

Ref: APL/EHS/23-24/02

Gut No. 378, P.No. 8,
A'bad-Pune Highway,
Village - Waluj (Bk),
Aurangabad - 431 133
Maharashtra - INDIA

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Jun 01, 2023

To,

Deputy Director General of Forests (Central).
West Central Zone, Regional Office
Near Secretariat Building, opp. VCA Ground
Civil Lines, Nagpur-440001

Subject: Submission of six monthly EC compliance report for Active pharmaceutical ingredients manufacturing plant "Ajanta Pharma Ltd." at Gut no 378, Plot No 08, village Waluj, 11 KM stone, Aurangabad, Maharashtra.

Ref EC orders: MoEF Clearance No. J-11011/359/2008-IA-II (I) dated October 06, 2022.

Respected Sir,

Pertaining to the above cited captioned subject, we are enclosing herewith six monthly (January 2023 – June 2023) condition wise compliance report of Environmental Clearance for Part-A specific conditions and Part-B general condition of our active Pharmaceutical Ingredients (API's) manufacturing plant at Gut no 378, Plot No 08, village Waluj, 11 KM stone, Aurangabad, Maharashtra.

Kindly acknowledge the receipt of the same.

Thanking You

For Ajanta Pharma Limited

Gopal Rathi
(VP-Operations)
Authorized Signature

CC: 1. Regional Officer MPCB, Aurangabad.

2. Member Secretary, CPCB New Delhi.

Encl: 1. Data sheet

2. Six Monthly Compliance report (details compliance of EC Conditions).
3. Additional details (monitoring Report, etc attached as Annexure)

Page 1 of 1

SIX MONTHLY COMPLIANCE REPORT

PERIOD: JANUARY 2023 TO JUNE - 2023



AJANTA PHARMA LTD, WALUJ AURANGABAD (MAHARASHTRA)

EC File No: J-11011/359/2008-IA-II(I) Dated October 06, 2022

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5. PROJECT BACKGROUND

Ajanta Pharma is a specialty pharmaceutical company engaged in development, manufacturing and marketing of quality finished dosages. Ajanta operates 7 state-of-the-art manufacturing facilities in India and Mauritius. One of the active pharmaceutical ingredients (API) manufacturing unit is in operational namely M/s. Ajanta Pharma Ltd. at 11KM Stone Gut No. 378, Plot No 8, Aurangabad –Pune Highway, Village-Waluj, Taluka. Gangapur, District. Aurangabad- 431133.

Presently industry is involved in API manufacturing, which are used in drug formulation mainly Anti-malarial, Anti-inflammatory, Analgesic, Treatment of dyspepsia, Peptic ulcer diseases(PUD) & gastroesophageal reflux disease, Anti-allergic, Antihistaminic, Antiglaucoma, Antithrombotic, Fibrinolytic, Anticoagulant, Antilipemic, Antihypertensive, Antianginal, Antiarrhythmic, Anti-bacterial, Treatment of Acute Coronary Syndrome, Anti-diabetic, In treatment of premature ejaculation, Treatment of attention deficit hyperactivity disorder, chronic fatigue syndrome & major depressive disorder, Dermatitis, Allergies, Antianginal, Glucocorticoid etc. The existing consented manufacturing capacity is 23.6 MT/Month. Existing unit had already obtained environmental clearance from Ministry of Environment, Forest & Climate change vide letter no F. No. J-11011/ 359/ 2008-IA-II (I) dated 06th, 2022.

1. INFORMATION SHEET

Monitoring the Implementation of Environmental Safeguards Ministry of Environment & Forest

Western Region, Regional Office, Nagpur

MONITORING REPORT

PART – I

DATA SHEET

Sl. No.	Particulars		Details																							
1.	Project type: River Valley / Mining / Industry / Thermal / Nuclear / Others (specify)	:	Industry																							
2.	Name of the Project	:	Active Pharmaceutical Ingredients (API) Manufacturing Industry “M/s. Ajanta Pharma Ltd.”																							
3.	Clearance letter (s) / OM No. and date	:	F. No. J-11011/ 359/ 2008-IA-II (I) dated 10 th June 2009 F. No. J-11011/ 359/ 2008-IA-II (I) dated 6 th October 2022																							
4.	Location a) District (s) b) State (s) c) Location latitude / longitude	: : :	Aurangabad Maharashtra <table border="1"> <thead> <tr> <th>Point</th> <th>Latitude</th> <th>Longitude</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>19°48'20.84"N</td> <td>75°13'41.91"E</td> </tr> <tr> <td>B</td> <td>19°48'18.44"N</td> <td>75°13'41.42"E</td> </tr> <tr> <td>C</td> <td>19°48'17.88"N</td> <td>75°13'43.78"E</td> </tr> <tr> <td>D</td> <td>19°48'19.35"N</td> <td>75°13'44.09"E</td> </tr> <tr> <td>E</td> <td>19°48'19.22"N</td> <td>75°13'43.59"E</td> </tr> <tr> <td>F</td> <td>19°48'21.18"N</td> <td>75°13'43.25"E, C n</td> </tr> </tbody> </table>			Point	Latitude	Longitude	A	19°48'20.84"N	75°13'41.91"E	B	19°48'18.44"N	75°13'41.42"E	C	19°48'17.88"N	75°13'43.78"E	D	19°48'19.35"N	75°13'44.09"E	E	19°48'19.22"N	75°13'43.59"E	F	19°48'21.18"N	75°13'43.25"E, C n
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5.	Address for Correspondence a) Address of the Concerned Project Chief Engineer (with Pin code & Telephone / Telex / Fax Numbers) b) Address of the Concerned Project Engineer / Manager (with Pin code & Telephone / Telex / Fax Numbers)	: :	Mr. Shashikant Kolhe (Plant Manager) At 11KM Stone, Gut No. 378; Plot No 8, Aurangabad –Pune Highway, Village-Waluj, Taluka. Gangapur, District. Aurangabad- 431133																							
			Mr. Pankaj Barbind (AGM- EHS) At 11KM Stone, Gut No. 378; Plot No 8, Aurangabad –Pune Highway, Village-Waluj, Taluka. Gangapur, District. Aurangabad- 431133 Mob: 9657171293 e-Mail : pankaj.barbind@ajantapharma.com																							

6.	Salient features a) of the Project	:	Project Spectrum	Industry is engaged in manufacturing of consented 259 nos. of API & Intermediate and having production capacity 23.6 MT/Month.	
			Total Plot Area	3200.75 Sq. meter.	
			Project Resident Population size	NA	
			Direct Employment	75	
			Water Demand	83.2 KLD	
			Source of Water	MIDC Waluj	
			Waste Water generation	Approx. 25.2 KLD (4 KLD Domestic waste water + 21.2 KLD Industrial effluent)	
			Sewage Treatment Plant (STP)	One approx. 10.0 KLD STP MBBR technology	
			Effluent Treatment Plant (ETP)	One approx. 25 KLD with primary, secondary & tertiary treatment upgraded with installation of ETP RO and evaporator. A complete ZERO LIQUID DISCHARGE FACILITY.	
			Treated Waste Water Reuse	Final treated water is reused for utility (CT make-up water).	
			Nonhazardous Solid Waste generation	Disposal to Authorized recycler.	
b) of the Environmental Management Plans					
<p><i>Environmental and Social Monitoring –</i></p> <p><i>Effluent Treatment Plant</i></p> <p>Industry have a defined treatment unit comprises of primary, secondary, tertiary unit. Although wastewater characterization results show that effluent water quality standards are met</p> <p><i>Air pollution</i></p>					

	<p>APL has taken effective measures to control air pollution by providing stacks, condenser and wet scrubber to different air pollutant emitting equipment.</p> <p>Waste management</p> <p>Solid waste management was well organized within the APL Plant at Waluj.</p> <p>.</p> <p>Corporate Social Responsibility – Details of last year CSR expenses for FY 2021-2022 attached. Total Expenses under CSR for Ajanta group 13.49 Cr.</p>		
7.	<p>Breakup of the Project Area</p> <p>a) Submergence area: forest & non-forest</p> <p>b) Others</p>	:	<p>NA</p> <p>There is no forest area involved</p> <p>Total Plot Area: 3200.75 Sq. Meter.</p> <p>Drawing attached for Area break-up.</p>
8.	<p>Breakup of the project affected population with the enumeration of those losing Houses / Dwelling units only, Agricultural Land & Landless Laborers / Artisans:</p> <p>a) SC, ST / Adivasi b) Others</p> <p>(please indicate whether these figures are based on any scientific and systematic survey carried out or only provisional figures, if a survey is carried out give details & year of survey)</p>	:	Not applicable.
9 a)	<p>Financial Details: Project cost as originally planned and subsequent revised estimates and the year of price reference</p>	:	14.90 Cr.
b)	Allocation made for environmental management plans with item wise and year wise breakup	:	Break Up Attached.
c)	Benefit cost ratio/Internal rate of Return and the year of assessment	:	Product manufactured are utilize for own formulation unit so benefit cost ratio cannot be calculated.
d)	Whether includes the cost of environmental management as shown in the above	:	Yes.
e)	Actual expenditure incurred on the project so far	:	Rs. 14.90 Cr
f)	Actual expenditure incurred on the environmental management plans so far	:	Rs.2.2 Cr
10	Forest Land Requirement		No Forest land is involved in the project

a)	The status of approval for diversion of forest land for non-forestry use	:	NA
b)	The status of clearing felling	:	NA
c)	The status of compensatory afforestation, if any	:	NA
d)	Comments on the viability & sustainability of compensatory afforestation program in the light of actual field experience so far	:	NA
11	The status of clear felling in non-forest areas (such as submergence area or reservoir, approach roads.), if any with quantitative information required.	:	NA
12	Status of construction (Actual & /or planned)	:	Area statement attached.
a)	Date of commencement (Actual & / or planned)	:	25 Aug 2009
b)	Date of completion (Actual &/or planned)	:	01 Oct 2009 (For 1 st Clearance) 06 Oct 2022 (For recent clearance)
13	Reasons for the delay if the project is yet to start	:	NA
14	Dates of Site Visits		
a)	The dates on which the project was monitored by the Regional Office on previous occasions, if any	:	<ul style="list-style-type: none"> i. Hon. Director of MOEF has given visit on 25.11.2013 against letter no. 5-71/2010(ENV) 2195 dated : 30.11.2010 ii. Hon. Scientist D of MoEF Nagpur visited on 29.11.2018. iii. Hon. Director of MoEF Nagpur visited on Mar 12,2022.
b)	Date of site visits for this monitoring report	:	Hon. Director of MoEF Nagpur visited on Mar 12, 2022 for certification of compliance of present EC condition.

CONDITION -WISE COMPLIANCE REPORT OF ENVIRONMENT CLEARNACE**Ministry of Environment and Forest, Govt. Of India**

EC Order No.: F. No J-11011/359/2008-IA-II(I) dated Oct 06. 2022

Sr. No	Specific Condition	Status of Compliance along with details
i	The Unit shall comply with all the Specific and General EC conditions, as mentioned in the existing ECs. The implementation report shall be submitted to the IRO, MoEF & CC in this regard.	Complied. EC Copy Attached as Annexure – 1 .
ii	As committed, the PP shall develop Greenbelt by planting 145 nos. of additional plants inside the existing plant in same area by increasing the plant density and additional 835 number of trees adjacent to the factory premises. The saplings selected for the plantation should be of sufficient height, preferably 6-ft (about 2 m). The budget earmarked for the plantation i.e. ₹ 18.53 Lakh shall be kept in separate account and should be audited annually. PP should annually submit the audited statement along with proof of activities viz. photographs (before & after with geo-location date & time), details of the expert agency engaged, details of species planted, number of species planted, survival rate, density of plantation etc. to the Regional Office of MoEF & CC before 1st July of every year for the activities carried out during the previous year.	We have started addition of new trees inside & outside premises, during monsoon season we plan to increase further plantation.
iii	A separate Environmental Management Cell (having qualified persons with Environmental Science / Environmental Engineering / specialization in the project area) equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions. PP shall engage Environment / occupational/health/safety, manager, Sr. Executive. In addition to this one safety & health officer as per the qualification given in Factories Act 1948 shall be engaged within a month of grant of EC. PP should annually submit the audited statement of amount spent towards the engagement of qualified persons in EMC along with details of person engaged to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during the previous year	A separate Environment Management cell is available at site having qualification like M. Tech and having well experience in the field. Team of chemist, operator and manager is available to maintain day to day activities.

iv	<p>The company shall comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, and risk mitigation measures relating to the project shall be implemented. The budget propose under EMP is ₹ 235.93 Lakhs (Capital cost) and ₹ 58.5 Lakhs (Recurring cost) shall be kept in separate account and should be audited annually. The PP should submit the annual audited statement along with proof of implementation of activities proposed under EMP duly supported by photographs (before & after with geo-location date & time) and other document as applicable to the Regional Office of MoEF &CC before 1st July of every year for the activities carried out during the previous year.</p>	We are maintaining compliance
v	<p>The total water requirement after expansion will be 83.2 KLD of which 61 KLD will be supplied by MIDC Waluj Supply and rest will be supplied from recycled water. The PP should ensure that Ground water utilization should not be above the permissible limit and only after obtaining valid NOC from CGWA/ Concerned Authority. The PP should submit the details of GW abstraction and utilization to the Regional Office of MoEF & CC before 1st July of every year for the activities carried out during the previous year. In addition to this the PP shall submit the target for reduction of GW utilization to Regional Office of MoEF & CC within a period of one year</p>	No ground water extraction facility is available and site. Site receives sufficient quantity of water from MIDC and rest is recycled by using installed ZLD facility.
vi	<p>No banned chemicals shall be manufactured by the PP. No banned raw materials shall be used in the unit. The PP shall adhere to the notifications/guidelines of the Government in this regard.</p>	Site do not manufacture any banned chemical as per the notification/guideline of the government in this regard.
vii	<p>The PP shall utilize modern technologies for capturing of carbon emitted and shall also develop carbon sink/carbon sequestration resources capable of capturing more than emitted. The implementation report shall be submitted to the IRO, MoEF&CC in this</p>	We are working on this proposal.

