

EXECUTIVE SUMMARY

**PROPOSED EXPANSION OF API &
INTERMEDIATE MANUFACTURING UNIT**

FOR
PUBLIC HEARING

BY
M/S. AJANTA PHARMA LTD.

**11 KM STONE, GUT NO. 378, PLOT NO. 8, AURANGABAD –
PUNE ROAD, VILLAGE WALUJ, TALUKA - GANGAPUR,
DISTRICT-AURANGABAD, MAHARASHTRA - 431133.**

PROPOSED EXPANSION OF MANUFACTURING QUANTITY – 21.042 MT/M

TOR NO. – IA-J-11011/33/2018-IA-II(I), DATED 11TH MARCH, 2018

MONITORING PERIOD – MARCH 2018 TO MAY 2018

ESTIMATED COST - ₹ 150 LAKH.

Environmental Consultant –

 **buildingenvironment Building Environment India Pvt. Ltd.**

QCI Accredited

1. INTRODUCTION

M/s. Ajanta Pharma Ltd. is an existing API manufacturing industry located at 11KM Stone, Gut No. 378, Plot No 8, Aurangabad – Pune Highway, Village-Waluj, Taluka. Gangapur, District. Aurangabad, Maharashtra 431133 and it is in operation since 1979. 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, Antibacterial, 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 industry has already obtained environmental clearance (EC) from MoEFCC, New Delhi for existing activity vide Letter F. No. J-11011/359/2008-IA-II (I) dated 10th June, 2009. EC is valid for total production capacity 21.042 MT/Month. In the year 2009 EC was obtained 32 nos. of products thereafter industry has revised the number of products 85 nos. of products without increasing existing total production capacity under product mix in accordance with EIA Notification 14th September 2006. Now, Industry has proposed for expansion number of products from 85 nos. to 258 nos. maintaining existing/consented production capacity i.e. 21.042 MT/Month.

In the proposed expansion there is no construction activity is involved. Existing infrastructure such as land, built-up area, storage area, plant & machinery, auxiliary systems such as boiler, cooling tower, ETP, STP etc. are adequate for proposed expansion. The capital investment in proposed expansion would be increased by ₹. 1.50 Cr i.e. from existing ₹. 13.5 Cr to ₹. 15 Cr due to implementation of Zero Liquid Discharge (ZLD) scheme by installation of Multi Effect Evaporator and revamping & retrofitting of existing Environmental Management System.

2. NEED OF THE PROJECT

Now a day's, rate of human health diseases is increasing rapidly. Medical treatment with the help of drugs/medicines is a common practice in which medicines/drugs play an important role in recovering the health & control the diseases. Pharmaceutical industries require raw materials in the form of synthetic chemicals, bulk drugs, intermediates to prepare final products as medicines. Bulk drug intermediates are the active raw materials used in drugs that are useful as therapeutic agents. The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, and it accounts for 20% in the volume terms and 1.4% in value terms of the Global Pharmaceutical Industry as per a report by Equity Master. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume.

Many pharma companies succeed largely because their major operations are based in Maharashtra. The government support received by the industry has been substantial and the presence of a pragmatic and stable state government has been one of the main reasons the state has managed to remain a principal destination for all pharma companies whether Indian or MNC. Maharashtra has been a hub for the pharma industry, both in terms of manufacturing as

well as supply of materials. Aurangabad industrial belt occupies 40% of chemical producing industries for pharma and other industries. In view of future market demand, it is the best opportunity to set up a business in Aurangabad which may lead to employment generation to local youth and economical upliftment of Waluj region.

Ajanta operates 7 state-of-the-art manufacturing facilities in India and Mauritius. Out of 7 units 4 units are located in Aurangabad region viz. Waluj, Chikalhana, Chittegaon & Paithan. Except Waluj remaining three units are drug formulation units. Waluj unit is the only API unit and it is the source of raw material to the other units. Demand of new medicine/ formulations increasing rapidly in domestic as well international market in that case Waluj unit is inefficient to supply all required API, hence Ajanta Pharma is purchasing required API from other vendor which results in increase in cost of finished/final drug products. Therefore, proposed expansion of Waluj unit is necessary.

3. PROJECT PROPONENT

Ajanta Pharma Limited is an Indian pharmaceutical company that is headquartered in Mumbai, Maharashtra, India. Established in 1973 by the Agarwal family, Ajanta Pharma develops, manufactures and markets branded generics to emerging markets in 30+ countries (across Asia, Africa, CIS, Middle East and SE Asia), and generics to developed markets like USA. Ajanta Pharma is having 9 nos. of members in the director group.

List of Directors of M/s. Ajanta Pharma Ltd.

Sr. No.	Name	Designation
1	Mr. Mannalal Agrawal	Chairman
2	Mr. Madhusudan Agrawal	Vice Chairman
3	Mr. Yogesh Agrawal	Managing Director
4	Mr. Rajesh Agrawal	Joint Managing Director
5	Mr. Chandrakant Khetan	Non-Executive, Independent Director
6	Mr. K. H. Vishwanathan	Non-Executive, Independent Director
7	Dr. Anil Kumar	Non-Executive, Independent Director
8	Mr. Prabhakar Dalal	Non-Executive, Independent Director
9	Dr. Anjana Grewal	Non-Executive, Independent Director

4. PURPOSE OF EIA

In accordance with the EIA Notification 14th September 2006 and successive amendments, proposed project falls under the project activity 5(f) i.e. Synthetic organic chemicals industry. According to the amendment in EIA notification 2006 on 25th June, 2014, point no (ix), Column 2, since the proposed project is located outside the notified industrial area and the Water and Fuel consumption is greater than 25 m³/day and 25 TPD respectively, it is treated as category

“A” project and it would require environmental clearance from Expert Appraisal Committee (EAC-Industry 2), MoEFCC, New Delhi. proposed industry has obtained Terms of Reference (ToR) vide file no. No. IA-J-11011/33/2018-IA-II(I) dated 11th March 2018.

EIA study has been carried out in line with the ToR issued by EAC (Industry – 2), MoEFCC, New Delhi and industrial specific standard ToR prescribed by MoEFCC in April 2015.

5. PROJECT SITE LOCATION

It is expansion of existing project in terms of number of molecules/ products and no addition construction & infrastructural development is required hence alternative sites are not examined. Existing site is adjacent to well-developed Waluj MIDC area and requisite infrastructure such as road, water, electricity, CETP are already provided by MIDC.

