services Department - Annual Periodical Fire Certificate to the constructed Multi Storeyed Building of Eisai Pharmaceuticals India Pvt.Ltd., represented by GIRISH DIXIT, Plot Nos.96,97,98,124 & 126, Ramky Pharma City (SEZ), Parawada, District Visakhapatnam - 531019 Andhra Pradesh-INDIA - Regarding.

- Ref: 1. G.O.Ms.NO.71 Home (Prisons-A) Department, Dated.01-04-2010 & G.O.Ms.NO.140 Home(Prison & Fire Services) Department, Dt.04-09-2015.
 2. This Office Delegation of Powers Rc.No.3350/Audit/NOC/2012, Dated.09-03-2017.
 3. This Office NOC for Occupancy Rc No. 4731/B1/2013, Dated:17-11-2013, Dt.17/11/2013
 4. Renewal NOC For Occupancy 4731/B1/2013, Dated:17-11-2013, Dt.17/11/2019
 5. Online Application for Renewal NOC of GIRISH DIXIT, Plot Nos.96,97,98,124 & 126, Ramky Pharma City (SEZ), Parawada, District Visakhapatnam - 531019 Andhra Pradesh-INDIA - Inspection report called for Regarding.
 6. Online Inspection Report submitted by Officers of this Department on 02-02-2021.

<< 0 >>

The Management of Eisai Pharmaceuticals India Pvt.Ltd., represented by GIRISH DIXIT, Plot Nos.96,97,98,124 & 126, Ramky Pharma City (SEZ), Parawada, District Visakhapatnam - 531019 Andhra Pradesh-INDIA has requested to issue Annual Periodical Fire Certificate for period 2020-2021 duly remitting the Fire Precautionary fee for Rs.299920/- vide challan No. 411823630a72020, Dated 15/10/2020 at Through Online, Through Online.

Eisai Pharmaceuticals India Pvt.Ltd. With Allied (13) Blocks

1. This certificate is being issued as per G.O.Ms.No 140 Home (prisons & Fire Services) Department, Dt: 04.09.2015.
2. The No Objection Certificate for Occupancy was issued vide reference cited (3) and the Management has also obtained Annual Periodical Renewal Fire Certificate for vide reference 4th cited to the constructed Multi Storeyed Building.
3. The Officers of the department have recommended to issue The Annual Periodical Renewal Fire Certificate GIRISH DIXIT Plot Nos.96,97,98,124 & 126, Ramky Pharma City (SEZ), Parawada, District Visakhapatnam - 531019 Andhra Pradesh-INDIA, subject to the following conditions.

Sl	As Builder	As Occupant	As Security Personnel
1	All the fire protection arrangements shall be maintained in good condition as seen during inspection.	All the escape/exit routes shall not be kept locked/blocked or encroached	All the occupants must know the correct method of operation of the fire fighting system installed.

2	Any loss of life or property due to non-functioning of fire safety measures and other installations shall be the responsibilities of the management.	All occupants shall be trained to operate the fire safety equipments during emergency.	Mock drills should be conducted once in 3 months for initial two years. Thereafter, once in every 6 months.
3	Addition / alteration, if any in the building may be verified by building authority.	Mock drills should be conducted once in 3 months for initial two years. Thereafter, once in every 6 months.	All security personnel shall be trained to operate the fire safety equipments during emergency.
4	This is Only for Fire Safety Point of View.	Raise the alarm if the fire cannot be controlled; Evacuate the area completely at once with nearest safe exit.	Attack the fire using available fire equipment only if you feel capable of controlling. If not, take all steps to isolate the area by closing doors and windows.

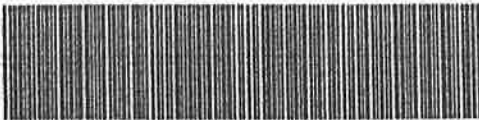
4. This Annual Periodical Renewal Fire Certificate is valid from 17/11/2020 to 16/11/2023.

5. The Responsibility/liability of the owner/occupier or both to maintain Fire safety measures in good condition in all times, in accordance with AP Fire safety Act 1999 and Rules, 2006.

The following deficiencies are identified by the officers of the department and needs to be attended to by the management.

Recommended:

1. This Renewal NOC is issued from Fire Safety Point of view only basing on recommendation of the inspection Committee and this Renewal NOC is not for claiming proprietary or ownership rights. Further, in case of any deviation noticed with respect to this Renewal NOC after issuance of this Renewal NOC, the same Renewal NOC shall be liable for cancellation at any time.
2. This Renewal NOC is valid for Three years only and It is the responsibility of the Builder/Owner to apply for renewal of No Objection certificate, duly remitting the user charges as per G.O.Ms.No.169, Home (Prisons & Fire Service) Department. Dt. 19-12-2019. Two months before expire of this No Objection Certificate.
3. The occupier/Owner /Builder/Management concerned of the building premises, shall maintain the Fire Prevention and Fire Safety Measures provided by the building as per Occupancy NOC at all times for good use by the Occupant (or) Members of Fire Services (or) Both in the event of outbreak of Fire.
4. The Renewal NOC issued based on Inspection Committee report.



14698/VSP/MSB/2020

Your Sincerely,

[Handwritten Signature]

Director

State Disaster Response & Fire Services
Andhra Pradesh, Vijayawada.

Copy to GIRISH DIXIT, Eisai Pharmaceuticals India Pvt.Ltd. Plot Nos.96,97,98,124 & 126, Ramky Pharma City (SEZ), Parawada, District Visakhapatnam - 531019 Andhra Pradesh-INDIA

Copy to Chief Office for Record Purpose

Copy to Regional Fire Officer Concerned

Copy to District Fire Officer Concerned

Copy to Assistant District Fire Officer Concerned



EISAI PHARMACEUTICALS INDIA PVT LTD.

h/c
human health care

External Safety Audit



Date: February 02, 2021.