	regard.	
viii	The PP shall comply with the environment norms for Pharmaceuticals/Bulk Drugs Industry as notified by the Ministry of Environment, Forest and Climate Change, vide GSR 541(E), dated 06.08.2021 under the provisions of the Environment (Protection) Rules, 1986.	We are maintaining compliance to mentioned environment norms for Pharmaceutical/bulk Drugs industry as mentioned by the Ministry of Environment, Forest and climate change, vide GSR 541(E), dated 06.08.2021 under the provisions of the Environment (Protection) Rules, 1986.
ix	All necessary precautions shall be taken to avoid accidents and action plan shall be implemented for avoiding accidents. The PP shall implement the onsite/offsite emergency plan/mock drill etc. and mitigation measures as prescribed under the rules and guidelines issued in the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996.	On Site Emergency plan is available at & regular mock drills are conducted as per frequency. Mock Drill details are submitted to Directorate of Industrial Health & Safety (DISH) Aurangabad. Submission copy attached as Annexure 2 .
x	The volatile organic compounds (VOCs)/Fugitive emissions shall be controlled at 99.97 % with effective chillers/modern technology. Regular monitoring of VOCs shall be carried out.	All reactors are having provision of chilled brine condenser. Also primary & secondary condensers are available. VOC is measured and recorded using hand held VOC meter as well as through MoEF approved Laboratory. Report copy attached as Annexure 3 .
xi	The PP shall explore possibilities for recycling and reusing of treated water in the unit to reduce the fresh water demand and waste disposal.	ZLD system has been installed and Treated water is consumed in cooling tower to reduce fresh water demand and waste disposal
xii	As already committed by the PP, Zero Liquid Discharge shall be ensured, the total wastewater generation after expansion will be 25.2 KLD (Industrial: 21.2 KLD & Domestic: 4 KLD). Domestic sewage will be treated in STP, and rest of the wastewater will be treated in ETP with evaporator & RO. 22 KLD treated water from ETO-RO system will be completely reused within the premises while 4 KLD STP treated water will be reused in in-house gardening.	We are maintaining treatment of waste water through ETP, RO, and Evaporator system to maintain zero liquid discharge and ensuring treated water for cooling Tower makeup. Attached photograph of ZLD system in Annexure 4 .

xiii	Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB servers. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.	Continuous online (24x7) monitoring system for stack emissions has already been installed for measurement of flue gas discharge and the pollutants concentration, and the data is transmitted to the CPCB and MPCB servers. For online continuous monitoring of effluent, the unit has already installed web camera with night vision capability and flow meters are in place. CEMS Daily report copy attached as Annexure 5 .
xiv	The storage of toxic/hazardous raw material shall be bare minimum with respect to quantity and inventory. Quantity and days of storage shall be submitted to the Regional Office of Ministry and SPCB along with the compliance report.	Only required quantity of raw materials as per PPC is maintained at site in a secured location.
xv	The occupational health centre for surveillance of the worker's health shall be set up. The health data shall be used in deploying the duties of the workers. All workers & employees shall be provided with required safety kits/mask for personal protection.	Occupational health center is provided at facility. Periodic health check-up is maintained as per Factory Act requirement.
xvi	Training shall be imparted to all employees on safety and health aspects for handling chemicals. Safety and visual reality training shall be provided to employees. Action plan for mitigation measures shall be properly implemented based on the safety and risk assessment studies.	Regular safety trainings are imparted to all employees.
xvii	The unit shall make the arrangement for the protection of possible fire hazards during manufacturing process in material handling. Fire-fighting system shall be as per the norms.	Firefighting arrangements are in place, Ring type fire hydrant system is installed at site for handling fire emergency. Fire alarm and detection system is in place. Photos are attached in Annexure 6 .
xviii	The solvent management shall be carried out as follows:	
	a) Reactor shall be connected to chilled brine condenser system.	All reactors are connected with primary & secondary condenser & provision of chilled brine system is available. Photo Copy Attached as Annexure – 7 .

	b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.	Solvent transfer pumps are provided with mechanical seal & SCADA system is available transferring the solvent. Photo Copy attached as Annexure – 8.
	c) Solvents shall be stored in a separate space specified with all safety measures.	Solvent are stored in PESO approved area. PESO license Copy attached in Annexure- 9.
	d) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.	Proper earthing bonding provision are made at site for the equipment
	e) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.	Flame proof fittings are installed in plant areas
	f) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation	Solvent are stored in 200 Lts. Drums as per PESO permission.
xix	The storm water from the roof top shall be channelized through pipes to the storage tank constructed for harvesting of rain water in the premises and harvested water shall be used for various industrial processes in the unit. No recharge shall be permitted within the premises. Process effluent/ any wastewater shall not be allowed to mix with storm water	Rain Water harvesting is available from beginning of project.
xx	The PP shall undertake waste minimization measures as below	
	a) Metering and control of quantities of active ingredients to minimize waste;	Adequate measures are in place to control waste of material.
	b) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.	No bi-products are generated
	c) Use of automated filling to minimize spillage.	Solvent are transferred through the SCADA system.
	d) Use of Close Feed system into batch reactors.	All the solvents are transferred into the reactors through SCADA system.
	e) Venting equipment through vapor recovery system.	Complied.

	f) (Use of high pressure-hoses for equipment cleaning to reduce wastewater generation.	Complied.
Sr. No	General Condition	Status of Compliance along with detail
i	No further expansion or modifications in the plant, other than mentioned in the EIA Notification, 2006 and its amendments, shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change/SEIAA, as applicable. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry/SEIAA, as applicable, to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.	No new expansion or modification to plant
ii	The Project proponent shall strictly comply with the rules and guidelines issued under the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996, and Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016 and other rules notified under various Acts.	Noted
iii	The energy source for lighting purpose shall be preferably LED based, or advanced having preference in energy conservation and environment betterment	Old lights are replaced by LED lights for reduced energy consumption. Photos of installation is attached as Annexure- 10.
iv	The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under the Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).	Noise level are monitored on regular basis Reports attached in Annexure- 11.
v	The company shall undertake all relevant measures for improving the socioeconomic conditions of the surrounding area. The	Activities are maintained for improving socio economic conditions around local villages, 85% local villagers are preferred for providing with

	activities shall be undertaken by involving local villages and administration. The company shall undertake Eco developmental measures including community welfare measures in the project area for the overall improvement of the environment.	job in factory. Local vendors are preferred for supply, transportation etc.
vi	The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.	We are maintaining all expenses towards environmental operations, implementations with separate allotted budget to department.
vii	A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, ZillaParishad/Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.	No suggestion / representation were received while processing the proposal, however copy of clearance is available in public domain on Parivesh Portal.
viii	The project proponent shall also upload/submit six monthly reports on Parivesh Portal on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data to the respective Integrated Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.	Required submission of Six-Monthly compliance report is maintained. Last submission copy attached as Annexure – 12 .
ix	The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Integrated Regional Office of MoEF&CC by e-mail.	Form- V is submitted every year to MPCB through online portal herewith attaching as Annexure -13 .

x	The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry and at https://parivesh.nic.in/ . This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.	Information to public through advertise was given in two local papers.
xi	The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.	Required consent to operate obtained from State Pollution Control board after obtaining EC from MoEF.
xii	This Environmental clearance is granted subject to final outcome of Hon'ble Supreme Court of India, Hon'ble High Court, Hon'ble NGT and any other Court of Law, if any, as may be applicable to this project.	Noted.

ANNEXURE

1. Environmental Clearance Copy.
2. Other as mentioned above.



**ENVIRONMENTAL
CLEARANCE**

PARIVESH
*(Pro-Active and Responsive Facilitation by Interactive,
and Virtuous Environment Single-Window Hub)*



**Government of India
Ministry of Environment, Forest and Climate Change
(Impact Assessment Division)**

To,

The Vice President
AJANTA PHARMA LIMITED

Gut No. 378, Plot No. 8, Aurangabad-Pune Highway, Village-Waluj, Taluka-Gangapur, District-Aurangabad, Maharashtra, Aurangabad, Maharashtra-431136

Subject: Grant of Environmental Clearance (EC) to the proposed Project Activity under the provision of EIA Notification 2006-regarding

Sir/Madam,

This is in reference to your application for Environmental Clearance (EC) in respect of project submitted to the Ministry vide proposal number IA/MH/IND3/281546/2022 dated 04 Jul 2022. The particulars of the environmental clearance granted to the project are as below.

1. EC Identification No.	EC22A021MH178642
2. File No.	J-11011/359/2008-IA-II(I)
3. Project Type	Expansion7
4. Category	A
5. Project/Activity including Schedule No.	5(f) Synthetic organic chemicals industry (dyes & dye intermediates; bulk
6. Name of Project	Expansion of Active Pharmaceuticals Ingredients (API) Unit under Para 7(ii) of EIA Notification, 2006 at Gut No. 378, Plot No. 8, Aurangabad-Pune Highway, Village-Waluj, Taluka-Gangapur, District-Aurangabad, Maharashtra-431136 by M/s Ajanta Pharma Ltd.
7. Name of Company/Organization	AJANTA PHARMA LIMITED
8. Location of Project	Maharashtra
9. TOR Date	N/A

The project details along with terms and conditions are appended herewith from page no 2 onwards.

Date: 06/10/2022

(e-signed)
Mr. Motipalli Ramesh
Scientist E
IA - (Industrial Projects - 3 sector)

Note: A valid environmental clearance shall be one that has EC identification number & E-Sign generated from PARIVESH. Please quote identification number in all future correspondence.

This is a computer generated cover page.

F. No. J-11011/359/2008-IA-II (I)
Government of India
Ministry of Environment, Forest and Climate Change
(Impact Assessment Division)

Indira Paryavaran Bhawan,
Jorbagh Road,
New Delhi - 110003

Dated: 6th October, 2022

To

M/s Ajanta Pharma Limited

Gut No. 378, Plot No. 8, Aurangabad-Pune Highway,
Village-Waluj, Taluka-Gangapur,
District-Aurangabad, Maharashtra
Email: ajantapharmaeco@gmail.com

Subject: Expansion of APIs production capacity from 21.042 TPM to 23.6 TPM located at Gut No. 378, Plot No. 8, Aurangabad-Pune Highway, Village- Waluj, Taluka- Gangapur, District- Aurangabad, Maharashtra by Ajanta Pharma Limited - Environmental Clearance [Under Para 7 (ii)]

Sir,

This has reference to your proposal No. IA/MH/IND3/281546/2022 dated 4th July,2022 on the above subject matter.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for Environmental Clearance to the project for proposed Expansion of APIs from 21.042 TPM to 23.6 TPM, located at Gut No. 378, Plot No. 8, Aurangabad-Pune Highway, Village- Waluj, Taluka- Gangapur, District- Aurangabad, Maharashtra by Ajanta Pharma Limited.

3. The project/activity is covered under Category 'A' of item 5(f), Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates) of Schedule of Environment Impact Assessment (EIA) Notification, 2006 (as amended) as it is located outside the industrial area and appraised at Central Level by Expert Appraisal Committee (EAC).

4. The proposal was earlier placed in 33rd EAC Meeting held on 20-22 June, 2022, wherein the EAC returned the proposal for requisite information and the PP again applied for Environment Clearance on 4.7.2022 in Form-2 and submitted EIA/EMP Report and other documents. The PP reported in Form-2 that it is an expansion project under para 7(ii). The proposal was again placed in the 35th EAC Meeting held on July 28-29, 2022, wherein the PP and an accredited Consultant, Sadekar Enviro Engineers Pvt. Ltd. [Accreditation number NABET/EIA/2124/SA 0146 Valid up to 18.4.2023] made a detailed presentation on the salient features of the project and informed the following:

5. The PP reported that the proposed land area is 0.32005 Ha and no R & R is involved in the Project. The details of products and by-products are as follows:

S. No.	As per Environment Clearance granted		After proposed Expansion (As per OM vide F. No. 22-33/2019-IA.III dated 28 th January 2021)					
	Product	Allowed Capacity (MT/month)	Particulars of Products	Production Capacity (MT/month)	Remark			
1	Lumefantrine	0	API and intermediates	23.6	Addition of 9 no. of API products of total production capacity 2.558 TPM has been planned in the proposed expansion.			
2	Artemether	0						
3	Nepafenac	1.6						
4	Loteprednol Etabonate							
5	Bromfenac Sodium							
6	Prednisolone Acetate							
7	Tafluprost							
8	Iguratimod							
9	Desonide 21- Phosphate							
10	Levobetaxolol Hydrochloride							
11	Apremilast							
12	Difluprednate							
13	Mesalamine							
14	Nimesulide, Pilocarpine HCl							
15	Indomethacin							
16	Meclofenamate Sodium							
17	Fenspiride Chlorhydrate							
18	Fluorometholone Acetate							
19	Roflumilast, Atogepant							
20	Mometasone Furoate Monohydrate							
21	crisaborole	0.8						
22	Polmacoxib							
23	Piclidenoson							
24	Lifitegrast							
25	Betaxolol Hydrochloride							
26	Cyclosporine							
27	Dexamethasone							
28	Propyphenazone							
29	Dimethyl fumarate	0.7						
30	Triamcinolone Hexacetonide							
31	Apabetalone							
32	Amtolmetin Guacil							
33	Naproxinod							

