

Project No: AESPL/IND-E/15-16/EIA/020

**Executive Summary of
Draft Environmental Impact Assessment report**

**Proposed Expansion of Synthetic Organic
Chemicals (API's & Intermediates)**

Manufacturing Facility

At

megafine

Megafine Pharma (P) Ltd.

**Plot No. 31 to 35, 48 to 51, 1 to 5, 26 & K/ Gut No 201,
Lakhmapur, Tal. Dindori, Dist. Nashik, Maharashtra**

**Baseline Monitoring:
Summer 2017**

May 2019



Environmental Consultant:

Aditya Environmental Services Pvt. Ltd., Mumbai

QCI- NABET Accredited EIA Consultant

www.aespl.co.in

EXECUTIVE SUMMARY

1.1 Introduction

Megafine, established in 1995, is a privately owned and professionally managed enterprise with its corporate office in Mumbai and two multipurpose manufacturing sites at Nashik & Vapi in India, both successfully inspected by US-FDA & the Nashik facility is also approved by EMEA, PMDA & KFDA. Both the plants are also certified by WHO GMP, ISO 9001:2015, 14001:2015 & OHSAS 18001:2007 and have been audited by several Innovators and leading Generic companies from time to time.

The total plot area is 23,605 sq. m. The expansion will be affected by addition of new machineries, utilities, increased automation and addition of new products. The total estimated cost of proposed project Rs. 75 Crores.

Unit is having valid Consent to operate Format 1.0/BO/CAC-Cell/UAN No. 0000038464/1st CAC-1810000570 dated 12.10.2018 valid up to 31.12.2019 for manufacturing of existing Products.

The proposed establishment is at existing plot at Plot No. 31 to 35, 48 to 51, 1 to 5, 26 & K / Gut No. 201, Lakhmapur, Tal. Dindori, Dist. Nashik, Maharashtra.

The project is located at latitude 20°15'32.31" N and longitude 73°50'38.47" E (centre coordinates) with elevation of 615 m above Sea level.

The site is well connected by rail and road. Nearest Nashik road railway station is at distance of 45 km. Town Dindori is at a distance of 6.2 km on SSW. Nearest airport is HAL Ozhar Nashik at 25 km. State highway no. 17 is ~ 1 km away from site.

1.2 Manufacturing process & Proposed products

Manufacturing activities in the expansion project include various processes. The activities shall also include operation of various utilities. The manufacturing process is described in chapter 2.

There are total 21 therapeutic categories proposed to be manufactured. The site also has Research & Development (R & D) activity under manufacturing plant.

In general manufacturing process includes receipt of raw material, chemical reaction, Distillation, neutralization, condensation, Layer separation, crystallization, Filtration, Centrifugation, washing, drying, milling, blending, micronisation, labelling and packaging, distribution and Research & Development (R & D) activity.

New Multi-purpose plant shall have dedicated solvent recovery systems consisting of reboiler vessels, packed columns and primary condenser having cooling water circulation, secondary condenser having chilled water and tertiary condenser with chilled brine circulation.

All unit processes and unit operations shall be carried out under stringent controls and monitoring through local indicators and manual monitoring. Safety system – PLC, Auto shutdown, inertization and interlock system shall be provided wherever necessary.

Existing & Proposed Products, By-Products

Sr. No.	Therapeutic Category (type)	Existing capacity (MTPA) (*)	Proposed capacity, (MTPA)	Total (MTPA)
1	Coagulant	0.45	9.15	9.6
2	Antidepressants	46.3	61.8	108.1
3	Thrombotic	0.25	2.25	2.5
4	Alzhemiers	4	3.5	7.5
5	Antianginal	0.1	0.45	0.55
6	Antihypertensive	57.2	3.25	60.45
7	Schizophrenia	54.5	48.3	102.8
8	Over Active Bladder	1.55	2.4	3.95
9	Multiple sclerosis	12	-7	5
10	Acute coronary syndrome	0.35	0.2	0.55
11	Psoriatic Arthritis	0	1.5	1.5
12	Cystic fibrosis	0	1.1	1.1
13	Insomnia	0	0.8	0.8
14	Antiemetic	0	0.6	0.6
15	Antidiabetic	0.5	3.5	4
16	Anti Ocular Hypertensive	0.1	0.4	0.5
17	Cough suppressant and not antidepressants	0	11	11
18	Antifungal	25	0	25
19	Anthelmintic	136	164	300
20	Post-Operative Distention	0	0.5	0.5
21	Anti-hyperparathyroidism	0	4	4
22	Research & Development (R & D) activity	--	--	--
	Total	338.3	311.7	650