M/s. Ajanta Pharma Ltd. is located at 11KM Stone, Gut No. 378, Plot No 8, Aurangabad –Pune Highway, Village-Waluj, Taluka. Gangapur, District. Aurangabad, Maharashtra. Project site is located at 14 km in South direction from Aurangabad city & at 200 meter in South direction from Waluj MIDC. Geographical location of industry is 19°48'19.28"N, 75°13'42.70"E with elevation of 536 m from mean sea level. Project site is spread in to 3200.50 Sq. M area. For expansion purpose no additional plot or construction activity will be required.

Site is well connected by rail and road. Nearest railway station is Aurangabad located at 10 km North of the site and Aurangabad - Ahmednagar State Highway-30 is 300 meters away from existing site. Site is located at a distance of 15 km from the city of Aurangabad. M/s. Ajanta Pharma Ltd. is adjacent to well-developed Waluj MIDC industrial estate. Nearest human habitation is at Waluj Village, 400 meters South of the plant.

6. LAND DETAILS

Land is already in possession M/s. Ajanta Pharma Ltd. Land use pattern of the site is declared as non-agriculture as per government record 7/12. Out of the total plot area 2833.50 Sq.M. of area is constructed for industrial purpose and 790.00 Sq.M. of area is developed as green belt/lawn area.

7. TECHNICAL DETAILS OF THE PROJECT

Detailed technical description of the project are presented in **Table 1**

Table 1: Project Highlights

Sr. No	Particulars	Details	
1.	Ownership of Land	The industry is existing on the land owned By M/s. Ajanta Pharma Ltd.	
2.	Type & category	Red/LSI	
3.	Production Details	<p>Currently, the industry is manufacturing 85 nos. of products having total manufacturing capacity of 21.042 MT/Month. The industry has proposed expansion from 85 to 258 products without altering the total manufacturing capacity of 21.042 MT/Month. The list of existing and proposed products has been presented in EIA report.</p> <p>Specialty products targeting different therapeutic segments for treatment of patient 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.</p>	
4.	Water consumption	Existing: 40 KLD Proposed: 20 KLD Total: 60 KLD	
5.	Waste water generation	Sewage	4 KLD (Existing) 0 KLD (Proposed)
		Effluent	18.5 KLD (Existing) 1.7 KLD (Proposed) Total – 20.2 KLD (Existing + Proposed)
6.	Waste Water Treatment Facility	Sewage	4 KLD of generated sewage is treated in STP having capacity of 10 KLD
		Effluent	Currently the generated trade effluent is being treated in ETP having capacity 25 KLD and 18.5 KLD treated effluent is sent to CETP for final disposal. In the proposed expansion RO & Evaporator will be installed at ETP to adopt Zero Liquid Discharge Scheme.

7.	Usage of treated waste water	After treatment, treated water will be recycled in cooling tower make up and boiler make up.							
8.	Water consumption	Particulars				Existing (KLD)	Proposed (KLD)		
		Domestic				5	0		
		Industrial Process				20	0		
		Cooling tower makeup				10	24.7		
		Boiler make up				5	7.5		
		Gardening				0	8.5		
		Washing				1.0	0		
		Scrubber				0.5	0		
9.	Boiler Details	Capacity	850 kg/hr						
		Fuel	HSD/ LDO (We are using Diesel)						
10.	Stack Details	Sr. No.	Stack Attached to	APC System	Height in Mtrs.				
		1	Boiler	---	30				
		2	Scrubber	---	20				
		3	DG Set	---	4.5*				
		(* above the roof level of the building)							
11.	Power Requirement	450 kW (Source: MSEDCL)							
12.	DG Set (Back Up)	Capacity	400 kVA – 1 no. (Existing) 100 kVA – 1 no. (Proposed)						
		Fuel	HSD						
13.	Solid Waste	<u>Hazardous Waste -</u>							
		Hazardous Waste Generation Details							
		Sr. No	Description	Cat	UOM	Existing	Proposed	Total	Method Of Disposal
		1	Spent Oil/ used waste	5.1	kg/ month	25	5	30	Through authorised recycler/ reproprocessor
		2	Spent Solvents	20.2	kg/ Month	7500	8000	15500	Sale to authorised recycler/reprocessor
		3	Distillation residue	20.3	kg/ month	500	1300	1800	CHWT SDF
4	Spent Catalyst/ Spent Carbon	28.2	kg/ month	500	250	750	CHWT SDF		

		5	Discarded containers	33.3	no. / Month	125	140	265	Sale to authorized recycler
		6	Sludge from waste water treatment	34.3	kg/month	150	50	200	CHWT SDF
		7	Off specification product	28.3	kg/month	NA	1200	1200	CHWT SDF
		8	Spent organic solvent	28.5	kg/month	NA	10000	10000	Sale to authorized recycler/reprocessor
Non – Hazardous Waste –									
		Sr. No.	Description	UOM	Existing	Proposed	Total	Treatment	
		1	Wooden Material	Kg/M	200	200	400	Sale to Authorized recycler	
		2	Glass scrap	Kg/M	200	200	400	Sale to Authorized recycler	
		3	HDPE Drums	Nos/M	75	50	125	Sale to Authorized recycler	
		4	Plastic scrap & Kachra	Kg/M	100	100	200	Sale to Authorized recycler	
		5	Paper waste	Kg/M	100	50	150	Sale to Authorized recycler	
		6	e-Waste	Kg/A	0	100	100	Sale to Authorized recycler	
14.	CETP Membership	Yes.							
15.	Legal action taken (if any):	No.							

8. BASELINE ENVIRONMENT

Baseline study with respect to environmental attributes such as Air, Water, Soil, Noise, Ecology, Socio-economic within 10 km radial area from project site was carried out for the period of 1st March 2018 to 31st May 2018.

Geographical location of the study area was mapped on Survey of India (SOI) toposheet nos. 47 M/1, 47M/2, 47M/5, 47M/6. The site is a flat terrain (Plateau) and already constructed for existing activity. The geographical co-ordinates of the proposed site are Latitude: 19°48'19.28"N, Longitude: 75°13'42.68"E. Approximately 71 nos. of villages fall under 10 km radius from the project site. No Ecological sensitive area/ Reserve Biosphere, State & National boundaries, Defense installations, Notified Critically Polluted Area, Archeological Monuments is recorded within 5 km radius from the project site. Reserve forest near Nakshatrawadi – 9.0 km from project site is noted as per Survey of India geographical map. Main water bodies are Kham River – 1.4km East; Nagjhari River - 6.6km West, Kohli Nallah- 8.9km South, Jogeshwari Talav – 1.8km North West.