34	Neramaxane Mesylate				
35	Tofacitinib Citrate				
36	Nadifloxacin				
37	Zucapsaicin				
38	Nalbuphine Sebacate	0.2			
39	Sufentanil Citrate				
40	Penicillamine	0.4			
41	Hydroxychloroquine sulphate				
42	Baricitinib				
43	Benvitimod				
44	Ilaprazole	0.6			
45	Lansoprazole sodium				
46	Lafutidine				
47	Dexlansoprazole	0.2			
48	Omeprazole Sodium				
49	Tegoprazan				
50	Diquafosol Tetrasodium				
51	Omidenepag Isopropyl	0.1			
52	Metaxalone	0.05			
53	Rebamipide	0.1			
54	Linaclotide	0.1			
55	Nitroglycerin	0.05			
56	Olopatadine Hydrochloride	0.332			
57	Bilastine				
58	Bepotastine Besilate				
59	Tacalcitol MH				
60	Palonosetron Hydrochloride				
61	Silodosin	0.1			
62	Fexapotide	0.1			
63	Mirabegron	0.1			
64	Colestipol Hydrochloride	0.1			
65	Aripiprazole	0.2			
66	Olanzapine	0.05			
67	Ropinirol HCl	0.1			
68	Latanoprost	0.12			
69	Brinzolamide				
70	Bimatoprost				
71	Ripasudil Hydrochloride Dihydrate	0.38			

72	Limaprost				
73	Netarsudil				
74	Latanoprostene Bunod				
75	Travoprost				
76	Brimonidine Tartrate				
77	Travilermide				
78	Glycerol	0.05			
79	Cortexolone 17a- Propionate	0.05			
80	Vilanterol trifenatate	0.05			
81	Rolapitant	0.05			
82	Varenicline Tartrate	0.05			
83	Ulipristal Acetate	0.05			
84	Dabigatran Etexilate	0.1			
85	Rivaroxaban	0.6			
86	Edoxaban				
87	Betrixaban				
88	Pentosan Polysulfate Sodium, Imeglimine HCl				
89	Elinogrel				
90	Divalproex sodium	0.05			
91	Ursodiol	0.01			
92	Raltegravir Potassium	0.35			
93	Maraviroc				
94	Daclatasvir Dihrochloride				
95	Valganciclovir Hydrochloride				
96	Simeprevir				
96	Gemifloxacin Mesylate	0.65			
97	Minocycline Hydrochloride				
98	Besifloxacin Hydrochloride				
99	Retapamulin				
100	Sodium Hyaluronate				
101	N-acetyl-L- carnosine				
102	Ospemifene		1		
103	Ozenoxacin				
104	Solithromycin				
105	Erythromycin Ethyl Succinate, Pemafibrate				
106	Moxifloxacin Hydrochloride				

107	Tobramycin				
108	Rifaximin				
109	Doxycycline Hyclate				
110	Doxycycline Monohydrate				
111	Levofloxacin Hemihydrate				
112	Sarecycline				
113	Nemonoxacin				
114	Flucloxacillin Sodium				
115	Amadacycline				
116	Almotriptan	1			
117	Sumatriptan				
118	Frovatriptan Succinate				
119	Lasmiditan				
120	Eletriptan Hydrobromide				
121	Zolmitriptan				
122	Rimegepant				
123	Sevelamer Carbonate				
124	Aclidinium Bromide	1.41			
125	Solifenacin Succinate				
126	Azelnidipine				
127	Cilnidipine				
128	Azilsartan Medoxomil Potassium				
129	Metoprolol Succinate				
130	Fimasartan Potassium Trihydrate				
131	Rosuvastatin calcium				
132	Efonidipine Hydrochloride Ethanolate				
133	Olmesartan				
134	Perindopril Arginine				
135	Phentermine Hydrochloride	0.8			
136	Sacubitril				
137	Nifedipine				
138	Chlorthalidone				
139	Diltiazem Hydrochloride				
140	Telmisartan				
141	Timolol Maleate				

142	Dalcetrapib Thiol				
143	Valsartan				
144	Ambrisentan				
145	Sacubitril- Valsartan				
146	Sacubitril- Telmisartan				
147	Polaprezinc	0.05			
148	Bempedoic acid	0.05			
149	Ivabradine Hydrochloride	0.1			
150	Delmopinol Hydrochloride	0.1			
151	Octenidine Hydrochloride				
152	Bibrocathol				
153	Lanthanum Carbonate	0.05			
154	Asenapine Maleate	0.1			
155	Clozapine				
156	Propafenone Hydrochloride	0.05			
157	Deferasirox	0.05			
158	Trientine Hydrochloride	0.05			
159	Cinacalcet Hydrochloride	0.03			
160	Tavaborole		0.4		
161	Efinaconazole				
162	Luliconazole				
163	Fenticonazole Nitrate	0.2			
164	Flucytosine				
165	Voriconazole				
166	Bremelanotide				
167	Topiroxostat				
168	L-Methylfolate Glucosamine	0.1			
169	Odanacatib	0.02			
170	Sapropterin Dihydrochloride	0.04			
171	Dendrimer	0.05			
172	Colesevelam Hydrochloride		0.9		
173	Teneligliptin Hydrobromide hydrate				
174	Sitagliptin Phosphate				
175	Alogliptin				
176	Vildagliptin				
177	Linagliptin				
178	Chiglitazar				

179	Canagliflozin Hemihydrate	1.2			
180	Dapagliflozin Propanediol Monohydrate				
181	Anagliptin				
182	Trelagliptin succinate				
183	Empagliflozin				
184	Ipragliflozin				
185	Saxagliptin				
186	Mirogabalin				
187	Sotagliflozin				
188	Canagliflozin				
189	Dapagliflozin Propanediol Monohydrate				
190	Dapagliflozin				
191	Lobeglitazone				
192	Luseogliflozin				
193	Tofogliflozin				
194	Gemigliptin				
195	Evogliptin				
196	Emixustat Hydrochloride				
197	Retagliptin Phosphate				
198	Ertugliflozin				
199	Omarigliptin				
200	Semaglutide				
201	Vardenafil HCl Trihydrate	0.7	0.3		
202	Sildenafil Citrate Mask				
203	Mirodenafil				
204	Sildenafil Citrate				
205	Tadalafil	0.1			
206	Dapoxetine Hydrochloride				
207	Ticagrelor				
208	Voclosporin	0.05			
209	Alcaftadine				
210	Azelastine Hydrochloride				
211	Cloperastine Fendizoate	0.1			
212	Acotiamide HCl Hydrate				
213	Obeticholic acid				
214	Ibrutinib	0.05			
215	Pirfenidone	0.05			

216	Vortioxetine HBr	0.05			
217	Hypochlorous Acid	0			
218	Apixaban				
219	Dienogest	0.05			
220	Carboxymethyl cellulose sodium	0.05			
221	Hydroquinone	0.05			
222	Pyridoxine Hydrochloride	0.05			
223	Ivacaftor	0.05			
224	Febuxostat	0.2			
225	Lesinurad	0.1			
226	Netupitant	0.05			
227	Indacaterol Maleate	0.05			
228	Vilazodone Hydrobromide	0.1			
229	Potassium Citrate	0.05			
230	Alosetron Hydrochloride	0.05			
231	Tizanidine Hydrochloride	0.05			
232	Isosorbide Mononitrate	0.07			
233	Entacapone	0.05			
234	Cytidine- 5' Disodium Monophosphate	0.1			
235	Uridine Diphosphate Disodium				
236	Phloroglucinol Dihydrate	0.1			
237	Triamcinolone Acetonide	0.07			
238	Spirironolactone	0.07			
239	Trimethyl Phloroglucinol	0			
240	Vadadustat	0.05			
241	Suvorexant	0.08			
242	Finerenone	0.05			
243	Vilaprisan	0.05			
244	Olumacostat Glasaretil	0.06			
245	Nolasiban	0.05			
246	Picotamide	0.4			
247	Clopidogrel bisulfate	0.3			
248	Montelukast Sodium	0.2			
249	R & D Project	0.3			
250	Elobixibat	0			
251	Flupirtine Maleate	0			

252	Cetilistat	0			
253	Cholestyramine	0			
254	Duloxetine Hydrochloride	0			
255	Omadacycline	0			
256	Finafloxacin Hydrochloride				
257	Cethromycin				
258	R & D Products	0.3			
259	Bexagliflozin	0			
TOTAL PRODUCTION CAPACITY		21.042		23.6	

6. The PP reported that earlier EC has been granted by the Ministry vide F. No. J-11011/359/2008-IA.II (I) dated 13.10.2020 (Increasing the number of API products from 85 to 259 within the total production capacity of 21.042 TPM). The project has been granted Certified Compliance by IRO, MoEF&CC vide F. No. EC-1506/RON/2022-NGP/9556 dated 11.04.2022 after site inspection on 12.3.2022.

7. The PP reported that there is no violation case as per the Notification No. S.O.804(E) dated 14.03.2017 and no direction is issued under E (P) Act/Air Act/Water Act.

8. The PP reported that there are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc. within 10 km distance from the project site. The PP reported that no forest land is involved for the proposed project. Kaum River is flowing at 1.13 km (E) from the project site. The PP reported that no Schedule-I species exist within 10 km study area of the project.

9. The PP reported that total water requirement after expansion will be 83.2 KLD of which 61 KLD will be supplied by MIDC Waluj Supply and rest will be supplied from recycled water. The total wastewater generation after expansion will be 25.2 KLD (Industrial: 21.2 KLD & Domestic: 4 KLD). Domestic sewage will be treated in STP, and rest of the wastewater will be treated in ETP with evaporator & RO. 22 KLD treated water from ETO-RO system will be completely reused within the premises while 4 KLD STP treated water will be reused in in-house gardening. The project will be maintaining the status of "**ZLD**" **Unit**. The PP submitted the copy of agreement with MIDC for water withdrawal.

10. The PP reported that the power requirement of the plant will be 450 kW which will be supplied by MSEDC. For power backup, 400 kVA DG set (with appropriate stack height as per CPCB norms) has already been installed on the site, which is used to run ETP, STP and common lights. Also, a separate 100 KVA DG has been installed for Zero Liquid Discharge scheme 1 no. of LDO based boiler has been installed in the plant with stack height of 30 m for controlling emissions within statutory limit.

11. Details of Process Emissions Generation and their Management:

Stack No.	Source	Height of Stack	Type of Fuel	Air Pollution Control System
1	Boiler	30	LDO (30 Lit/Hr)	Stack
2	Process Reactor	20	-	Venturi Scrubber
3	DG set of	4.5 above	Diesel (45 Lit/Hr)	Stack with acoustic

	400 KVA & 100 KVA	the roof		enclosure
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12. Details of Solid Waste Generation and its Management:

S. No.	Particulars	Hazardous Waste Category	Unit	Existing (As per CTO)	Total After Expansion	Method of Disposal
HAZARDOUS WASTE						
1	Spent Oil/Used Oil	5.1	lit/month	30	30	Sale to Authorized Recycler/Reprocess or CHWTSDF
2	Spent Solvents	20.2	TPM	7.5	7.5	Sale to Authorized Recycler/Reprocess or CHWTSDF
3	Distillation Residue	20.3	TPM	1.8	1.83	Disposal of CHWTSDF
4	Spent Catalyst/Spent Carbon	28.2	TPM	0.75	0.75	Disposal of CHWTSDF
5	Empty barrels/containers /liners/contaminated with hazardous chemicals/waste	33.1	No./month	265	265	Sale to Authorized Recycler/Reprocess or CHWTSDF
6	Sludge from Wastewater Treatment	35.3	TPM	0.2	0.2	Disposal of CHWTSDF
7	Off-specification Products	28.4	TPM	1.2	1.2	Disposal of CHWTSDF
8	Spent organic Solvent	28.6	TPM	18.0	18.36	Sale to Authorized Recycler/Reprocess or CHWTSDF
NON-HAZARDOUS WASTE						
1	Wooden material	-	kg/month	400	400	Sale to Authorized Recycler
2	Glass Scrap	-	kg/month	400	400	
3	HDPE Drums	-	No./month	125	125	
4	Plastic Scrap	-	kg/month	200	200	
5	Paper Waste	-	kg/month	150	150	
6	E-Wastes	-	kg/annum	100	100	

13. The PP has submitted the following pollution load information as per Ministry's O.M. dated 28.01.2021 w.r.t permissible pollution load i.e., quantity and quality, including composition of emissions, discharge and solid waste generation.

EFFLUENT WATER (Kg/month)							
Water input per kg	TDS load	COD Load	Total effluent	Organic residue	Spent Carbon (Kg/month)	Spent solvent	Spent organic solvent
13202.83	36.45	136.87	13158.17	61.00	24.91	257.35	612.16

14. The Budget earmarked towards Environmental Management Plan (EMP) is ₹ 235.93 lakhs (capital) and the Recurring cost (operation and maintenance) will be about ₹58.5 lakhs per annum which includes Air Pollution control [₹ 23.8 lakh (capital) and ₹ 1.5 lakh/annum (Recurring)], ETP [₹ 164.3 lakh (capital) and ₹ 34 lakh/annum (Recurring)], Noise Pollution Control [₹ 2.5 lakh (capital) and ₹ 0.5 lakh/annum (Recurring)], Environmental Monitoring & Management [₹ 4.8 lakh/annum (Recurring)], Occupational Health and others [₹2 lakh/annum (Recurring)], Green Belt Development [₹ 18.53 lakh (capital) and ₹ 3.7 lakh/annum (Recurring)] and Solid & Hazardous Waste Management [₹ 4.8 lakh (capital), ₹ 7.5 lakh (Recurring)], PEE'S [₹ 2.5 lakh/annum (Recurring, Online Effluent monitoring system [₹ 22 lakh (capital) ₹ 2 lakh (Recurring)], Industry proposes to allocate ₹ 11.41 crore towards CER.