(*) Consent to operate Format 1.0/BO/CAC-Cell/UAN No. 0000038464/1st CAC-1810000570 dated 12.10.2018 valid up to 31.12.2019

1.3 Fuel requirement

Two boiler of 6 TPH and 3 TPH are proposed to be installed to fulfill heating requirement of the proposed project.

Fuel requirement

	Boiler (6 TPH steam)	Boiler (3 TPH steam)
Fuel used & Quantities	Bio briquette: 24 TPD	Bio briquette: 12 TPD

1.4 Water Consumption

Fresh water will be fulfilled through Irrigation Dept. Total water requirement after expansion will be 450 cmd, out of which 300 cmd will be fresh from Irrigation Dept. & 150 cmd will be treated recycle effluent.

Overall water (Fresh + Recycle) requirement after expansion

Sr No	Required for	Existing, cmd	Proposed additional, cmd	Total, cmd
1	Domestic	15	30	45
2	Industrial processing	15.9	74.1	90
3	Industrial cooling / Boilers	103.4	186.6	290
4	Gardening	5	20	25
	Grand Total	139.3	310.7	450

1.5 Description of the Environment

Considering the local and regional setting of the area surrounding the plant facility, surrounding area of 10 km of the plant site is considered as study area for setting up environmental baseline to study/ predict the impacts in surroundings due to the proposed establishment project, as per MoEFCC guidelines. Environmental data monitoring was done during Summer 2017 for meteorology, air quality, water quality, noise levels and soil characteristics, by setting up monitoring stations as prescribed. Further, existing ecological and socio-economic features were also studied.

1.5.1 Land Environment

The soil samples were collected at 8 locations having different land use. Soil texture of all sampling location is fine sand.

pH of soil varies from 6.59 to 7.38 which is neutral to slightly alkaline. For most agronomic crops the suitable soil pH should be between 6.9- 7.0. Hence pH is not much of a concern. Conductivity of soil is observed within range of 'Average'. Potassium content & % TOC is less. Phosphorous content in the soil is varies from very less to less. From above observation, it is observed that the soil is having low content of macro nutrient & fertilizers shall be required suitably.

1.5.2 Meteorology & Climate

The temperature data recorded in study area is ranging from 15.2 °C to 38.4 °C. From the wind rose graph it was observed that average wind speed is 1.6 m/s. Out of total data 51% contributing as calm. The winds flow predominantly from directions west to east during the summer season.

1.5.3 Air Environment

The baseline air quality was established by monitoring major air pollutants PM₁₀, PM_{2.5}, SO₂, NO_x, CO, and nMHC at eight locations (including onsite) in study area for 24 hours during period of Summer 2017. The air quality was observed to be within the NAAQS norms for residential and rural area.

- Concentration of PM₁₀ ranged from 46.7 µg/m³ to 69.2 µg/m³. It is noted that the PM₁₀ results are within permissible limit of 100 µg/m³ for 24 Hrs.
- Concentration of PM_{2.5} ranged from 12.9 µg/m³ to 22.1 µg/m³. It is noted that the PM_{2.5} results are within permissible limit of 60 µg/m³ for 24 Hrs.
- Concentration of SO₂ ranged from 7.8 µg/m³ to 15.1 µg/m³. It is noted that the SO₂ results are within permissible limit of 80 µg/m³ for 24 Hrs.
- Concentration of NO_x ranged from 7.7 µg/m³ to 15.6 µg/m³. It is noted that the NO_x results are also within permissible limit of 80 µg/m³ for 24 Hrs.
- Concentration of CO ranged from 0.18 mg/m³ to 0.72 mg/m³. It is noted that the CO results are also within permissible limit of 4 mg/m³ for 24 Hrs.
- Concentration of nMHC is found to be BDL.