Land use of study area was identified on the basis of satellite imagery and it was noted that study area covers 314.1 Sq.KM. of land out of which land use pattern is categorized as agricultural 3.4%, barren land 2.3%, built up land 14.5%, fallow land 22.8%, open land 44.7%, vegetation 12.1% and water body 0.2%. It can be concluded that study area is having marginal agricultural land & most of the land is waste land.

Air environment of the study area was examined from data procured from Chikhalthana IMD and it was noted that minimum temperature in cold season goes upto 10.7°C and in hot season upto 48°C. The Aurangabad District has received an average annual rainfall of 737.5 mm. Annual wind pattern reveals that predominant wind direction is West to East. Primary air environment data for the study period (March to May 2018) was recorded at site and it was noted that average wind speed ranges from 1.78 m/s. to 2.37 m/s. Predominant wind direction was observed to be from West to East. Average temperature recorded in the range of 30.15°C to 34.79°C. There was no rainfall recorded during the monitoring period.

Ambient air quality of the study area was recorded at 8 nos. of locations including project site and sensitive receptors within 5km radial area from the project site. Ambient air quality was found to be within the prescribed NAAQS limits for industrial, residential, rural and other areas. Air pollutant concentration were recorded as PM₁₀ from 53.73 µg/m³ to 70.45 µg/m³; PM_{2.5} from 26.15 µg/m³ to 34.56 µg/m³; SO₂ from 11.00 µg/m³ to 26.35 µg/m³; NO_x from 22.49 µg/m³ to 30.64 µg/m³; CO from 0.077 mg/m³ to 0.140 mg/m³ other environmental pollutant viz. VOC, NH₃, H₂S were recorded onsite and near Residential Colony Opp. Garware Polyester. Other parameters Cl₂, HCL, HBr, HF were recorded below detection limit. The PM₁₀ and PM_{2.5} concentrations at all the AAQM locations were primarily caused due to local phenomena including industrial & Vehicular activities and natural dust getting air borne due to different manmade activities and blowing wind.

Noise levels at 5 nos. of locations viz. Project Site, Shivajinagar, Waluj Bk. Village, Waluj Kh. Village and Ramrai Village were recorded considering commercial, residential & silence zone criteria. Daytime highest noise Ld value was recorded at Near Garware Polyester i.e. 63.8

dB(A) due local activity such as market place, vehicle horn, hawker's movement etc. Night-time highest Ln value was recorded at Project site itself due industrial activity & vehicle movement is envisaged in the night time.

To ensure water quality analysis 4nos. Surface water samples and 6 nos. of Ground water samples were selected & analysed within 5km radial area from project site. Surface water quality of Kham River & Jogeshwari Talav are found non-potable due to high percentage of TDS, COD, BOD, DO, Chlorides, Sulphates, Total Hardness as CaCO₃, Total Alkalinity as CaCO₃, presence of Total Coliform and Faecal Coliform etc.

Ground water quality at all location was found to be non-potable due to exceeds of all parameters compare to IS 10500:2012.

The geological formations of the area are characterized by the Deccan traps (Upper cretaceous to lower Eocene). The granitic rocks have given rise to red as well as black cotton soils. Major part of this area has deep black soil derived from the trap rock. Soil quality of the area were analysed at 6 nos. of locations viz. Project Site, Waluj Bk, Near Jogeshwari Dam, Naigaon, Ramrai and Pandharpur. After analysis of soil quality in respect of pH, Electrical conductivity, Soil porosity, Organic matter and NPK; study area soil is having moderate fertility as per Department of Agriculture. (Source: Method Manual, Soil Testing in India, 2011).

As majority of study area has waste open land & marginal agricultural fields and natural vegetation is sparsely distributed. Selected project site does not have significant vegetation. Vegetation on site includes few saplings of *Acacia leucophloea* (Hiwar) & *Prosopis juliflora* (Vilayati Babhul) few bushes of *Cassia auriculata* (Tarwad) and dry grass. During Ecological & Biodiversity assessment of the study area, overall 66 plant species were documented in which 46 trees, 13 shrubs, 6 herbs & 1 climber species were listed. *Prosopis julifera* (Types of Bhabul), *Azadirachta indica* (Kadulimb), *Acacia nilotica* (Babhul), *Leucaena leucocephala* (Subabhul) species were the most common species. No threatened or scheduled floral species were found in the study area. Overall 19 agricultural species were currently cultivated in study area; in which Jowar, Cotton, sugarcane is most common in the study area. Most of the farmers take Kharif crops with Jowar, Soybean and Pigeon pea as the most dominant

Overall, 22 nos. of bird species were documented from the study area in which Green Bee Eater (Raghu) , Little Brown Dove (HOLA), Indian Bush Lark (Chandol) were seen frequently whereas Peafowl (Mor), Kite (Ghar), Bulbul were seen occasionally. 10 nos. mammal's species were documented from the study area in which Squirrels, Mouse were most commonly found whereas, Blackbuck (Kalvit) , Langur (Vanar), Wild Boar (Randukkar), were seen occasionally as these are visitors to the study area.

10 km study area covers 71 nos. of villages. For socio-economic study 16 nos. of villages were selected from 5km radial area from the project site. The population of 5km study area is recorded 165993 nos. which comprises of 53% of males & 47% females. Study area is having 71% literacy rate. The occupational pattern of area shows that the percentage of main + marginal workers and non-workers is 37 % and 63% respectively. The main workers comprise majority of cultivators followed by other workers, agricultural labour and household labours.

Out of total population 61068 nos. of population was recorded as non-working population as per census data 2011.

9. ANTICIPATED IMPACTS & MITIGATION MEASURES

A simplex matrix tool is used to identify predicted impact due to development of proposed project. Severity of impacts are categorized as low, moderate and high on the basis of baseline & predicted value. Similarly extent of impact & duration impact are categorized as low, moderate and high. Project impacts were defined for operation phase only because there is no construction activity is involved. Operation phase impacts involve due to uncontrolled industrial operations viz. fugitive & process emission, failure of environmental management system viz. ETP & STP, flue gases emission from stacks due to burning of fuel.