15. The PP has developed a green belt in 790 m² i.e., 24.7% of total plot area. Additionally, the industry has developed 1 Acres of land as greenbelt adjacent to the factory premises and has also started plantation work adjacent to the factory premises and till date, about 176 trees have been planted. Now, it is proposed to plant additional 550 no. of trees in this plot. The PP has earmarked a budget of ₹18.53 lakh for development of greenbelt inside and outside the plant area in proposed expansion.

16. The PP proposed to set up an Environment Management Cell (EMC) by engaging Environment/ occupational/health/safety, manager, Sr. Executive for the functioning of EMC.

17. The PP submitted that the Total Carbon sequestered per year by the existing plantation (inside plant and outside plant premises) will be 12159 tons per year, considering the 10-year-old Greenbelt of 145 trees inside the plant premises and 835 trees outside the plant premises (total Trees 980). Assuming the diameter and tree height at the age of 10 years as per the standards, the total Carbon sequestered per year by the proposed greenbelt at its initial age will be **105 tons per year**.

18. The PP submitted the disaster and Onsite and Offsite Emergency Plans in the EIA report.

19. The PP submitted an undertaking with reference to O.M. No. J-11013/41/2006-IA. II (I) dated 5.10.2011 "*I hereby give undertake that the data and information given in EIA Report and the enclosures are true to the best of my knowledge and content (information*

and data) in the EIA Report pertains to the project and not being copied from other EIA reports. I am aware that if at any stage, it is observed or brought to notice to the Ministry of Environment, Forest and Climate Change that the contents of the EIA Report pertains to a project have been copied from other EIA reports, such projects shall be summarily rejected and proponent will have to initiate the process including conduct of Public Hearing and in case of those project where decision has already been taken and environment clearance granted based on copied EIA Report, the environment clearance granted would be withdrawn and the procedure for obtaining environmental clearance will be initiated de-novo. Also, I own the contents of the EIA Report.”

20. The estimated project cost is ₹ 14.90 Crore. The existing manpower of the project is 75 no. There will be no additional manpower requirement for the proposed expansion. Hence, employment generation is not envisaged.

21. The EAC, constituted under the provision of the EIA Notification, 2006 comprising of Expert Members/domain experts in various fields, examined the proposal submitted by the PP in the desired formats along with reports prepared and submitted by the Consultant accredited by the QCI/ NABET on behalf of the PP.

The EAC noted that the PP has given an undertaking that the data and information given in the application and enclosures are true to the best of their knowledge and belief and no information has been suppressed in the reports. If any part of data/information submitted is found to be false/ misleading at any stage, the project will be rejected and Environmental Clearance given, if any, will be revoked at the risk and cost of the PP.

The EAC noted that the EIA reports are in compliance of the ToR issued for the project, reflecting the present environmental status and the projected scenario for all the environmental components. The Committee deliberated on the proposed mitigation measure towards Air, Water, Noise and Soil pollutions. The Committee suggested that the storage of toxic/explosive raw materials/products shall be undertaken with utmost precautions and following the safety norms and best practices.

The EAC deliberated on the water agreement made between the PP and the MIDC for water withdrawal and suggested to submit the Agreement and the PP submitted the same, EAC also suggested to submit the undertaking for no violation, and for Owning of Data. The PP submitted the same.

The EAC deliberated on the Onsite and Offsite Emergency plans and various mitigation measures to be proposed during implementation of the project and advised the PP to implement the provisions of the Rules and guidelines issued under the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996.

The EAC deliberated on the proposal with due diligence in the process as notified under the provisions of the EIA Notification, 2006, as amended from time to time and accordingly made the recommendations to the proposal. The Expert Members of the EAC found the proposal in order and **recommended for grant of environmental clearance**. The minutes of the meeting and all the project documents are available on PARIVESH portal which can be accessed at <http://parivesh.nic.in>.

The recommendation of EAC and grant of environmental clearance by regulatory authority to the project/activity is strictly under the provisions of the EIA Notification 2006 and its subsequent amendments. It does not tantamount/construe to approvals/consent/permissions etc. required to be obtained or standards/conditions to be followed under any other Acts/ Rules/ Subordinate legislations, etc., as may be applicable to the project. The project proponent shall obtain necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and

Control of Pollution) Act, 1981, as applicable from time to time, from the State Pollution Control Board, prior to construction & operation of the project.

22. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-3), the Ministry of Environment, Forest and Climate change hereby accords Environmental clearance to the project for **Expansion of APIs production capacity from 21.042 TPM to 23.6 TPM located at Gut No. 378, Plot No. 8, Aurangabad-Pune Highway, Village- Waluj, Taluka- Gangapur, District- Aurangabad, Maharashtra by Ajanta Pharma Limited** under the provisions of the EIA Notification, 2006, subject to the compliance of terms and conditions as under:-

A. Specific Conditions:

- (i) The Unit shall comply with all the Specific and General EC conditions, as mentioned in the existing ECs. The implementation report shall be submitted to the IRO, MoEF&CC in this regard.
- (ii) As committed, the PP shall develop Greenbelt by planting 145 nos. of additional plants inside the existing plant in same area by increasing the plant density and additional 835 number of trees adjacent to the factory premises. The saplings selected for the plantation should be of sufficient height, preferably 6-ft (about 2 m). The budget earmarked for the plantation i.e. ₹ 18.53 Lakh shall be kept in separate account and should be audited annually. PP should annually submit the audited statement along with proof of activities viz. photographs (before & after with geo-location date & time), details of the expert agency engaged, details of species planted, number of species planted, survival rate, density of plantation etc. to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during the previous year.
- (iii) A separate Environmental Management Cell (having qualified persons with Environmental Science/Environmental Engineering/specialization in the project area) equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions. PP shall engage Environment/ occupational/health/safety, manager, Sr. Executive. In addition to this one safety & health officer as per the qualification given in Factories Act 1948 shall be engaged within a month of grant of EC. PP should annually submit the audited statement of amount spent towards the engagement of qualified persons in EMC along with details of person engaged to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during the previous year.
- (iv) The company shall comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, and risk mitigation measures relating to the project shall be implemented. The budget propose under EMP is ₹ 235.93 Lakhs (Capital cost) and ₹ 58.5 Lakhs (Recurring cost) shall be kept in separate account and should be audited annually. The PP should submit the annual audited statement along with proof of implementation of activities proposed under EMP duly supported by photographs (before & after with geo-location date & time) and other document as applicable to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during the previous year.
- (v) The total water requirement after expansion will be 83.2 KLD of which 61 KLD will be supplied by MIDC Waluj Supply and rest will be supplied from recycled water. The PP should ensure that Ground water utilization should not be above the permissible limit

and only after obtaining valid NOC from CGWA/ Concerned Authority. The PP should submit the details of GW abstraction and utilization to the Regional Office of MoEF&CC before 1st July of every year for the activities carried out during the previous year. In addition to this the PP shall submit the target for reduction of GW utilization to Regional Office of MoEF&CC within a period of one year

- (vi) No banned chemicals shall be manufactured by the PP. No banned raw materials shall be used in the unit. The PP shall adhere to the notifications/guidelines of the Government in this regard.
- (vii) The PP shall utilize modern technologies for capturing of carbon emitted and shall also develop carbon sink/carbon sequestration resources capable of capturing more than emitted. The implementation report shall be submitted to the IRO, MoEF&CC in this regard.
- (viii) The PP shall comply with the environment norms for Pharmaceuticals/Bulk Drugs Industry as notified by the Ministry of Environment, Forest and Climate Change, vide GSR 541(E), dated 06.08.2021 under the provisions of the Environment (Protection) Rules, 1986.
- (ix) All necessary precautions shall be taken to avoid accidents and action plan shall be implemented for avoiding accidents. The PP shall implement the onsite/offsite emergency plan/mock drill etc. and mitigation measures as prescribed under the rules and guidelines issued in the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996.
- (x) The volatile organic compounds (VOCs)/Fugitive emissions shall be controlled at 99.97 % with effective chillers/modern technology. Regular monitoring of VOCs shall be carried out.
- (xi) The PP shall explore possibilities for recycling and reusing of treated water in the unit to reduce the fresh water demand and waste disposal.
- (xii) As already committed by the PP, Zero Liquid Discharge shall be ensured, the total wastewater generation after expansion will be 25.2 KLD (Industrial: 21.2 KLD & Domestic: 4 KLD). Domestic sewage will be treated in STP, and rest of the wastewater will be treated in ETP with evaporator & RO. 22 KLD treated water from ETO-RO system will be completely reused within the premises while 4 KLD STP treated water will be reused in in-house gardening.
- (xiii) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB servers. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.
- (xiv) The storage of toxic/hazardous raw material shall be bare minimum with respect to quantity and inventory. Quantity and days of storage shall be submitted to the Regional Office of Ministry and SPCB along with the compliance report.

- (xv) The occupational health centre for surveillance of the worker's health shall be set up. The health data shall be used in deploying the duties of the workers. All workers & employees shall be provided with required safety kits/mask for personal protection.
- (xvi) Training shall be imparted to all employees on safety and health aspects for handling chemicals. Safety and visual reality training shall be provided to employees. Action plan for mitigation measures shall be properly implemented based on the safety and risk assessment studies.
- (xvii) The unit shall make the arrangement for the protection of possible fire hazards during manufacturing process in material handling. Fire-fighting system shall be as per the norms.
- (xviii) The solvent management shall be carried out as follows: (a) Reactor shall be connected to chilled brine condenser system. (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages. (c) Solvents shall be stored in a separate space specified with all safety measures. (d) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done. (e) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses. (f) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (xix) The storm water from the roof top shall be channelized through pipes to the storage tank constructed for harvesting of rain water in the premises and harvested water shall be used for various industrial processes in the unit. No recharge shall be permitted within the premises. Process effluent/ any wastewater shall not be allowed to mix with storm water.
- (xx) The PP shall undertake waste minimization measures as below (a) Metering and control of quantities of active ingredients to minimize waste; (b) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes. (c) Use of automated filling to minimize spillage. (d) Use of Close Feed system into batch reactors. (e) Venting equipment through vapor recovery system. (f) Use of high pressure-hoses for equipment cleaning to reduce wastewater generation.

B. General Conditions:

- (i) No further expansion or modifications in the plant, other than mentioned in the EIA Notification, 2006 and its amendments, shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change/SEIAA, as applicable. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry/SEIAA, as applicable, to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- (ii) The Project proponent shall strictly comply with the rules and guidelines issued under the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989, as amended time to time, the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996, and Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016 and other rules notified under various Acts.
- (iii) The energy source for lighting purpose shall be preferably LED based, or advanced

having preference in energy conservation and environment betterment.

- (iv) The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under the Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- (v) The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. The activities shall be undertaken by involving local villages and administration. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- (vi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.
- (vii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad/Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.
- (viii) The project proponent shall also upload/submit six monthly reports on Parivesh Portal on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data to the respective Integrated Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
- (ix) The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Integrated Regional Office of MoEF&CC by e-mail.
- (x) The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry and at <https://parivesh.nic.in/>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.
- (xi) The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

(xii) This Environmental clearance is granted subject to final outcome of Hon'ble Supreme Court of India, Hon'ble High Court, Hon'ble NGT and any other Court of Law, if any, as may be applicable to this project.

23. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.

24. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of the Environment (Protection) Act, 1986.

25. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

26. The above conditions shall be enforced, *inter-alia* under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of Law relating to the subject matter.

This issues with approval of the competent authority.

(Dr. Motipalli Ramesh)
Scientist 'E'

Copy to: -

1. The Deputy DGF (C), MoEF&CC Regional Office(WCZ), Ground Floor, East Wing, New Secretariat Building, Civil Line, Nagpur - 1
2. The Secretary, Environment Department, Government of Maharashtra, 15th Floor, New Administrative Building, Mantralaya, Mumbai - 32
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, Delhi - 32
4. The Member Secretary, Maharashtra Pollution Control Board, Kalpataru Point, 3rd and 4th Floor, Opp. Cine Planet, Sion Circle, Mumbai – 22
5. The Member Secretary, Central Ground Water Authority, Jamnagar House, 18/11, Man Singh Road Area, New Delhi, Delhi 110001
6. The District Collector, District Aurangabad, Maharashtra
7. Guard File/Monitoring File/PARIVESH

(Dr. Motipalli Ramesh)
Scientist 'E'
Tel. 011-20819249
Email: ramesh.motipalli@nic.in

Signature Not Verified
Digitally signed by Mr. Motipalli
Ramesh
Scientist E
Date: 10/6/2022 12:06:12 PM

Ref: APL/EHS/22-23/020

Mar 15, 2023

To,

**The Joint Director,
Industrial Health & Safety,
Aurangabad.**

Sub: Submission of Mock Drill report Mar - 23.

Respected Sir,

With reference to above subject, we are herewith submitting the "Mock Drill" detail report. To assess emergency preparedness, response time of various teams & performance of the existing emergency system the drill commenced at our site on Mar 09, 2023.

This is for your information & record.

Thanking You

Your faithfully

For Ajanta Pharma Limited

15-3-23

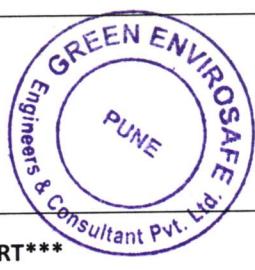
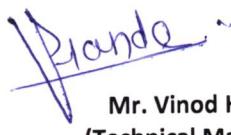
Authorized Signature

Encl: As mentioned above.