With Comparison of NAAQ standards, Ambient Air monitoring results are below the specified norms.

Thus, it can be concluded that ambient air quality in the area is not polluted.

1.5.4 Noise Environment

The onsite data was observed well within standard for Day & Night time.

Day time: Noise level of Lakhmapur village is exceeded during Day time due to local disturbances.

Night time: Noise levels of Dahegaon, Ghodewadi, Ozarkhed, Lakhmapur, Kadwamhalungi & Waghad village is exceeded during Night time due to local disturbances.

1.5.5 Water Environment

Water sampling includes collection of Borewell water at 3 locations, well water at 4 locations, river water sample at upstream & downstream within study area & tap water from onsite.

It is observed that there is large variation in TDS, dissolved solids, Ca and Mg content. In general TDS levels are high in Bore well samples and low in river water. In general, Bore well waters having medium salinity between 250 to 750 uS/cm are suitable for plants with moderate salinity control. Well waters with low salinity between 100 to 250 uS/cm are suitable for irrigation for most crops on most soils with little likelihood that salinity will develop in the soils. Coliform presence was observed in few open dug well water samples. E coli were present only at Kadwamhalungi water sample.

No major heavy metals, pesticides were detected in water samples- Fluoride was detected at few places in low concentration.

1.5.6 Biological Environment

According to 'India State of Forest Report, 2017', Forest Survey of India; forest cover in Nashik district is about 6.9 % of geographical area.

Study area under consideration encompasses part of Dindori taluka of Nashik district. According to bio-geographic zone classification of India, study area falls under 'Deccan Peninsula – Central Plateau'.

Field visits to site and surrounding reveals that, study area is dominated by agriculture/ vinery. Hills are intermittently present distributed all over study area. Besides hilly area, different habitats observed in study area like vinery/ agricultural fields, water bodies, human settlements etc. These habitats possess different characteristic which supports typical composition of flora and fauna within them.

Field observations at the site shows the species planted in green belt are mostly showy. Green belt will be suitably developed for proposed project.

1.5.7 Socio Economic Environment

The study area comprises 37 villages from Dindori Tehsil of Nashik district.

Socio-economic survey was conducted in 13 villages of the study area located in all directions & distances with reference to the proposed project site.

As per 2011 census record:

- Total population of the study area is 111209 out of which 57026 (51 per cent) are males and 54183 (49 per cent) are females.
- There are 21153 households in the study area with average family size is 5.3 persons per household.
- Sex ratio within study area is 950 females per 1000 male which is higher as compared with Nashik district.
- Literacy rate of the study area has increased from 65 % in 2001 to 71 % in 2011. The male and female literacy rates are 76% and 65% respectively.

Observations from site survey:

Majority of respondents opined positively regarding industrial development activity since they are aware industries provide employment opportunities in skilled & semi-skilled works. 2 surveyed villages i.e. Awankhed & Palkhed expressed pollution problem due to nearby operating industries.

Main concern of these villages that pollution problem should be sorted out by authorities and industrialists by well-planned precautionary measures for pollution. Villagers expressed that the industrial activity should be beneficial in terms of local employment so that the standard of living of nearby population will enhance & suitably will develop the area.

Along with local recruitment villagers also expecting the development of infrastructural facilities in the form of village roads, health facilities, dairy farm activity, higher educational facilities & library, youth training centre etc.

1.6 Anticipated Environmental Impacts & Mitigation Measures

Environmental impact identification & Mitigation measures is based on the type, scale and location of proposed project activity. Environmental components that may be affected negatively and positively due to proposed activity are identified.