Table 2: Construction Phase Impact

Sr. No.	Environmental Attributes	Impact (Low/High /Moderate)	Extent of Impact (Short Term/ Long Term)
1.	Soil Quality & Topography	Low	Long Term
2.	Air Quality	Medium	Short Term
3.	Water Quality	Medium	Short Term
4.	Noise	Low	Short Term
5.	Geology and Hydrogeology	Low	Long Term
6.	Biological Environment	Low	Short Term
7.	Socio-Economics	Beneficial ++	Long Term
8.	Health & Safety	Low	Short Term
9.	Impact on Traffic	Low	Short Term

9.2 Operation phase mitigation measures

- ✓ The process/fugitive emission are scrubbed with the help of Venturi Scrubber. The same scrubber shall be used for control of process/ fugitive emission arising due to the proposed expansion.
- ✓ Ammonia sensor is installed within the plant area to raise alarm situation if ammonia level increases beyond permissible limit.
- ✓ Generated solid waste are being categorized as hazardous & non-hazardous waste and it is being stored at designated area for final disposal.
- ✓ Industry is already installed 10 KLD of STP plant for existing sewage treatment scheme and same system will be continued in proposed expansion
- ✓ After expansion 20.2 CMD of effluent will be generated and it will be treated in existing 25 CMD of ETP & RO system. At present industry is being disposed additional treated effluent to Aurangabad CETP after proposed expansion industry will adopt Zero Liquid Discharge by installing heat based Multi Effect Evaporator and condensate will utilize for cooling tower make up.

- ✓ After expansion hazardous waste such as Spent Oil/ used waste (30 kg/month), Spent Solvents (15500 kg/month) will be sold to authorized vendor or recycled similarly other hazardous waste distillation residue (1800 kg/month), Spent Catalyst/Spent Carbon (750 MT/month) sludge from waste water treatment (200 kg/month), Off specification product (1200 MT/month), Spent organic solvent (10000 kg/month) and discarded containers (265 nos/month) will be sent to CHWTSDF, MEPL Ranjangaon.
- ✓ Other non-hazardous waste like wooden material, glass scrap, HDPE Drums, plastic waste & Kachra, paper waste, e-waste will be disposed off through local vendor/authorized vendor as per characteristics of waste.
- ✓ HSD (Diesel) is being used boiler which is less pollutant compare to conventional fuel e.g. Coal. From boiler 0.00474 kg/hr of suspended particulate matter is being emitted and to control that emission stack height of 30 meter is provided.
- ✓ Scrubber is installed to reactor to control process emission.
- ✓ Proposed 100 kVA DG sets will be procured as per CPCB norms and will be operated in case of power failure only.
- ✓ Acoustic Enclosure is recommended for all blowers with noise level exceeding 90 dB, with transmission Loss Rating of 20+ dBA.
- ✓ All compressors is installed at a common location i.e. compressor house
- ✓ Operating/ noise generating equipment's shall be placed in enclosed room only. To ensure noise level not to exceed beyond plant area, regular ambient noise level monitoring will be carried out.
- ✓ Direct contact of chemicals with soil will be avoided by storing chemical on concrete platform.
- ✓ Spillage of product & raw materials handling will be avoided by adopting good manufacturing practices.
- ✓ 3 nos. of recharge pits are constructed for recharge of storm water
- ✓ 790 sq.m. of green area already is developed within the plant premises. In addition to that industry has developed separate 1 acre of land as green belt adjacent to the factory premises.
- ✓ Proposed project would generate 10-15 nos. of temporary/permanent job opportunities to local people.
- ✓ Daily 2 nos. of trucks will ply from local market to site to carrying raw material & finished goods hence there is no need to new construction/widen exiting Aurangabad-Ahmednagar road.

10. SITE & TECHNOLOGY ALTERNATIVE ANALYSIS

Analysis of alternatives presumed during the predesigned stage of the project. It depends various factors viz. Product category, site, technology, market scenario, availability infrastructure, economy & fund.

Table 3: Matrix of Alternative Site Analysis

Sr. No.	Site Selection Criteria	Existing Site
		Waluj
1	Non-Agricultural Land	✓
2	Project Approval by DISH	✓
3	Project Approval by State Pollution Control Board	✓
4	Project Approval by Local Body	✓
5	No R & R Issue	✓
6	Surrounding Industrial Development	✓
7	No Human Settlement- 500 meter	✓
8	Topography (Flat)	✓
9	Site Connectivity (Approach Road)	✓
10	Availability of Water (MIDC pipeline)	✓
11	No Notified Critically Polluted Area as per CPCB within 5 km radius	✓
12	No Archeological Monuments within 7 km radius	✓
13	Availability of Electricity (MSEDCL)	✓
14	Availability of labour Force	✓
15	Availability of Local Market for finished products	✓

Table 4: Technology Analysis Study

Sr. No.	Parameters	Indicator	Selected	Remark
i.	Process	Continuous / Batch	Batch	<p>Batch is more suitable than continuous process because in batch process it is easy to control water requirement, temperature, steam and reaction time.</p> <p>In continuous process there is a necessity of maintaining all parameters continuously otherwise whole production will get disturbed.</p>
ii.	Boiler Fuel Requirement	Less polluting	Furnace Oil/ HSD	<p>Conventional fuel like Coal contains 35-42% ash and sulphur 1-2% Hence use of coal put additional load on environment</p> <p>Furnace oil contains 0.1% ash (max) & sulphur 1.5% hence compared to coal it is cleaner fuel.</p>
iii.	Cooling Tower	Natural Draft/ Forced Draft	Natural Draft	<p>Site is having annual wind speed 10-11 km/hr hence Natural draft cooling tower is proposed. It reduces operating cost compared to Forced draft cooling tower</p>
iv.	ETP Technology	Conventional/ ZLD	ZLD	<p>Usually in synthetic organic industry, treated effluent by using conventional method cannot be used for irrigation purpose.</p> <p>Hence industry has proposed ZLD scheme in which effluent will be treated in ETP followed by RO & Multi Effect Evaporator to achieve Zero Liquid Discharge.</p>
v.	Charging of Chemicals	Manually/ Automatic	Automatic	<p>Manual charging of chemicals results in fugitive emission and it will be uncontrolled.</p> <p>Automatic charging from tank will reduce fugitive emission.</p>
vi.	Electrical Power	Conventional/ Solar	Solar	<p>Solar power will be for common area lighting to reduce load on conventional source.</p>

11. POST PROJECT ENVIRONMENTAL MONITORING PLAN

A proper monitoring program will be required in order to ensure effectiveness of implementation of suggested mitigation measures. The environmental monitoring will help in assessing the changes in environmental conditions by monitoring the effective implementation of mitigation measures, and measuring deteriorations in environmental quality for further preventive actions. Through it is existing unit, industry has already developed monitoring programme to ensure quality of the environment. In addition to that additional post project monitoring programme is recommended for betterment of the environment.