29/3/2023
लू. संख्या ५०, अंग्रेजी सुला
- अरोग्य संस्थान, मातृस्थान विभाग
काशगार संख्या ५०८, १ से महान्
रुद्रपुर राजस्थान, कोटा जनपद
राजस्थान ४३१ ००९

Recognised by Ministry of Environment and Forests (MoEF) / Central Pollution Control Board Govt. of India (CPCB) and ISO/IEC 17025:2017 (NABL), ISO 9001:2015, ISO 45001 : 2018 and ISO 14001 : 2015 Certified Company

TEST REPORT			
Test Report No: -	GESEC/PRO/WZM/2022-23/02/362	Report Date	28/02/2023
Sample ID-	GESEC/PRO/WZM/2022-23/02/362		
Name & Address of the Customer	M/S. Ajanta Pharma Limited Gut No.378, P.No.8, Aurangabad Pune Highway Waluj, Aurangabad-431133		
WORK ZONE AIR Sample Details			
Type	Sampling Location	Sampling done by	
Work zone Air	Production Area First Floor	Envirotech Research Private Limited	
Sampling Time			
Start Time	Stop Time	Total Hrs.	
11.40 AM	12.40 PM	1 Hrs.	
Metrological Data/Environmental Conditions			
Ambient Temperature °C	26.8		
Relative Humidity % RH	35		
Date of Sampling	Sample Receipt Date	Analysis Start Date	Analysis End Date
20/02/2023	21/02/2023	21/02/2023	27/02/2023
PO No	4100191253	PO Date	15-01-2023
Name of Instrument	Handy Sampler (PMP 06)		
Date of Calibration	01-07-2022	Due Date of Calibration	30-06-2023
Calibration Certificate No.	Digital timer (ACE/SD/ENVIROTECH2107C PMP 12) Flow Meter (ACE/SD/ENVIROTECH2107C PMP 11)		
Parameters	Method	Unit	As per Factory Act
RSPM	IS 5182 (Part 4): 2006 (RA 2005)	mg/m³	N.S.
SO2	IS 5182 (Part 2): 2001 (RA 2012)	mg/m³	<5000
HCL	EPA Method	mg/m³	N.S.
Remark-	<ul style="list-style-type: none"> ➤ All Limits within as per Factory act. N.S.: Not Specified. 		
		  Mr. Vinod Hande (Technical Manager) Reviewed & Authorized By	

END OF REPORT

Page 1 of 1

Terms and conditions

- The report is refer only to the sample tested and not applies to the bulk.
- The results shown in this test report may differ based on various factors including temperature, humidity, pressure, retention time etc.
- The test report cannot be reproduced wholly or in part and cannot be used for promotional or publicity purpose without the written consent of laboratory, GESEC.
- Samples will be retained for a period of seven (7) days after completion of analysis. Longer retention periods can be arranged, on request of the customer.
- We strictly maintain the confidentiality of all test result of sample(s) collected by us/ supplied by customer and not reveal to third party unless required by the statutory or legal requirement.
- MoEF approved Lab by Govt. of India. From date. 16/02/2022 to 29/02/2024.

Zero Liquid Discharge Facility.



After Primary, Secondary & Tertiary Treatment, ETI Treated water feeds to Reverse Osmosis (RO) Plant.



After the RO Treatment
The Rejected RO Stream
feeds to Evaporator Plant



The Treated Water from Evaporator plant (Process Condensate) is transferred through Magnetic Flow Meter where OCEMS camera is installed.



The Treated Water from RO (RO Permeate) is transferred through Magnetic Flow Meter where OCEMS Camera is installed.



All the Treated water from RO & Evaporator is used for cooling tower make up (Recycle & Reuse)



Maharashtra Pollution Control Board

Site Name: Ajanta Pharma Ltd

Report: Average Report

From Date: 2023-05-01 14:45 To Date: 2023-05-02 14:30

Description		Stack_1-PM(mg/Nm3)
Prescribed Standards		0 - 50
Maximum Data		34.57
Minimum Data		26.04
Geometric Mean		29.03
Median		28.51
Standard Deviation		1.96
Maximum Value At Time		2023-05-02 04:15:00
Minimum Value At Time		2023-05-01 22:00:00
Valid Data Points		96
Total Data Points		96
Data Availability %		100.0%

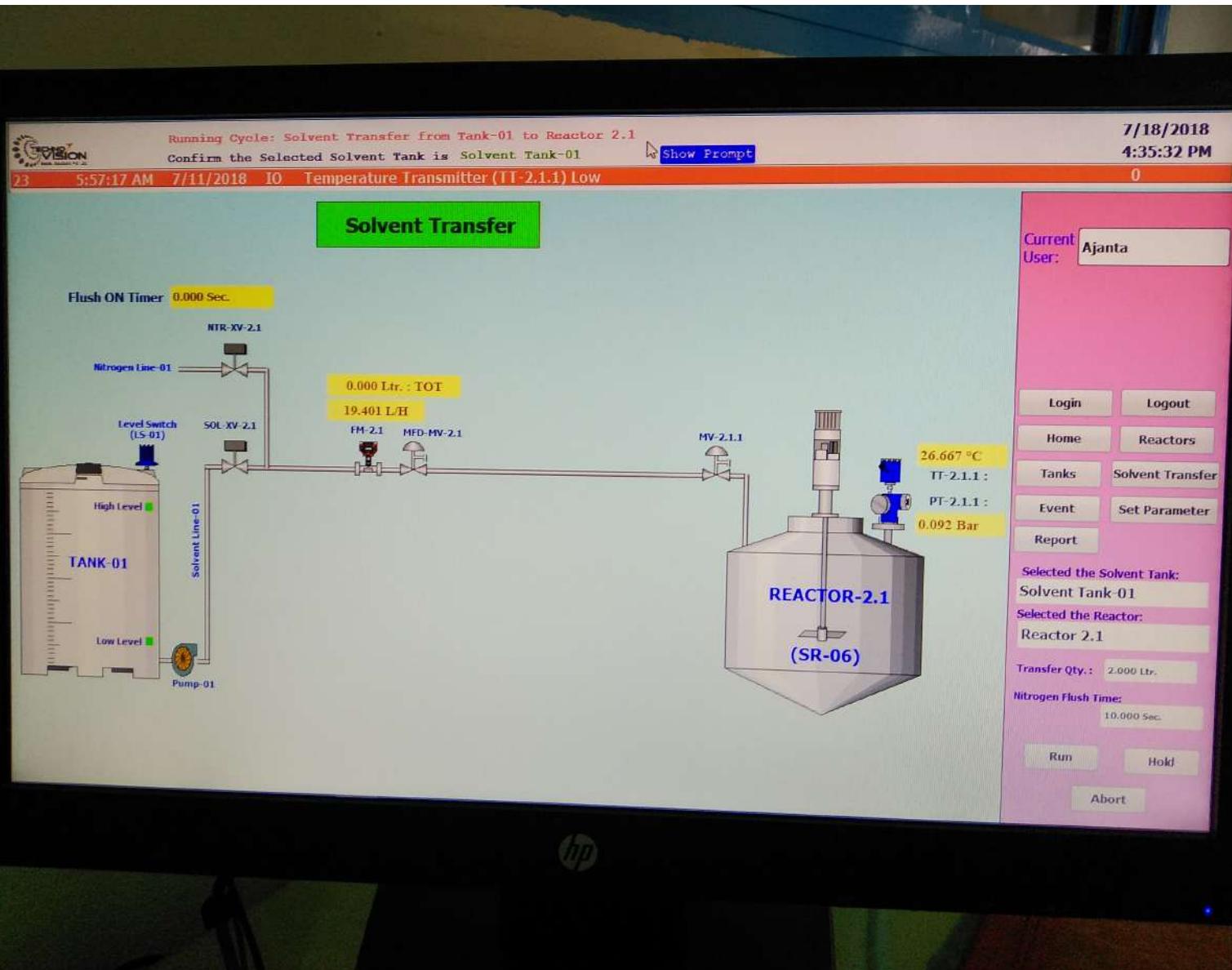
SI No	Time	Stack_1-PM(mg/Nm3)
1	2023-05-01 14:45:00	32.99
2	2023-05-01 15:00:00	28.29
3	2023-05-01 15:15:00	30.29
4	2023-05-01 15:30:00	31.37
5	2023-05-01 15:45:00	28.69
6	2023-05-01 16:00:00	31.75
7	2023-05-01 16:15:00	28.43
8	2023-05-01 16:30:00	26.58
9	2023-05-01 16:45:00	27.99
10	2023-05-01 17:00:00	29.51
11	2023-05-01 17:15:00	28.38
12	2023-05-01 17:30:00	28.91
13	2023-05-01 17:45:00	27.32
14	2023-05-01 18:00:00	27.27
15	2023-05-01 18:15:00	32.62
16	2023-05-01 18:30:00	32.92
17	2023-05-01 18:45:00	27.75
18	2023-05-01 19:00:00	27.74
19	2023-05-01 19:15:00	26.83
20	2023-05-01 19:30:00	27.42
21	2023-05-01 19:45:00	28.01
22	2023-05-01 20:00:00	28.74
23	2023-05-01 20:15:00	28.63
24	2023-05-01 20:30:00	31.22
25	2023-05-01 20:45:00	26.58
26	2023-05-01 21:00:00	28.70

Fire Fighting System



Fugitive Emission Control Measures







भारत सरकार

Government of India

वाणिज्य और उद्योग मंत्रालय

Ministry of Commerce & Industry

पेट्रोलियम तथा विस्फोटक सुरक्षा संगठन (पीसो)

Petroleum & Explosives Safety Organisation (PESO)

ए-१ और ए-२ विंग, पांचवा तल, केंद्रीय कार्यालय परिसर, सी.डी.डी. बेलापुर

नवी मुंबई (महा.)- 400614

A1 & A2 wing, 5th Floor, C.G.O. complex, CBD Belapur, Navi Mumbai (M.S.), Mumbai - 400614

E-mail: jtccemumbai@explosives.gov.in

Phone/Fax No 022 27575946 27573881

दिनांक /Dated 14/12/2018

संख्या /No : P/WC/MH/16/607 (P227511)

सेवा में /To,

M/S. AJANTA PHARMA LIMITED.,
 Aurangabad -Pune Highway (KM STONE-11),
 Waluj, Tal -Gangapur,
 Waluj,
 Aurangabad,
 Taluka: Gangapur,
 District: AURANGABAD,
 State: Maharashtra
 PIN: 431136

20 नवंबर २०१८

विषय /Sub: Plot No, GUT NO.- 378, PLOT NO.- 8, AURANGABAD-PUNE HIGHWAY, 11 KM Stone, WALUJ, TAL- GANGAPUR, District: AURANGABAD, State: Maharashtra, PIN: 999999 में स्थित विट्यगाल पेट्रोलियम घर्ग A अंकरण शेड -अनुज्ञित सं P/WC/MH/16/607 (P227511) - नवीकरण के संदर्भ में

Existing Petroleum Class A Storage Shed at Plot No, GUT NO.- 378, PLOT NO - 8, AURANGABAD-PUNE HIGHWAY 11 KM Stone, WALUJ, TAL- GANGAPUR, District: AURANGABAD, State: Maharashtra, PIN 999999 P/WC/MH/16/607 (P227511) -Reg Renewal of Licence

महोदय /Sir
(s),

कृपया आपके पावर क्रमांक - दिनांक 15/11/2018 का अवलोकन करें।
 Please refer to your letter No. - , dated 15/11/2018

अनुज्ञित संख्या P/WC/MH/16/607 (P227511) दिनांक 31/07/2012 दिनांक 31/12/2023 तक नवीनीकृत कर इस पर के साथ लैटडे जा रही है।

Licence No. P/WC/MH/16/607 (P227511) dated 31/07/2012 is returned herewith duly renewed upto 31/12/2023.

कृपया पेट्रोलियम नियम 2002 के अधीन बनाए गए नियम 148 में दी गई प्रक्रिया का कड़ाई से पालन करें। अनुज्ञित के नवीकरण हेतु समस्त दस्तावेजों को अनुज्ञित की वैधता समाप्त होने की तिथि से कम से कम 30 दिन पूर्व to Jt. Chief Controller of Explosives, West Circle, Mumbai, so as to reach his कार्यालय को प्रेषित करें।

Please follow the procedure strictly as laid down in rule 148 of the Petroleum Rules, 2002 and submit complete documents for the Renewal of the licence to Jt. Chief Controller of Explosives, West Circle, Mumbai, so as to reach his office at least thirty days before the date on which Licence expires.

कृपया पावती दें।

Please acknowledge the receipt.

राबिन्द्र जैन (Yours faithfully)
 Rabindra Jain
 Biruly

((राबिन्द्र जैन बिरली)
 (RABINDRA JAIN BIRULY))
 उप विस्फोटक नियंत्रक
 Dy. Controller of Explosives
 केंद्रीय समन्वय विस्फोटक नियंत्रक
 For Jt. Chief Controller of Explosives
 नवी मुंबई (महा.)/Mumbai

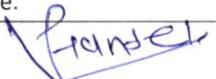
(अधिक जानकारी जैसे आवेदन की स्थिति, शुल्क तथा अन्य विवरण के लिए हमारी वेबसाइट : <http://peso.gov.in> देखें।
 (For more information regarding status, fees and other details please visit our website: <http://peso.gov.in>)



Recognised by Ministry of Environment and Forests (MoEF) / Central Pollution Control Board Govt. of India (CPCB)
 and ISO/IEC 17025:2017 (NABL), ISO 9001:2015, ISO 45001 : 2018 and ISO 14001 : 2015 Certified Company

TEST REPORT

Test Report No: -	GESEC/PRO/WNLM/2023-24/04/306		Report Date	29/04/2023
Sample ID:	GESEC/PRO/WNLM/2023-24/04/306			
Name & Address of the Customer	M/S. Ajanta Pharma Limited Gut No.378, P.No.8, Aurangabad Pune Highway Waluj, Aurangabad-431133			
Work Zone Noise Sample Details				
Type	Work Zone Noise			
Sampling done by	Envirotech Research Private Limited			
Standard method	As Per IS: 9876 : 1981			
Date of Sampling	24/04/2023			
PO No	4100201269	PO Date	20-04-2023	
Instrument/ Calibration Details				
Name of Instrument	Noise Meter (GB:2301167)			
Date of Calibration	01-07-2022	Due Date of Calibration	30-06-2023	
Calibration Certificate No.	Digital Sound Level Meter (ACE/SD/ENVIROTECH2207A 1)			
Test Location	Unit	Noise Level Readings Average	The Factories Act 1948, standards	
NEAR COMPRESOR	dB (A)	82.0	≤90	
Remark- ➤ The Factories Act, 1948, has prescribed 90 dB (A) as an upper limit of noise level for 8 hours exposure.				