To

The Environmental Engineer,
Regional Office, APPCB,
Madhavadhara,
Visakhapatnam-530009.

Subject: Submission of External Safety Audit Report-Reg

Dear Sir,

We are herewith submitting the external safety audit report along with recommendation compliance reports for your perusal and record.

Please acknowledge receipt.

Thanking you.

Yours Sincerely,

For Eisai Pharmaceuticals India Pvt.Ltd.

Mr. Y. Tirupathi Reddy
Sr. Manager-EHS

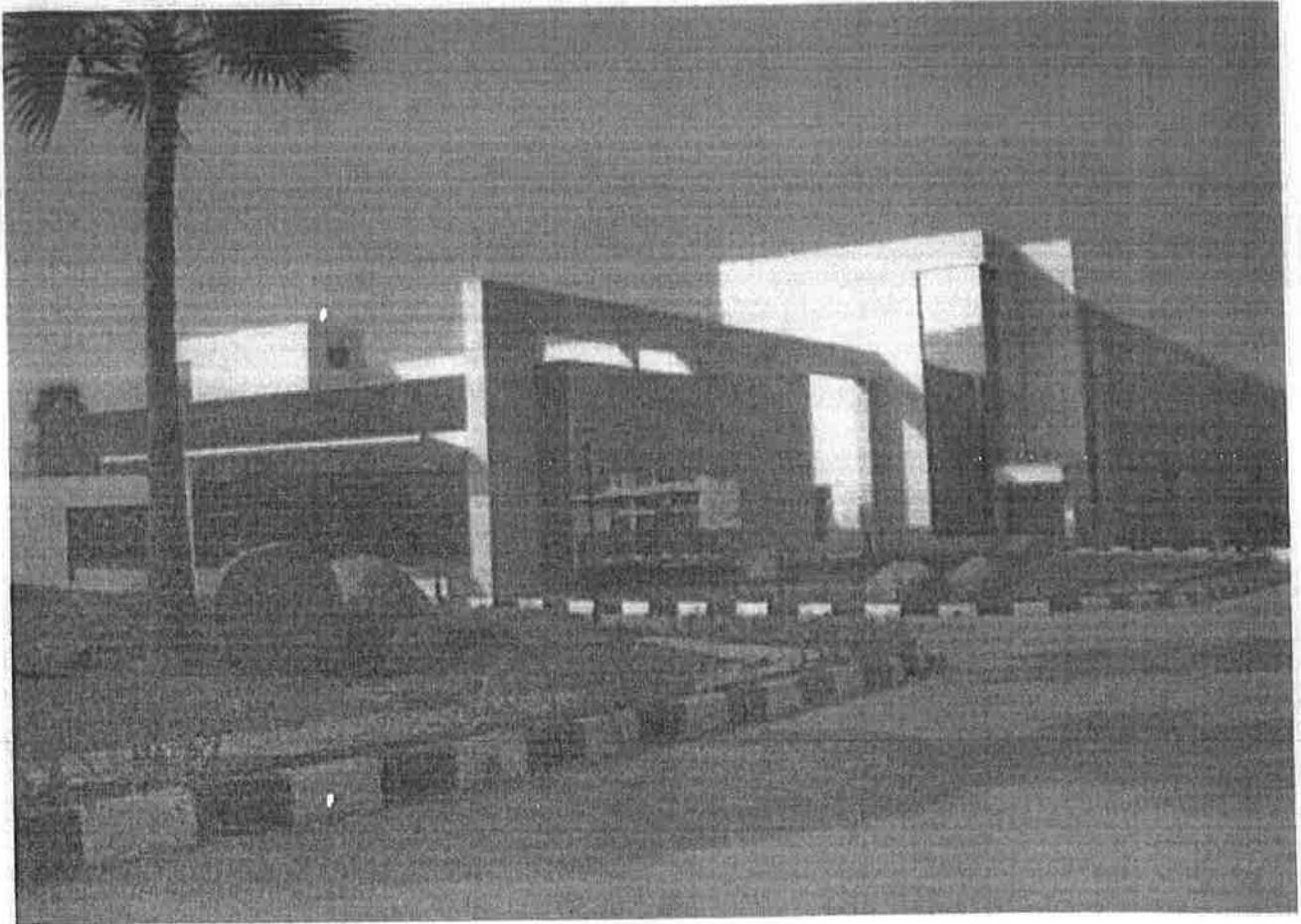


Encl.: As above

Report Title	SAFETY AUDIT – BIS 14489
Client Name	EISAI Pharmaceuticals India Private Limited
Assessment Date	15th & 16th December 2020
Report No.	TSM22515122020R1
TSM Project No.	225-2020
Submitted to	Mr. Tirupathi Reddy
Submission Date	22-12-2020
Prepared by	Mr. Vishal
Reviewed by	Mr. Arvind
Approved by	Mr. Arvind
Assessor Details	TSM TheSafetyMaster™ Pvt Ltd S 221 – 2nd floor, SPL 1/J, RIICO Indus. Area, Bhiwadi-301019, India Tel. +91-1493-220093, +917665231743 Email: info@thesafetymaster.com Web: www.thesafetymaster.com

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Safety Audit – BIS 14489



Report

For

EISAI Pharmaceuticals India Private Limited

Plot No 96,97, 98, 124, 126, Lankelapalem Rd, Paravada,
Visakhapatnam, Andhra Pradesh 531021

By

TSM TheSafetyMaster Private Limited

S 221 – 2nd floor, SPL 1/J, RIIICO Indus. Area,
Bhlwadi-301019, India
Tel. +91-1493-220093

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