Table 5: Existing Monitoring Programme

Environmental Monitoring plan			
Sr. No.	Description	Quantity/ Location	Frequency
1	Boiler Stack Emission Monitoring General parameters Nitrogen Dioxide (NO ₂), Sulphur dioxide (SO ₂), Total Particulate Matter (TPM)	1	Monthly
2	DG Stack Emission Monitoring General parameters Sulphur dioxide (SO ₂), Total Particulate Matter (TPM)	1	Monthly
3	Scrubber Stack Emission Monitoring Chemical Parameters Hydrobromic Acid General parameters Ammonia (NH ₃), Nitrogen Dioxide (NO ₂), Sulphur dioxide (SO ₂), Total Particulate Matter (TPM) Specific Parameters Acid fumes as HCl	1	Monthly
4	24 Hrly. Ambient air Monitoring General parameters (2 Locations) Carbon Monoxide (CO), Nitrogen Dioxide (NO ₂), Respirable Suspended Particulates Matter (PM ₁₀), Sulphur dioxide (SO ₂)	2	Monthly
5	24 Hrly. Ambient air monitoring General parameters Ammonia (NH ₃), Arsenic (As), Benzene (C ₆ H ₆), Benzo(a)pyrene (BaP), Carbon Monoxide (CO), Lead (Pb), Nickel (Ni), Nitrogen Dioxide (NO ₂), Ozone (O ₃), Particulate Matter (PM _{2.5}), Respirable Suspended Particulates Matter (PM ₁₀), Sulphur dioxide (SO ₂)	1	Monthly

6	Workplace Air Monitoring General parameters Quarterly Ammonia (NH ₃), Respirable Suspended Particulates Matter (PM ₁₀), Sulphur dioxide (SO ₂) Specific Parameters Acid fumes as HCl	1	Quarterly
7	Spot Noise	5	Monthly
8	Noise Monitoring DG Insertion Loss	1	Monthly

Table 6: Monitoring Program for Operation Phase

Types of Monitoring	Parameters for Monitoring	Frequency	Responsibility	Monitoring Locations
Stacks Monitoring	PM ₁₀ , PM _{2.5} , SO ₂ , NO _x , CO, HC, VoC Acid Mist, NH ₃ , Cl ₂ , HBr, H ₂ S, HF OR As per CPCB Standards	Monthly/ As per EC & Consent Conditions	EHS Manager	1. Boiler Stack 2. Scrubber 3. DG Set
Ambient Air Quality	PM ₁₀ , PM _{2.5} , SO ₂ , NO _x , CO, HC, VoC Acid Mist, NH ₃ , Cl ₂ , HBr, H ₂ S, HF OR As per CPCB Standards	Quarterly/ As per EC & Consent Conditions	EHS Manager	1. Shivajinagar 0.4 km 2. Residential Colony Opp Garware Polyester 0.5 km 3. Waluj Bk 1 km
Work Zone Air Quality	PM ₁₀ , PM _{2.5} , SO ₂ , NO _x , CO, HC, VoC Acid Mist, NH ₃ , Cl ₂ , HBr, H ₂ S, HF OR As per CPCB Standards	Monthly/ As per EC & Consent Conditions	EHS Manager	1. Near Main Gate

Work Place Noise	As per Factories Act, 1948 dB(A) OR As per CPCB Standards	Quarterly/ As per EC & Consent Conditions	EHS Manager	1. Reactor Area
Ambient Noise Level	Noise Level as per CPCB Norms OR As per CPCB Standards	Quarterly/ As per EC & Consent Conditions	EHS Manager	1. Near factory main Gate
Water Quality	Drinking Water Quality (as per IS:10500) OR As per CPCB Standards	Half Yearly/ As per EC & Consent Conditions	EHS Manager	1. Drinking Water Source
Treated Wastewater	pH, TDS, TSS, BOD, COD, Oil & Grease, Chloride, Metals, Alkalinity, Acidity, Heavy metals, etc. OR As per CPCB Standards	Monthly/ As per EC & Consent Conditions	EHS Manager	Existing ETP of 25 KLD and STP of 10 KLD.
Storm Water Drains	Storm Water drains should not have any treated waste water	Monthly	EHS Manager	Other water/ waste water sources.
Soil Quality	Physical and Chemical parameters, including organic content and heavy metals	Yearly	EHS Manager	Agricultural Soil
Soil Contamination	Inspection of Storage area of fuel, hazardous waste, etc.	Quarterly	Stores Manager	Project Site
General Hygiene	General Cleanliness e.g. removal of Garbage, Clearing of Roads, etc.	Monthly	EHS Manager	Project Site
Health	General Health Checkup of all employees	Annual	Medical Officer	Project Site/ Workers engaged

	Identification of water logged areas having disease vector carriers like mosquitoes	Monthly		
Ecology	Green Belt Development and Maintenance Status	Six Monthly	EHS Manager	Greenbelt
Occupational Health & Safety	<ul style="list-style-type: none"> • Fire Fighting system • Usage of Protective Clothing and PPEs such as Protective Shoes, Glasses, etc. • Follow up of EHS Guidelines 	Fortnightly Inspections Quarterly Mock Drills	EHS Manager	Fuel, Chemicals & Hazardous Waste Storage Area
Emergency Response Plan	<ul style="list-style-type: none"> • Fire Prevention Measures • Signage • Fire Detection & Alarm System • Fire Fighting System & devices • Evacuation Plan <p>Emergency Procedures covering response to</p> <ul style="list-style-type: none"> • Spill/ leak of fire fuels • Electrical Emergency • Medical Emergency • Bomb Threats • Road Accidents • Earthquake 	Six Monthly	Emergency Response Team	Project Site