 Mr. Vinod Hande
 (Technical Manager)
 Reviewed & Authorized By

*****END OF REPORT*****
Terms and conditions

- The report is refer only to the sample tested and not applies to the bulk.
- The results shown in this test report may differ based on various factors including temperature, humidity, pressure, retention time etc.
- The test report cannot be reproduced wholly or in part and cannot be used for promotional or publicity purpose without the written consent of laboratory, GESEC.
- Samples will be retained for a period of seven (7) days after completion of analysis. Longer retention periods can be arranged, on request of the customer.
- We strictly maintain the confidentiality of all test result of sample(s) collected by us/ supplied by customer and not reveal to third party unless required by the statutory or legal requirement.
- MoEF approved Lab by Govt. of India. From date. 16/02/2022 to 29/02/2024.



Gut No. 378, P.No. 8,
A'bad-Pune Highway,
Village - Waluj (Bk),
Aurangabad - 431 133
Maharashtra - INDIA

T +91 240 6718 201
F +91 240 6718 208
E info@ajantapharma.com
W www.ajantapharma.com

Ref: APL/EHS/22-23/021

Dec 01, 2022

To,

Deputy Director General of Forests (Central),
West Central Zone, Regional Office
Near Secretariat Building, opp. VCA Ground
Civil Lines, Nagpur-440001

Subject: Submission of six monthly EC compliance report for Active pharmaceutical ingredients manufacturing plant "Ajanta Pharma Ltd." at Gut no 378, Plot No 08, village Waluj, 11 KM stone, Aurangabad, Maharashtra.

Ref EC orders: MoEF Clearance No. J-11011/359/2008-1A-II (I) dated October 13, 2020.

Respected Sir,

Pertaining to the above cited captioned subject, we are enclosing herewith six monthly (July 2022 – Dec 2022) condition wise compliance report of Environmental Clearance for Part-A specific conditions and Part-B general condition of our active Pharmaceutical Ingredients (API's) manufacturing plant at Gut no 378, Plot No 08, village Waluj, 11 KM stone, Aurangabad, Maharashtra.

Kindly acknowledge the receipt of the same.

Thanking You

For Ajanta Pharma Limited

S P Kolhe
(Plant Head)
Authorized Signature

CC: 1. Regional Officer MPCB, Aurangabad.

2. Member Secretary, CPCB New Delhi.

Encl: 1. Data sheet

2. Six Monthly Compliance report (details compliance of EC Conditions).

3. Additional details (monitoring Report, etc attached as Annexure)



Maharashtra Pollution Control Board

महाराष्ट्र प्रदूषण नियंत्रण मंडळ

FORM V

(See Rule 14)

Environmental Audit Report for the financial Year ending the 31st March 2022

Unique Application Number

MPCB-ENVIRONMENT_STATEMENT-0000047558

Submitted Date

26-09-2022

PART A

Company Information

Company Name

Ajanta Pharma Limited

Application UAN number

MPCB-CONSENT-0000099235/CO-2101001039

Address

Plot No. 08, Gut No. 378, 11 Km
Stone, Aurangabad Pune Highway,
Village Waluj, Taluka Gangapur,
District Aurangabad.

Plot no

Plot No. 08

Taluka

Gangapur

Village

Waluj

Capital Investment (In lakhs)

1490

Scale

LSI

City

Aurangabad

Pincode

431133

Person Name

Pankaj Barbind, Shashikant Kolhe

Designation

Sr. Manager Corporate EHS, DGM Manufacturing

Telephone Number

02406718204

Fax Number

02406718208

Email

pankaj.barbind@ajantapharma.com

Region

SRO-Aurangabad I

Industry Category

Red

Industry Type

R58 Pharmaceuticals

Last Environmental statement submitted online

yes

Consent Number

AS(T)/UAN No. 0000099235/CO-2101001039

Consent Issue Date

2021-01-22

Consent Valid Upto

2022-08-31

Establishment Year

2009

Date of last environment statement submitted

Sep 30 2021 12:00:00:000AM

Industry Category Primary (STC Code) & Secondary (STC Code)

Product Information

Product Name

CILNIDIPINE

Consent Quantity

16.92

Actual Quantity

1.0475

UOM

MT/A

BRINZOLAMIDE

1.44

0.046

MT/A

LOTEPREDNOL ETABONATE

1.6

0.029

MT/A

NEPAFENAC

1.6

0.011

MT/A

IGURATIMOD

1.6

0.204

MT/A

EFONIDIPINE

16.92

0.109

MT/A

AZELNIDIPINE	16.92	0.063	MT/A
NETRASUDIL	4.56	0.00038	MT/A
VALSARTAN	9.6	0.857	MT/A
SILDENAFIL CITRATE MASK COMPLEX	3.6	0.449	MT/A
DAPAGLIFLOZIN	14.4	0.016	MT/A
TOFACITINIB CITRATE	8.4	0.011	MT/A
VERDENAFIL HCL TRIHYDRATE	8.4	0.108	MT/A
RIPASUDIL HYDROCHLORIDE	4.56	0.008	MT/A
R&D PROJECT	3.6000	0.033	MT/A

By-product Information

By Product Name	Consent Quantity	Actual Quantity	UOM
NA	0	0	MT/A

Part-B (Water & Raw Material Consumption)

1) Water Consumption in m3/day

Water Consumption for Process	Consent Quantity in m3/day	Actual Quantity in m3/day
Cooling	21.50	4.00
Domestic	47.20	18.00
All others	5.00	5.00
Total	8.50	2.00
	82.20	29.00

2) Effluent Generation in CMD / MLD

Particulars	Consent Quantity	Actual Quantity	UOM
Trade Effluent	20.2	4	CMD
Domestic Effluent	4	3	CMD

2) Product Wise Process Water Consumption (cubic meter of process water per unit of product)

Name of Products (Production)	During the Previous financial Year	During the current Financial year	UOM
CILNIDIPINE	62	53	KL/A
VALSARTAN	30	48	KL/A
SILDENAFIL CITRATE MASK COMPLEX	208	234	KL/A
BRINZOLAMIDE	8.2	5.1	KL/A
NEPafenac	1.72	13	KL/A

3) Raw Material Consumption (Consumption of raw material per unit of product)

Name of Raw Materials	During the Previous financial Year	During the current Financial year	UOM
NA	0	0	MT/A

4) Fuel Consumption

Fuel Name	Consent quantity	Actual Quantity	UOM
LDO	175.33	30	KL/A

Part-C

Pollution discharged to environment/unit of output (Parameter as specified in the consent issued)

[A] Water

Pollutants Detail	Quantity of Pollutants discharged (kL/day)	Concentration of Pollutants discharged(Mg/Lit) Except PH,Temp,Colour	Percentage of variation from prescribed standards with reasons	Standard Reason		
				Quantity	Concentration	%variation
pH	0	7.4	-	5.5 to 9	ZLD Facility, Treated effluent from RO & Evaporator is recycled for cooling tower makeup.	
TDS	0.4	100	-	2100	ZLD Facility, Treated effluent from RO & Evaporator is recycled for cooling tower makeup.	
COD	0.248	62	-	100	ZLD Facility, Treated effluent from RO & Evaporator is recycled for cooling tower makeup.	

[B] Air (Stack)

Pollutants Detail	Quantity of Pollutants discharged (kL/day)	Concentration of Pollutants discharged(Mg/NM3)	Percentage of variation from prescribed standards with reasons	Standard Reason		
				Quantity	Concentration	%variation
TPM	0.030	19.2	-	50	-	
SOx	0.28	16.5	-	50	-	

Part-D

HAZARDOUS WASTES

1) From Process

Hazardous Waste Type	Total During Previous Financial year	Total During Current Financial year	UOM
20.3 Distillation residues	3.190	4.629	MT/A
28.3 Spent carbon	0.763	0.975	MT/A
20.2 Spent solvents	88.37	83.298	MT/A
28.6 Spent organic solvents	10	7.591	MT/A
33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	490	450	Nos./Y

2) From Pollution Control Facilities

Hazardous Waste Type	Total During Previous Financial year	Total During Current Financial year	UOM
35.3 Chemical sludge from waste water treatment	1.307	1.434	MT/A

Part-E

SOLID WASTES

1) From Process

Non Hazardous Waste Type	Total During Previous Financial year	Total During Current Financial year	UOM
Wooden material	50	45	Kg/Annum
Glass Scrap	789	610	Kg/Annum

Paper Waste	450	398	Kg/Annum
HDPE Drums	300	272	Nos./Y

2) From Pollution Control Facilities

Non Hazardous Waste Type	Total During Previous Financial year	Total During Current Financial year	UOM
0	0	0	MT/A

3) Quantity Recycled or Re-utilized within the unit

Waste Type	Total During Previous Financial year	Total During Current Financial year	UOM
5.1 Used or spent oil	0.04	0.026	MT/A

Part-F

Please specify the characteristics(in terms of concentration and quantum) of hazardous as well as solid wastes and indicate disposal practice adopted for both these categories of wastes.

1) Hazardous Waste

Type of Hazardous Waste Generated	Qty of Hazardous Waste	UOM	Concentration of Hazardous Waste
20.3 Distillation residues	4.629	MT/A	Semi Solid Material, Disposal to MEPL for Incineration.
28.3 Spent carbon	0.975	MT/A	Semi Solid Material, Disposal to MEPL for Incineration.
20.2 Spent solvents	83.298	MT/A	Liquid Form Waste, Recycled through MPCB Authorized Recycler.
28.6 Spent organic solvents	7.591	MT/A	Liquid Form Waste, Recycled through MPCB Authorized Recycler.
33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	450	Nos./Y	Sale to MPCB Authorized Recycler after the Decontamination.
35.3 Chemical sludge from waste water treatment	1.434	MT/A	Semi Solid Material, Disposal to MEPL for Incineration.

2) Solid Waste

Type of Solid Waste Generated	Qty of Solid Waste	UOM	Concentration of Solid Waste
Wooden Scrap	45	Kg/Annum	Solid
Glass Scrap	610	Kg/Annum	Solid
Paper Waste	398	Kg/Annum	Solid
HDPE Drum	272	Nos./Y	Solid

Part-G

Impact of the pollution Control measures taken on conservation of natural resources and consequently on the cost of production.

Description	Reduction in Water Consumption (M3/day)	Reduction in Fuel & Solvent Consumption (KL/day)	Reduction in Raw Material (Kg)	Reduction in Power Consumption (KWH)	Capital Investment(in Lacs)	Reduction in Maintenance(in Lacs)
Zero Liquid Facility	4	0	0	0	30	0
Oriface at water lines	2	0	0	0	0.2	0

Part-H

Additional measures/investment proposal for environmental protection abatement of pollution, prevention of pollution.

[A] Investment made during the period of Environmental Statement

<i>Detail of measures for Environmental Protection</i>	<i>Environmental Protection Measures</i>	<i>Capital Investment (Lacks)</i>
Camera on Main Entrance	Compliance of HW notification	1.0
Automatic Solvent Transfer System through SCADA	Compliance of Consent Condition	12
Electrical Drum Unloading Trolley	Environmental Protection from Spillage of Chemicals	1

[B] Investment Proposed for next Year

Detail of measures for Environmental Protection Environmental Protection Measures Capital Investment (Lacks)

Green Belt maintenance	Environmental Protection	5.0
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Part-I

Any other particulars for improving the quality of the environment.

Particulars

Company has developed its own environmental policy & is committed to continuous improvement. we are continuously improving & adopting changes as suggested by regulator

Name & Designation

Pankaj Barbind

UAN No:

MPCB-ENVIRONMENT_STATEMENT-0000047558

Submitted On:

26-09-2022

MAHARASHTRA POLLUTION CONTROL BOARD

Tel: 24010706/24010437

Fax: 24023516

Website: <http://mpcb.gov.in>

Email: ast@mpcb.gov.in



Kalpataru Point, 2nd and
4th floor, Opp. Cine Planet
Cinema, Near Sion Circle,
Sion (E), Mumbai-400022

RED/L.S.I (R58)

Date: 14/11/2022

**No:- Format1.0/AS(T)/UAN No.MPCB-
CONSENT-0000142933/CR/2211001077**

To,

M/s. Ajanta Pharma Ltd.

**Gut No. 378, Plot No. 8,11 km Stone,
Aurangabad-Pune Highway, Village Waluj,
Tal. Gangapur, Dist. Aurangabad.**



Your Service is Our Duty

Sub: Grant of Renewal of Consent to Operate under Red/LSI category.

Ref:

1. Previous Consent to Operate accorded by Board vide Consent No. Format 1.0/AS(T)/UAN No. 0000099235/CO-2101001039, Date. 22.01.2021 valid upto 31.08.2022.
2. Environmental Clearance granted vide F.No. J-11011/359/200/-IA II(I), dated 13/10/2020.