Environment parameters are selected for impact assessment due to proposed activity during various phases. The maximum impacts during Construction & Operation phase were listed below:

Anticipated Impacts & Mitigation measures for different phases of project

Sr. No.	Step/Activity	Environmental Aspect	Anticipated Impact	Suggested Mitigation Measures
1.0	Construction Phase	Land Environment	Generation of Solid waste/ Improper disposal method	Segregation of Solid waste & Hazardous waste/ Separate storage for solid waste/ Disposal of solid waste as per MPCB norms
		Air Environment	Dust generation/ emission of SO ₂ , NO _x , CO from construction activities	Dust suppression & Water sprinkling system for Dust generating area/ Proper maintenance of equipment's & vehicles
		Noise Environment	From loading, unloading of material/ Equipment handling/ Noise generating equipment	Use of damping material/ Regular maintenance of equipment/ Isolation of noise generating equipment/
		Water Environment	Consumption of fresh water 10- 12 cmd / Improper disposal of sewage	Fresh water requirement will be fulfilled from existing facility. Sewage of ~5 cmd will be disposed off properly/ reused for gardening.
		Biological Environment	Generation of dust/ Improper disposal of sewage/	Existing green belt will be developed suitably. Sewage will be disposed off properly & reused for gardening.
		Socio Economic Environment	Employment generation/ Health of workers	Approx. 50-60 no. of persons will be employed from nearby area for construction phase. Adequate provision of PPE/ Suitable infrastructure facilities for workers
2.0	Operation Phase	Land Environment	Generation of Solid & Hazardous waste requiring disposal	Non-Hazardous & Hazardous waste will be segregated & stored in designated storage area. Hazardous waste will be disposed off as per CPCB/ MPCB norms.
		Air Environment	Emission of TPM & flue gases from Boiler / Fugitive emission/ Increase in conc. of SO ₂ : 1.87 µg/m ³	Bio briquette will be used as fuel for proposed boilers. Boiler will be provided with adequate Stack height & air pollution control system (mechanical dust collector). Regular monitoring of stacks as per MPCB/ CPCB norms. From the air

Sr. No.	Step/Activity	Environmental Aspect	Anticipated Impact	Suggested Mitigation Measures
			Increase in conc. of NO _x : 0.53 µg/m ³ Increase in conc. of PM ₁₀ : 0.78 µg/m ³	modelling study, it is observed that flue gas emission is within permissible standard.
		VOCs	Increase in VOC levels due to increased handling/processing of organic chemicals and storages	Adequate size scrubbers will be installed to scrub emissions generated from the process. Company will have strict VOC control through use of: All solvent handling reactor agitators and pumps will be provided with mechanical seal. All storage tanks shall be connected to a vent system through cooling water and chilled brine condensers to prevent loss of solvents
		Noise Environment	From loading, unloading of material/ Operation of pumps & machineries	Isolation of vibrating units & equipment/ Regular maintenance of equipment's/ Use of vibration dampening/ Adequate PPE for workers
		Water Environment	Additional fresh water consumption, Effluent generation, treatment & disposal	Fresh water will be sourced from Irrigation department for which NOC has been received. Water conservation measures: Effluent will be segregated, treated & recycled in order to have ZERO liquid discharge WWTP at site is comprising of Primary, Secondary & Tertiary treatment. Megafine propose to implement Rain water harvesting outside factory premises. Proposed RWH scheme will harvest conservatively 19,769 m ³ of incident rainfall annually.
		Biological Environment	Emission of pollutant/ Solid & Hazardous waste generation/ Effluent generation & disposal	8,170 sq. m of area will be developed as Green belt. Green belt will be developed to provide screening effect. ~800 No. of local indigenous

Sr. No.	Step/Activity	Environmental Aspect	Anticipated Impact	Suggested Mitigation Measures
		Socio Economic Environment	Employment generation/ Health of workers	species of Trees will be planted as part of green belt development. Approx. 100 nos. of persons will be employed during operation phase. Preferences shall be given to local employment. CER budget of Rs. 75 Lakhs for 5 years. Proposed project will result in Increased taxes to local Gram panchayat

1.7 Environment Monitoring Program

For tracking of the effectiveness of mitigation measures & EMP at specific interval, regular monitoring of the necessary environmental parameters is required.