12. BUDGETORY PROVISION

The indicative split up of capital and recurring cost for the environmental monitoring programme of existing & proposed activity is shown below

Table 7. Indicative Budgetary Allocation for EMP Implementation

Sr.No.	Component	Description	Capital cost Rs. In lacs	Operational & Maintenance cost (Rs. In Lacs/yr)
1	Air Pollution control	Stack for boiler, scrubber system, DG stack, VOC control system via primary secondary condenser	23.8	1.5
2	ETP	Effluent treatment through primary, secondary & tertiary system	64	22.5
3	Noise pollution control	Noise Level Monitoring	2.5	0.5
4	Environmental Monitoring and Management	Ambient air monitoring, stack emission monitoring, work place monitoring from MoEF approved lab on monthly basis.	NA	4.8
5	Occupational Health and Others	Medical check of staff from certified surgeon	NA	2
6	Green Belt	Green belt maintenance	2.6	1.2
7	Solid & Hazardous Waste Management	Hazardous waste Disposal to CHWTSDF Site	4.8	7.5
8	PEE'S	Personal Protective Equipment's	NA	2.5
9	Online Effluent monitoring system	Online effluent monitoring system connectivity CPCB & MPCB	15	2
Total			112.7	44.5

13. RESETTLEMENT AND REHABILITATION (R & R)

The land is already in the possession of Ajanta Pharma Ltd. and industry is in operation since 2009. For proposed expansion no additional land is required for infrastructure development. Hence R & R is not applicable.

14. PUBLIC CONSULTATION

The opinion of the local people about proposed project will be addressed after conductance of public hearing.

15. PROJECT BENEFITS

As the proposed expansion will be done within the existing plot area; all industrial infrastructure such as water supply and electricity are already provided by MIDC. In addition to that, industry has already developed 1 acre of private land as green belt adjacent to the existing factory. M/s. Ajanta Pharma Ltd. has already spent ₹. 12.36 Crore under CSR activity for financial year FY 2017-18 (Annexure III- CSR Policy & CSR Budget FY 2017-18). In addition to that industry will spend ₹.1,50,000/- under Corporate Environment Responsibility (CER) Rules, 2018 during period of Consent to Establish To Consent to Operate. Details of budget is presented in **Table 8**.

Table 8: Activity-wise development plan for Physical Infrastructure

Sr. No.	Activity (within 5km surrounding area)	Budgetary Provision	Year wise Implementation
1.	Donation to Waluj Primary School for development purpose	₹. 1.50 Lakhs	Period of Consent to Establish TO Consent to Operate
Total		₹. 1.50 Lakhs	

After expansion during operational phase of the unit industry would be spent 2% of net profit towards Social Infrastructure development of local area under section 135, of the Companies Act, 2013.

16. ENVIRONMENTAL MANAGEMENT PLAN

The Environmental Management Plan (EMP) is a site-specific plan developed to ensure that the project is implemented in an environmentally sustainable manner where all contractors and subcontractors, including consultants, understand the potential environmental risks arising from the proposed project and take appropriate actions to properly manage that risk. Environmental Management Plan is a must to fulfil bifocal aspect of the statutory compliance as well as that of social concern. EMP also ensures that the project implementation is carried out in accordance with the design by taking appropriate mitigative actions to reduce adverse environmental impacts during its life cycle. EMP is helpful in conserve resources, minimize waste generation, treatment of wastes and protect natural properties. The plan outlines existing

and potential problems that may adversely impact the environment and recommends corrective measures where required. Also, the plan outlines roles and responsibility of the key personnel and contractors who has the responsibility to manage the project site.

For effective implementation of monitoring programme EHS cell is established and which is being functional under the surveillance of industry top management. Delineated statutory compliance calendar will be identified and it should be strictly followed by Ajanta Pharma Ltd.

Environmental Cell of Industry

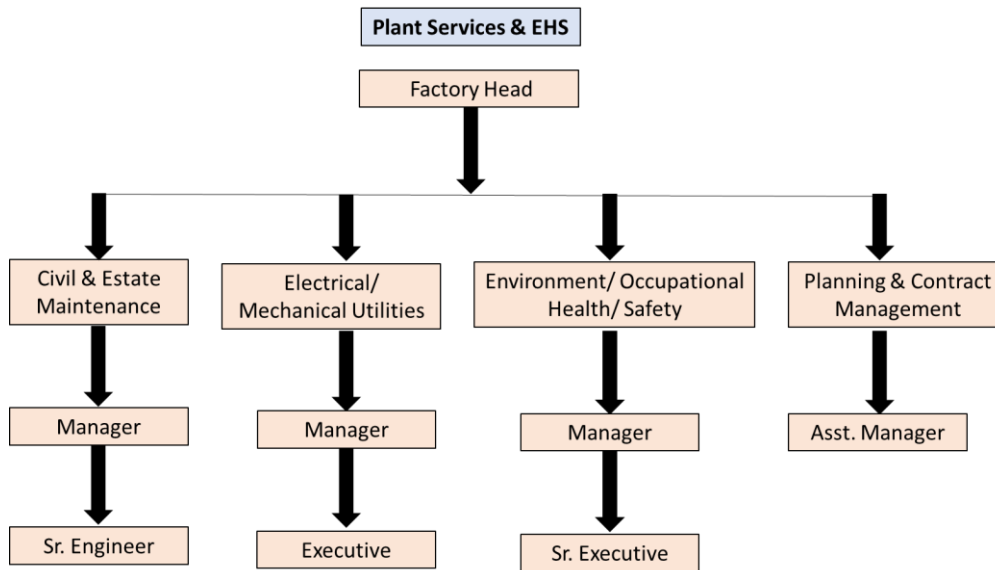


Table 9: EMP for Operation Phase

Sr. No.	Aspects	Source & Impacts	Mitigation Measures	Monitoring/ Action	Responsibility	Frequency of Audit/ Monitoring/ External Reporting
1.	Air Emission	<p>Source:</p> <ul style="list-style-type: none"> ❖ Fugitive emission from production process ❖ Emission from boiler ❖ Emergency operation of DG Sets ❖ Emission from vehicular movement ❖ Dust emission from dusty road <p>Impact:</p> <ul style="list-style-type: none"> ▪ Short Term in Increase in SPM & CO concentration 	<ul style="list-style-type: none"> ✓ Scrubber is provided to control the fugitive emission ✓ Furnace Oil is used in boiler. It contains 0.01% ash hence SPM emission quantity is too less compared to the conventional fuel like coal, wood etc. ✓ 30-meter stack is installed attached to boiler for better dilution & dispersion of pollutants. ✓ DG stacks is 4.5 meter above the roof or as per MPCB directions/ norms ✓ Provision of air filters to DG sets ✓ Only PUC holder trucks will be allowed at site 	<p>Review of status of implementation of suggested mitigation measures</p> <p>Monitoring provision for flue gases emitting from process & utilities</p> <p>Six monthly/as per Consent condition requirement for monitoring of stack emissions through MoEF recognized external laboratory</p>	EHS	<p>EHS Manager to review</p> <ul style="list-style-type: none"> ▪ Emission results of monitoring ▪ Results of manual samples collected from process emissions stack by external laboratory ▪ Ensure compliance of conditions of Consent to Operate issued under Air Act Annual renewals of CTO;