Your application No.MPCB-CONSENT-0000142933 Dated 04.07.2022

For: Grant of Consent to Operate under Section 26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization under Rule 6 of the Hazardous & Other Wastes (Management & Transboundary Movement) Rules 2016 is considered and the consent is hereby granted subject to the following terms and conditions and as detailed in the schedule I, II, III & IV annexed to this order:

1. **The consent to renewal is granted for a period up to 31/08/2023**
2. **The capital investment of the project is Rs.14.90 Crs. (As per C.A Certificate submitted by industry Existing CI is-Rs. 14.90 Crs + Expansion/Increase in C.I. - Rs. 0.00 Crs)**
3. **Consent is valid for the manufacture of:**

Sr No	Product	Maximum Quantity	UOM
Products			
1	Nepafenac, Loteprednol Etabonate, Bromfenac Sodium, Prednisolone Acetate, Tafluprost, Igratimod, Desonide 21 - Phosphate, Levobetaxolol HCl, Apremilast, Difluprednate, Mesalamine, Nimesulide, Indomethacin, Meclofenamate Sodium, Fenspiride Chlorhydrate, Fluorometholone acetate, Roflumilast, Mometasone Furoate Monohydrate	1.6	MT/A
2	Crisaborole, Polmacoxib, Piclidenoson, Lifitegrast, Betaxolol HCL, Cyclosporine, Dexamethasone, Propyphenazone, Dimethyl Fumarate, Triamcinolone, Apabetalone	0.8	MT/M

Sr No	Product	Maximum Quantity	UOM
3	Amtolmetin Guacil, Naproxinod, Neramaxane Mesylate, Tofacitinib Citrate, Nadifloxacin, Zucapsaicin	0.7	MT/M
4	Nalbuphine Sebacate, Sufentanil Citrate	0.2	MT/M
5	Penicillamine, Hydroxychloroquine, Baricitinib, Benvitimod	0.4	MT/M
6	Ilaprazole, Lansoprazole Sodium, Lafutidine	0.6	MT/M
7	Dexlansoprazole, Omeprazole Sodium, Tegoprazan, Diquafosol Tetrasodium	0.2	MT/M
8	Omidenepag Isopropyl	0.1	MT/M
9	Metaxalone	0.05	MT/M
10	Rebamipide	0.1	MT/M
11	Linaclotide	0.1	MT/M
12	Nitroglycerin	0.05	MT/M
13	Olopatadine HCL, Bilastine, Bepotastine Besilate, Tacalcitol MH, Palonosetron HCL, Flupirtine Maleate	0.332	MT/M
14	Silodosin	0.1	MT/M
15	Fexapotide	0.1	MT/M
16	Mirabegron	0.1	MT/M
17	Colestipol HCL	0.1	MT/M
18	Aripiprazole	0.2	MT/M
19	Olanzapine	0.05	MT/M
20	Ropinirol HCl	0.1	MT/M
21	Latanoprost, Brinzolamide, Bimatoprost	0.12	MT/M
22	Ripasudil Hydrochloride Hydrate, Limaprost, Netarsudil, Latanoprostene Bunod, Travoprost, Brimonidine Tartrate, Tavilermide	0.38	MT/M
23	Glycerol	0.05	MT/M
24	Cortexolone 17a-Propionate	0.05	MT/M
25	Vilanterol trifenatate	0.05	MT/M
26	Rolapitant	0.05	MT/M
27	Varenicline Tartrate	0.05	MT/M
28	Ulipristal Acetate	0.05	MT/M
29	Dabigatran Etexilate Mesylate	0.1	MT/M
30	Rivaroxaban, Edoxaban, Betrixaban, Pentosan Polysulfate Sodium, Elinogrel	0.6	MT/M
31	Divalproex Sodium	0.05	MT/M

Sr No	Product	Maximum Quantity	UOM
32	Ursodiol	0.01	MT/M
33	Raltegravir Potassium, Maraviroc, Daclatasvir Dihydrochloride, Valganciclovir, Simeprevir	0.35	MT/M
34	Gemifloxacin Mesylate, Minocycline HCl, Besifloxacin HCL, Retapamulin, Sodium Hyaluronate, N-acetyl-L-carnosine	0.65	MT/M
35	Ospemifene, Ozenoxacin, Solithromycin, Erythromycin Ethyl, Moxifloxacin HCL, Tobramycin, Rifaximin, Doxycycline Hyclate, Doxycycline Monohydrate, Levofloxacin Hemihydrate, Sarecycline, Nemonoxacin, Flucloxacillin Sodium, Amadacycline	1	MT/M
36	Almotriptan, Sumatriptan, Frovatriptan Succinate, Lasmiditan, Eletriptan HBr, Zolmitriptan, Rimegepant, Sevelamer Carbonate	1	MT/M
37	Aclidinium Bromide, Solifenacin Succinate, Azelnidipine, Cilnidipine, Azilsartan Medoxomil Potassium, Metoprolol Succinate, Fimasartan Potassium Trihydrate, Rosuvastatin Calcium, Efondipine Hydrochloride Ethanolate, Olmesartan, Perindopril Arginine	1.41	MT/M
38	Phentermine Hydrochloride, Sacubitril, Nifedipine, Chlorthalidone, Diltiazem Hydrochloride, Telmisartan, Timolol maleate, Dalcetrapib, Valsartan, Ambrisentan, Sacubitril- Valsartan, Sacubitril- Telmisartan	0.8	MT/M
39	Polaprezinc	0.05	MT/M
40	Bempedoic Acid	0.05	MT/M
41	Cholestyramine, Ivabradine HCL	0.1	MT/M
42	Delmopinol Hydrochloride , Octinidine HCL, Bibrocathol	0.1	MT/M
43	Lanthanum Carbonate	0.05	MT/M
44	Asenapine Maleate, Clozapine	0.1	MT/M
45	Propafenone HCL	0.05	MT/M
46	Deferasirox	0.05	MT/M
47	Trintine Hydrochloride	0.05	MT/M
48	Cinacalcet HCl	0.03	MT/M
49	Tavaborole, Efinaconazole, Luliconazole	0.4	MT/M
50	Fenticonazole Nitrate, Flucytosine, Voriconazole, Bremelanotide, Topiroxostat	0.2	MT/M
51	L-Methyl folate Glucosamine	0.1	MT/M
52	Odanacatib	0.02	MT/M
53	Sapropterin Dihydrochloride	0.04	MT/M
54	Dendrimer	0.05	MT/M
55	Colesevelam HCl, Teneligliptin Hydrobromide Hydrate, Sitagliptin Phosphate, Alogliptin, Vildagliptin, Linagliptin, Chiglitazar	0.9	MT/M

Sr No	Product	Maximum Quantity	UOM
56	Canagliflozin Hemihydrate, Dapagliflozin Propanediol Monohydrate, Anagliptin, Trelagliflozin Succinate, Empagliflozin, Ipragliflozin, Saxagliptin, Mircogabalin, Sotagliflozin, Canagliflozin, Dapagliflozine Propanediol, Dapagliflozin, Lobeglitazone, Luseogliflozin, Tofogliflozin, Gemigliptin, Evogliptin, Emixustat HCl, Retagliptin Phosphate, Ertugliflozin, Omarigliptin, Semaglutide	1.2	MT/M
57	Vardenafil HCl Trihydrate	0.7	MT/M
58	Sildenafil citrate Mask Complex, Mirodenafil, Sildenafil citrate, Tadalafil	0.3	MT/M
59	Dapoxetine HCl	0.1	MT/M
60	Ticagrelor, Voclosporin	0.05	MT/M
61	Alcaftadine	0.1	MT/M
62	Azelastine HCl, Cloperastine Fendzoate	0.1	MT/M
63	Acotiamide Hydrochloride Hydrate	0.3	MT/M
64	Obeticholic Acid	0.05	MT/M
65	Ibrutinib	0.05	MT/M
66	Pirfenidone	0.05	MT/M
67	Vortioxetine HBr	0.05	MT/M
68	Dienogest	0.05	MT/M
69	Carboxymethyl cellulose Sodium	0.05	MT/M
70	Hydroquinone	0.05	MT/M
71	Pyridoxine HCl	0.05	MT/M
72	Ivacaftor	0.05	MT/M
73	Febuxostat	0.2	MT/M
74	Lesinurad	0.1	MT/M
75	Netupitant	0.05	MT/M
76	Indacterol Maleate	0.05	MT/M
77	Vilazodone Hydrobromide	0.1	MT/M
78	Potassium Citrate	0.05	MT/M
79	Alosetron HCl	0.05	MT/M
80	Tizanidine HCl	0.05	MT/M
81	Isosorbide Mononitrate	0.07	MT/M
82	Entacapone	0.05	MT/M
83	Cytidine-5'-disodium monophosphate, Uridine Diphosphate	0.1	MT/M
84	Phloroglucinol Dihydrate	0.1	MT/M
85	Spironolactone	0.07	MT/M
86	Triamcinolone Acetonide	0.07	MT/M
87	Vadadustat	0.05	MT/M
88	Suvorexant	0.08	MT/M
89	Finerenone	0.05	MT/M
90	Vilaprisan	0.05	MT/M

Sr No	Product	Maximum Quantity	UoM
91	Olumacostat Glasaretil	0.06	MT/M
92	Nolasiban	0.05	MT/M
93	Picotamide	0.4	MT/M
94	Clopidogrel Bisulfate	0.3	MT/M
95	Montelukast Sodium	0.2	MT/M
96	R&D Project for study purpose	0.3	MT/M

Total Production quantity shall not exceed 21.042 TPM.

4. Conditions under Water (P&CP), 1974 Act for discharge of effluent:

Sr No	Description	Permitted (in CMD)	Standards to	Disposal Path
1.	Trade effluent	20.2	As per Schedule-I	Recycle 100% to achieve ZLD
2.	Domestic effluent	4.0	As per Schedule-I	On land for gardening

5. Conditions under Air (P& CP) Act, 1981 for air emissions:

Sr No.	Stack No.	Description of stack / source	Number of Stack	Standards to be achieved
1	S-1	Boiler	1	As per Schedule -II
2	S-2	Process Reactor	1	As per Schedule -II
3	S-3	D.G. Set of 400 KVA	1	As per Schedule -II
4	S-4	D.G. Set of 100 KVA	1	As per Schedule -II

6. Non-Hazardous Wastes:

Sr No	Type of Waste	Quantity	UoM	Treatment	Disposal
1	Wooden Material	400	Kg/M	Sale	Sale to Authorized Recycler
2	Glass Scrap	400	Kg/M	Sale	Sale to Authorized Recycler
3	HDPE Drums	125	No/M	Sale	Sale to Authorized Recycler
4	Paper Waste	150	Kg/M	Sale	Sale to Authorized Recycler

7. Conditions under Hazardous & Other Wastes (M & T M) Rules 2016 for treatment and disposal of hazardous waste:

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal
1	5.1 Used or spent oil	30.00	Ltr/M	Recycle*	Sale to authorised party / CHWTSDF
2	20.2 Spent solvents	7.50	MT/M	Recycle*	Sale to authorised party / CHWTSDF

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal
3	20.3 Distillation residues	1.80	MT/M	Preprocessing/Co-processing /Incineration	Co-processor through Authorized Preprocessor/ /CHWTSDF
4	28.2 Spent catalyst	0.75	MT/M	Recycle*	Sale to authorised party / CHWTSDF
5	33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	265	No/M	Recycle	Sale to authorised party / CHWTSDF
6	35.3 Chemical sludge from waste water treatment	200	Kg/M	Landfill after treatment	CHWTSDF
7	28.4 Off specification products	1.20	MT/M	Preprocessing/Co-processing /Incineration	Co-processor through Authorized Preprocessor/ /CHWTSDF
8	28.6 Spent organic solvents	18.00	MT/M	Recycle*	Sale to authorised party / CHWTSDF

* The applicant shall ensure disposal to the Actual user having permissions under Rule 9 of Hazardous and Other Wastes (M&TM) Rules, 2016.

8. **Conditions under Plastic Waste Management Rules, 2016 (Notification dtd. 18/03/2016):**

Sr No	Type of Waste	Quantity	UoM	Disposal Path
1	Plastic Scrap & Kachra	200.00	Kg/M	Sale to Authorized Recycler

9. **Conditions under E-Waste Management:**

Sr No	Type of Waste	Quantity	UoM	Disposal Path
1	E-Waste	100.00	Kg/Annum	Sale to Authorized Recycler

- The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding on the industry.
- This consent should not be construed as exemption from obtaining necessary NOC/ permission from any other Government authorities.

12. The Project Proponent shall also comply with the Industry specific standards notified under Environmental Protection Act, 1986.
13. The applicant shall comply with the conditions stipulated in Environmental Clearance granted vide letter dtd. 13/10/2020 and shall ensure display/upload six monthly compliance monitoring report on their official website.
14. The industry shall obtain necessary permission from the Directorate of Industrial Safety and Health (DISH).
15. The applicant shall not carry out any excess production or produce new products without Consent of the Board and without Environmental Clearance wherever it applicable.
16. The applicant shall properly collect, transport & regularly dispose-off the Hazardous Waste to CHWTSDF, in compliance of the Hazardous and other Waste (M & TH) Rule-2016 through online manifest system.
17. This Consent is issued without prejudice to the order passed as may be passed by the Hon'ble NGT, in the matter O.A. No. 1038/2018.
18. Industry shall comply the Boards Circular dtd. 05.02.2020 for use of cleaner fuel.
19. The industry shall dispose the by-products as Hazardous waste and shall comply the provisions of Hazardous & Other Wastes (M & TM) Rules,2016.
20. The industry shall ensure connectivity online monitoring system to the MPCB server including separate energy meter for pollution control system.
21. The applicant shall make an application for renewal of consent 60 days prior to date of expiry of the consent to operate.
22. This consent is issued as per the delegation of powers to HOD's vide Board Office Order No. 12 of 2020, dated 23/12/2020.