- Regular monitoring through MoEFCC recognized laboratory for compliance with conditions of EC, Consent to operate and provisions under Factory Act & Environmental Protection Act
- Monitoring of environmental samples shall be done as per the methods/guidelines provided by MoEFCC/ CPCB and /or relevant Indian Standards or methods as specified by Standard Methods
- Assessment of the changes in environmental conditions, if any, during the project operation/activities.
- Identification of any significant adverse transformation in environmental condition to plan additional mitigation measures; if & as required.

1.8 Additional Studies

1.8.1 Safety and risk assessment studies

Safety and risk assessment studies have been conducted for principal storage tanks and chemicals proposed to be handled onsite (OSBL tanks).

Systematic study based on ALOHA has been carried out for Methanol, Acetone, Toluene, Ethanol, Ethyl acetate, MDC, IPA & liquor ammonia tanks.

The details of consequence analysis studies have been presented in the EIA chapter 7. The precautions to be taken and recommendation for safe operations are mentioned at site.

Company has committed to comply with suggested recommendation.

1.9 Project Benefits

- Project will result in benefit to the country in form of foreign exchange revenues, duties etc.
- Enhanced production will also result in increased taxes to local gram panchayat and State Exchequer.
- Manpower requirement during Construction phase will be approximately 50-60 no. of persons from nearby local area
- Manpower requirement during Operation phase will be approximately 100 no. of Persons from nearby local area
- Further, the indirect employment via increased transportation, ancillary units & local economic activities with enhances spending power will also add in the employment potential.
- Indirect improvement in public infrastructure through CER activities carried by Megafine with enhances spending power will help to improve the overall quality of life in study area.

1.10 Environment Management Plan

The plan incorporates environment management measures during construction and operation phases. The capital outlay for environmental control & management measures estimated to be Rs. 300 lakhs.

Sr. No.	Particular	Capital Cost in Rs Lakhs for Five Years	Recurring cost (Rs Lakhs) per year
1	Air pollution control	60	10
2	Water pollution control	120	236
3	Environment Monitoring & Management	0	5
4	Process safety & Occupational Health	50	5
5	Green Belt enhancement & maintenance	5	2
6	Solid waste management	15	15
7	Energy saving measures (LED fittings)	20	6
8	Rain water harvesting	30	10
	Total	300	289

Corporate Environment Responsibility (CER) Budget of Rs. 75 Lakhs (1 % of expected capital investment) has been kept for 5 years. CER Budget breakup is as below:

Proposed Activities	Year wise allocation of Fund* (Rs. In Lakh) - April to March					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Health / Medical	2	2	4	3	3	14
Educational and Skill Development	2	1	1	2	2	8
Avenue Tree Plantation & Wildlife conservation fund	1	0	2	3	2	8
Improvement in Infrastructural Facilities	7	10	5	4	8	34
Livelihood Development Activities	3	2	3	3	0	11
Total	15	15	15	15	15	75

1.11 Conclusion:

The study for the proposed project of Megafine Pharm (P) Ltd. at Plot No. 31 to 35, 48 to 51, 1 to 5, 26 & K /Gut No. 201, Lakhmapur, Taluka Dindori, District Nashik, Maharashtra has revealed that the upcoming activities of synthetic organic chemicals will have some minimal impacts during operation phase. All other impacts of the project will remain far below acceptable limits after necessary mitigation as described & suggested in EIA report. The major impacts will also be brought under acceptable limits by implementing the required hazard prevention & control measures as suggested in the EIA report. Thus, it has been concluded that there would not be any major impacts on environment due to the proposed project.