			<ul style="list-style-type: none"> ✓ Vehicular speed limit is defined 20 KMPH within the plant area ✓ All internal road within plant area are asphalted & whenever dusty situation will be found on road, water sprinkling will be done. ✓ Half yearly health check -up is carried out for workers 			
2.	Water Use	<p>Source:</p> <ul style="list-style-type: none"> ❖ Extraction of ground water ❖ Run off storm water ❖ Run off water from toilets <p>Impact: Impact on ground water</p>	<ul style="list-style-type: none"> ✓ Project has planned use of MIDC water Supply ✓ Provision of 1 no. of rainwater harvesting pit together with storage of water for re-use. ✓ Sufficient recharge to be made annually to minimize impact on groundwater. 	Review of status of implementation of suggested mitigation measures	Facility Manager	Six monthly review of reporting by Facility Manager
3.	Wastewater generation	<p>Source: Discharge of untreated sewage & effluent</p> <p>Impact: Ground water pollution and increase in soil alkalinity</p>	<ul style="list-style-type: none"> ✓ In the proposed expansion, no sewage will be generated. The existing 4 KLD of Sewage is being treated in 10 KLD STP. ✓ Currently the generated effluent is being 	<p>Review of status of implementation of suggested mitigation measures</p> <p>Daily monitoring of essential parameters to</p>	EHS officer & Facility Manager	<p>Facility Manager to</p> <ul style="list-style-type: none"> ▪ Daily review of ETP log books ▪ Review of results of essential parameters and results of monthly collected treated water samples by external laboratory

			<p>treated in ETP having capacity 25 KLD and treated effluent is sent to CETP for final disposal.</p> <p>✓ In the proposed expansion, generated 1.7 KLD effluent along with the existing 18.5 KLD effluent will be treated in existing ETP of capacity 25 KLD followed by RO & Evaporator which will be installed at ETP to adopt Zero Liquid Discharge Scheme. The treated wastewater will be recycled for landscaping, CT make up.</p> <p>✓ Efforts should be taken towards treated waste water quality to achieve land irrigation parameters prescribed in SCHEDULE – VI, The Environment</p>	<p>be done in house.</p> <p>Six monthly monitoring of treated effluent quality through external laboratory</p>		<ul style="list-style-type: none"> ▪ Ensure compliance of conditions of Consent to Operate issued under Water Act ▪ Annual renewals of CTO and filing of cess returns; ▪ Six monthly monitoring of treated effluent.
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			<p>(Protection) Rules, 1986</p> <ul style="list-style-type: none"> ✓ Online Monitoring system has been installed to check the inlet and outlet parameters of ETP. ✓ Maintaining good house keeping in all the units so that wastewater generation is minimised; ✓ Regular maintenance of ETP & STP to avoid clogging ✓ Treated waste water monitoring is carried out to ensure compliance. 			
4.	Solid Waste generation (Hazardous & Non-hazardous)	<p>Source:</p> <ul style="list-style-type: none"> ❖ Hazardous waste generation from chemical product manufacturing ❖ Sludge from ETP ❖ Salts from MEE ❖ Non-hazardous waste from 	<ul style="list-style-type: none"> ✓ Demarcated area is provided for hazardous as well as non-hazardous solid waste ✓ Hazardous waste mainly Distillation residue, Discarded containers, Sludge from ETP, etc. is sent to the CHWTSDF, 	<p>Review of status of implementation of suggested mitigation measures</p> <p>Monthly review of non-hazardous and hazardous waste generated from the project</p> <p>Review conditions of</p>	Facility Manager	<p>Facility Manager to monthly review of waste logs</p> <p>Also, EHS Manager to ensure compliance of conditions of authorization or annual filing of hazardous wastes returns.</p>

		<p>industrial & domestic activity</p> <p>Impact:</p> <ul style="list-style-type: none"> ▪ Ground water pollution ▪ Soil contamination ▪ Sanitation and Hygiene problem plant processes and 	<p>MEPL Ranjangaon.</p> <ul style="list-style-type: none"> ✓ Other hazardous waste like Spent Oil/ used waste, Spent Solvents will be disposed off through authorized recycler/reprocessor. ✓ Implementing waste management plan delineated for Operation Phase ✓ Non-hazardous waste wooden material, Glass scrap, Plastic scrap & Kachra, paper wastes, e-waste is sold to authorized vendor. ✓ Waste bins 15 nos. are provided all across the project site; ✓ Arrangement for regular collection of waste; ✓ The sheds and all the contents of the storage bins/drums are clearly marked and identified for their hazards; ✓ Hazardous material, is kept 	<p>storage location and records related to hazardous wastes as per the conditions of authorization</p> <p>Maintain records on disposal of hazardous wastes</p>		
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			<p>in isolated area located away from the active working zone.</p> <p>✓ Nitrogen Blanketing and Earthing has been done in Hazardous waste storage area.</p>			
5.	Ambient Noise	<p>Source:</p> <ul style="list-style-type: none"> ❖ Increase in noise from process reactor, cooling tower, transfer pumps, DG set etc. ❖ Movement of vehicles inside the project site <p>Impact: It will affect occupational Health & Safety</p>	<p>✓ Provision of silencers at high noise generating utility equipment and erecting suitable enclosures to minimise the impact of high noise generating sources;</p> <p>✓ DG sets are provided with Acoustic Enclosures to minimise noise.</p> <p>✓ Ear plugs to be provided to the personnel working in high noise area;</p> <p>✓ Unwanted honking of horns to be restricted through signage.</p>	<p>Review of status of implementation of suggested mitigation measures</p> <p>Ambient noise monitoring along the plant periphery to be done through external laboratory on six monthly basis</p>	EHS	<p>Six monthly review by EHS Manager</p> <p>Six monthly monitoring of ambient noise</p>
6.	Socio – Economic	<p>Source: Employment</p> <p>Impact: There will be positive impact</p>	<p>✓ Preference to be given to the local candidate as per educational qualification during recruitment</p>	<p>Review status of implementation of planned CSR activities</p>	HR Head	<p>Quarterly as per requirement</p>