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Signed by: **Dr. V.M.Motghare**
Assistant Secretary (Technical)
For and on behalf of,
Maharashtra Pollution Control Board
ast@mpcb.gov.in
2022-11-14 17:43:52 IST

Received Consent fee of -

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	50000.00	MPCB-DR-13051	08/07/2022	NEFT

Copy to:

1. Regional Officer, MPCB, Aurangabad and Sub-Regional Officer, MPCB, Aurangabad I
 - They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Sion, Mumbai
3. CC/CAC desk- for record & website Updation purpose.

SCHEDULE-I
Terms & conditions for compliance of Water Pollution Control:

1. A] As per your application, you have provided Effluent Treatment Plant (ETP) of designed capacity of 25.00 CMD consisting of Primary (Collection tank, Neutralization tank, Equalization tank, Primary Clarifier/Primary Settling Tank), Secondary (Activated sludge process), Tertiary (Pressure sand filter, Activated carbon filter), Advanced treatment (Reverse osmosis, Multi effective evaporator), Sludge treatment ((Centrifuge and Sludge Drying Beds) for the treatment of 20.2 CMD of trade effluent.
 - B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent and recycle the entire treated effluent into the process for various purposes such as for cooling, process & Scrubbing with metering system so as to achieve Zero Liquid Discharge. There shall be no discharge on land or outside factory premises.
 - C] Industry shall install ensure the continuous operation of online continuous monitoring system as per CPCB guidelines & data to be transmitted directly from Data Logger to Board server .
2. A] As per your application, you have provided Sewage Treatment Plant of designed capacity 10 CMD for the treatment of 4.0 CMD of sewage.
 - B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards.

Sr.No	Parameters	Standards (mg/l)	
1	Suspended Solids	Not to exceed	100 mg/l
2	BOD (3 days 27 Deg. C.)	Not to exceed	30 mg/l

- C] The treated sewage shall be recycled for secondary purposes to the maximum extent and remaining shall be discharged on land for gardening within premise after confirming above standards. In no case, sewage shall find its way for gardening / outside factory premises.
3. The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification there of & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or an extension or addition thereto.
4. The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.
5. The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Act, 1974 and as amended, by installing water meters and other provisions as contained in the said act:

Sr. No.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	47.20

Sr. No.	Purpose for water consumed	Water consumption quantity (CMD)
2.	Domestic purpose	5.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	21.50
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00
5.	Gardening	8.50

6. The Applicant shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance/ CREP guidelines.



SCHEDULE-II
Terms & conditions for compliance of Air Pollution Control:

- As per your application, you have provided the Air pollution control (APC) system and erected following stack (s) to observe the following fuel pattern:

Stack No.	Source	APC System provided/proposed	Stack Height(in mtr)	Type of Fuel	Sulphur Content(in %)	Pollutant	Standard
S-1	Non IBR Boiler	Stack	30.00	LDO/HSD 30 Ltr/Hr	1.8	TPM	50 Mg/Nm ³
						SO2	20.73 Kg/Day
S-2	Process Reactor Vent	Packed Bed Wet	22.00	-	-	Acid Mist	35 Mg/Nm ³
						SO2 (process)	50 PPM
						NH3	15 Mg/Nm ³
						TPM	50 Mg/Nm ³
S-3	Non IBR Boiler	Acoustic Enclosure Stack	4.50	HSD 25 Ltr/Hr	1	SO2	3.2 Kg/Day
						TPM	50 Mg/Nm ³
S-4	Non IBR Boiler	Acoustic Enclosure Stack	4.50	HSD 20 Ltr/Hr	1	SO2	2.5 Kg/Day

(D.G Set stack height shall be above roof of building)

- The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance / CREP guidelines.
- The applicant shall operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

Parameters	Standards (mg/l)	
Total Particulate Matter	Not to exceed	50 mg/ Nm3
Process SO2	Not to exceed	50 mg/ Nm3
NH3	Not to exceed	5 ppm
Hydrobromic Acid Mist	Not to exceed	35 mg/ Nm3

- The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
- The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).
- Solvent Management shall be carried out as follows:
 - Reactors shall be connected to Water / Chilled Water /Brine Condenser system.
 - Reactors and solvent handling pumps shall have mechanical seals to prevent the leakages.
 - The condensers shall be provided with adequate Heat transfer area (HTA) and residence time so as to achieve more than 97% overall recovery

- d. Solvents shall be stored in a separate space specified with all safety measures.
- e. Proper earthing shall be provided in all the equipment's, wherever solvent handling is done.
- f. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- g. All the solvent storage tanks shall be connected with vent condensers with Water / chilled water / Brine circulation.
- h. Fugitive emissions shall be controlled at 99.95% with effective chillers.
- i. Solvent transfer shall be through pump.
- j. Metering and control of quantities of active ingredients to minimize wastes.
- k. Use of automatic filling to minimize spillage.
- l. Use of close feed system into batch reactors.
- m. Venting equipment through vapour recovery system.

SCHEDULE-III
Details of Bank Guarantees:

Sr. No .	Consent (C2E/ C2O /C2R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C to O	Rs. 5 Lakhs	Extension of Existing B.G.	Towards Compliance of Consent Conditions	31/08/2023	28/02/2024
2	C to E	Rs. 5 Lakhs	Extension of Existing B.G.	Towards obtaining Environmental Clearance and provision of ZLD for Entire Effluent generated from existing as well as expansionCompliance of Consent Conditions	31/08/2023	28/02/2024

****Existing BG obtained for above purpose if any, may be extended for period of validity as above.**

BG Forfeiture History

Srno.	Consent (C2E/C2O/C2R)	Amount of BG imposed	Submission Period	Purpose of BG	Amount of BG Forfeiture	Reason of BG Forfeiture
1	NA	NA	NA	NA	NA	NA

BG Return details

Srno.	Consent (C2E/C2O/C2R)	BG imposed	Purpose of BG	Amount of BG Returned
1	NA	NA	NA	NA

SCHEDULE-IV
General Conditions:

1. The waste generator shall.-
 - a) take steps to minimize generation of plastic waste and segregate plastic waste at source in accordance with the Plastic Waste Management Rules, 2016 or as amended from time to time.
 - b) not litter the plastic waste and ensure segregated storage of waste at source and handover segregated waste to urban local body or gram panchayat or agencies appointed by them or registered waste pickers', registered recyclers or waste collection agencies;
2. All institutional generators of plastic waste, shall segregate and store the waste generated by them in accordance with the Plastic Waste Management Rules, 2016 amendment from time to time and handover segregated wastes to authorized waste processing or disposal facilities or deposition centers either on its own or through the authorized waste collection agency.
3. All waste generators shall pay such user fee or charge as may be specified in the byelaws of the local bodies for plastic waste management such as waste collection or operation of the facility thereof, etc.;
4. Every person responsible for organizing an event in open space, which involves service of food stuff in plastic or multilayered packaging shall segregate and manage the waste generated during such events in accordance with the Plastic Waste Management Rules, 2016 amendment from time to time.
5. Consumers or bulk consumers of electrical and electronic equipment listed in Schedule I shall ensure that e-waste generated by them is channelised through collection centre or dealer of authorised producer or dismantler or recycler or through the designated take back service provider of the producer to authorised dismantler or recycler
6. Bulk consumers of electrical and electronic equipment listed in Schedule I shall maintain records of e-waste generated by them in Form-2 and make such records available for scrutiny by the concerned State Pollution Control Board
7. Consumers or bulk consumers of electrical and electronic equipment listed in Schedule I shall ensure that such end-of-life electrical and electronic equipment are not admixed with e-waste containing radioactive material as covered under the provisions of the Atomic Energy Act, 1962 (33 of 1962) and rules made there under;
8. Bulk consumers of electrical and electronic equipment listed in Schedule I shall file annual returns in Form-3, to the concerned State Pollution Control Board on or before the 30th day of June following the financial year to which that return relates. In case of the bulk consumer with multiple offices in a State, one annual return combining information from all the offices shall be filed to the concerned State Pollution Control Board on or before the 30th day of June following the financial year to which that return relates.
9. Specific Conditions for storage, Handling and Disposal of Waste from Electrical & Electronic equipment (WEEE):
 1. **Collection of WEEE** - The applicant must provide appropriate and dedicated vehicles duly identified as per the norms for transportation of Hazardous Waste. The applicant shall obtain all the required permits for transportation of WEEE from competent authority. The applicant shall ensure the safe transport of the WEEE without any spillage during transportation.

Storage for disassembled parts: The applicant must provide appropriate storage for disassembled spare parts from WEEE. Some spare parts (e.g. motors and compressors) will contain oil and/or other fluids. Such part must be appropriately segregated and stored in containers that are secured such that oil and other fluids cannot escape from them. These containers must be stored on an area with an area with an impermeable surface and a sealed drainage system.

2. **Storage for other components and residues:** Other components and residues arising from the treatment of WEEE will need to be contained following their removal for disposal or recovery. Where they contain hazardous substances they should be stored on impermeable surface and in appropriate containers or bays with weatherproof covering. Containers should be clearly labelled to identify their contents and must be secured so that liquids, including rain water cannot enter them. Components should be segregated having regard to their eventual destinations and the compatibility of the component types. All batteries should be handled and stored having regard to the potential fire risk associated with them.
3. **Balances :** WEEE Guidelines also requires that sites for handling of WEEE have "balances to measure the weight of the segregated waste". The objective is to ensure that a record of weights can be maintained of WEEE entering a facility and components and materials leaving each site (together with their destinations). The nature of the weighing equipment should be appropriate for the type and quantity of WEEE being processed.
4. Plastic, which cannot be recycled and is hazardous in nature, is recommended to be land filled in nearby CHWTSDF.
5. Ferrous and nonferrous metal recycling facilities fall under the purview of existing environmental regulations for air, water, noise, land and soil pollution and generation of hazardous waste and the same should be followed.
6. CFCs should be either reused or incinerated in common hazardous waste Incineration facilities at CHWTSDF.
7. Waste Oil should be either reused or incinerated in common hazardous waste incineration facilities.
8. PCB's containing capacitors shall be incinerated in common hazardous waste incineration facilities at CHWTSDF.
9. Mercury recovery and lead recycling facilities from batteries fall under the Hazardous & Other Wastes (M & TM) Rules, 2016.
10. Existing environmental regulations for air; water; noise, land and soil pollution and generation of hazardous waste and the same should be followed. In case Mercury or lead recovery is very low, they can be temporarily stored at e-waste recycling facility and later disposed in TSDF.
11. The industry shall maintain records of the e-waste purchased, processed in Form-2 and shall file annual returns of its activities of previous year in Form-3 as per Rules 11(9) & 13(3)(vii) of the E-Waste(M) Rules, 2016; on or before 30th day of June of every year.
10. The Energy source for lighting purpose shall preferably be LED based
11. The PP shall harvest rainwater from roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial applications within the plant
12. Conditions for D.G. Set
 - a) Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
 - b) Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.

- c) Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
- d) Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- e) A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use.
- f) D.G. Set shall be operated only in case of power failure.
- g) The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
- h) The applicant shall comply with the notification of MoEFCC, India on Environment (Protection) second Amendment Rules vide GSR 371(E) dated 17.05.2002 and its amendments regarding noise limit for generator sets run with diesel.

13. The applicant shall maintain good housekeeping.

14. The non-hazardous solid waste arising in the factory premises, sweepings, etc. be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal of solid waste.

15. The applicant shall not change or alter the quantity, quality, the rate of discharge, temperature or the mode of the effluent/emissions or hazardous wastes or control equipments provided for without previous written permission of the Board. The industry will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.

16. The industry shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.

17. The industry shall submit quarterly statement in respect of industries obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can downloaded from MPCB official site).

18. The industry shall submit official e-mail address and any change will be duly informed to the MPCB.

19. The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification No. B-29016/20/90/PCI-L dated. 18.11.2009 as amended.

20. The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or an extension or addition thereto.

21. The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.

22. The PP shall provide personal protection equipment as per norms of Factory Act

23. Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.

24. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.

25. The applicant shall provide an alternate electric power source sufficient to operate all pollution control facilities installed to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms and conditions of this consent.
26. The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the Hazardous and Other Wastes (M & TM) Rules 2016, which can be recycled /processed /reused /recovered and only waste which has to be incinerated shall go to incineration and waste which can be used for land filling and cannot be recycled/reprocessed etc. should go for that purpose, in order to reduce load on incineration and landfill site/environment.
27. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
28. Industry shall strictly comply with the Water (P&CP) Act, 1974, Air (P&CP) Act, 1981 and Environmental Protection Act, 1986 and industry specific standard under EP Rules 1986 which are available on MPCB website (www.mpcb.gov.in).
29. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of the collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes/sewers downstream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.
30. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
31. The industry should not cause any nuisance in surrounding area.
32. The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB (A) during day time and 70 dB (A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.
33. The industry shall create the Environmental Cell by appointing an Environmental Engineer, Chemist and Agriculture expert for looking after day to day activities related to Environment and irrigation field where treated effluent is used for irrigation.
34. The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.
35. The industry should comply with the Hazardous and Other Wastes (M & TM) Rules, 2016 and submit the Annual Returns as per Rule 6(5) & 20(2) of Hazardous and Other Wastes (M & TM) Rules, 2016 for the preceding year April to March in Form-IV by 30th June of every year.
36. The applicant shall install a separate meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
37. The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a yearly statement by 30th September every year on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end.

38. The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions.
39. The firm shall submit to this office, the 30th day of September every year, the Environment Statement Report for the financial year ending 31st March in the prescribed FORM-V as per the provisions of Rule 14 of the Environment (Protection) (second Amendment) Rules, 1992.
40. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
41. The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).
42. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous waste to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.

This certificate is digitally & electronically signed.