7.	House Keeping	<p>Source: Operational activity</p> <p>Impact: Aesthetics blockage of storm water drain & Rain Water harvesting pit</p>	<ul style="list-style-type: none"> ✓ System to upkeep housekeeping and general cleanliness by providing adequate manpower; ✓ Maintain clean curb cuts to avoid soil and vegetation build up; Green belt and landscape maintenance; ✓ Inspections of drains and area surrounding cooling tower to check any water logging situation. 	Review of status of implementation of suggested mitigation measures	Facility Manager	Fortnightly review of by Facility Manager
8.	Energy	<p>Utilization of non-renewal resources</p> <p>Heat gain in the building</p>	<ul style="list-style-type: none"> ✓ Provision of renewable energy to be used for street lighting; ✓ CFL have been used for internal lighting which helps save energy. 	Review of status of implementation of suggested mitigation measures	Facility Manager	Six monthly review by Facility Manager
9.	EHS including associated risks of flammables	<p>Source: Fire, Explosion, accident</p> <p>Impact: Health hazards, Damage to property</p>	<ul style="list-style-type: none"> ✓ The industry will adopt high standards, controls, mitigation measures to control risks associated with fire. ✓ The industry will adopt stringent 	Review of status of implementation of suggested mitigation measures	EHS Manager	Six monthly review by EHS Manager

			<p>world class emission standards employed and equipment's installed which would ensure that any additional risks of are mitigated.</p> <p>Following risk mitigation measures are adopted:</p> <ul style="list-style-type: none"> ✓ Proper marking is made for identification of locations of flammable storages; ✓ Proper system for collection and disposal of domestic and hazardous waste; ✓ All the required safety measures (working guideline, use of personal protective equipments like gloves, helmets, ear muffs, safety belts etc.) for any repair and maintenance work within the proposed facility have been provided; ✓ For safety of people 			
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			<p>occupying the building, regulations concerning fire safety are followed.</p> <p>✓ Nitrogen Blanketing and Earthing has been done in Hazardous Waste Storage area as well as Raw Material Storage area.</p> <p>Some of the requirements are:</p> <ul style="list-style-type: none"> • Installation of fire extinguishers all over the building, • Risk assessment study will be carried out to minimize potential risks by implementing suggested risk mitigation measures • Flammable gas detector – for high pressure cylinders and liquefied/dissolved gases <p>✓ Emergency Response Plan will be periodically</p>			
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			<p>updated. The Plan will set out procedures and measures to be taken to deal with an on-site emergency such as fire, explosion, gas leak, odour or other incident threatening safety & integrity of the company.</p> <ul style="list-style-type: none"> ✓ This plan will be reviewed and amended when needed to ensure that all parties concerned are informed with up-to-date information. ✓ The Site Operations Manager shall carry out exercises of part of the Emergency Response Plan at a regular interval as deemed necessary. ✓ The lesson learnt from these exercises shall be documented and used during 			
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			<p>the updating of the Emergency Response Plan.</p> <ul style="list-style-type: none"> ✓ Provision of water hydrants in operative conditions; ✓ Emergency exit; ✓ Proper labelling of exit and place of the protective system installation; ✓ Conducting mock drills; ✓ Trained personnel to use the fire control systems; ✓ Display of emergency evacuation maps in each floor; ✓ Regular training and awareness programs to be conducted for people as per training modules formulated by the management for efficient control and management of environmental, safety and 			
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			health related issues.			
10.	Disaster Management	<p>Source: Risk of damage due to fire, natural disaster and other emergency situations</p> <p>Impact: Loss of life, damage to property, financial loss to company</p>	<p>✓ During operation phase, potential risks include accidental fire, electrical shock, fall hazards by working at height, physical injury, mechanical failure, vehicular hazards etc.</p> <p>✓ These risks will be minimised by periodical operation and maintenance of equipment and periodical supervision by operation team.</p> <p>✓ Ensure adequate Fire Fighting system established onsite prior to commissioning of the Project as per the</p> <p>Fire Fighting Plan covering following aspects:</p> <ul style="list-style-type: none"> • Fire Prevention Measure and Systems Signage 	Review of status of implementation of suggested mitigation measures	EHS Manager Security Incharge	Six monthly review by EHS Manager and Security Incharge

			<ul style="list-style-type: none"> • Fire Detection & alarm System • Fire Fighting System and devices • Annually, update Emergency Response Plan and ensure organization available for its implementation 			
11.	Project Related Traffic	Potential Congestion on the approach roads	<ul style="list-style-type: none"> ✓ The company has provided a total area of 80 sqm. for parking space. ✓ Drop off zone for the people coming by buses, clearly identified for easy accesses to respective work areas will be provided. ✓ The vehicles bringing utility raw materials are regulated and managed by the project in such a way that the impact during peak hours of traffic remains minimum; ✓ Ensure well defined follow up of Vehicle 	Review of status of implementation of suggested mitigation measures	Facility Manager	Weekly review and reporting by PMC and Monthly review by the staff related to function.

			<p>Circulation Plan.</p> <ul style="list-style-type: none"> ✓ Internal roads are provided with adequate signage to maintain smooth flow of different type of Project related traffic; ✓ Separate pedestrian pathways; ✓ Employees will be encouraged to pool their vehicles plying on roads; 			
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17. CONCLUSION

Considering the probability of impacts, Ajanta Pharma has planned adequate mitigation measures and EMP. Overall, direct and indirect employment opportunities, improvement in basic infrastructures by development of industry etc. will be observed with negligible impact on environment. Further, it has also been planned by industry to organize various CER & CSR programs which will have considerable beneficial Social and Environmental impacts.

It can be concluded that on positive implementation of mitigation measures and environmental management plan during operational phase, there will be negligible impact on the environment.