

Executive Summary

1.0 Introduction:

Mehta API Pvt. Ltd. (Hereafter being referred as Mehta for brevity in this text) proposed expansion and addition of some new products in the category of Synthetic Organic Chemicals. The company has the capacity to manufacture multi step, highly complex, potent, chiral & semi-synthetic APIs.

Manufacturing unit was established in year 2007 and having a prior environmental clearance ((Ref.J-11011/413/2005-IA II(I)- dated February 17, 2006))for the existing products. However, Mehta is now proposing addition and expansion of API products at existing site located at Gut No. 546, 571, 519 & 520, MIDC Kumbhavali Village, Tarapur (Boiser), Taluka & District Palghar, Maharashtra 401506,for which prior environmental clearance is required. Existing production capacity of the unit is 18.34 TPM i.e. **220.08 TPA** and after proposed expansion it will become **298.713 TPA**.

As per the Schedule of EIA Notification SO 1533 dated September 14th, 2006 proposed project is classified in schedule of activities 5(f) and requires prior Environmental Clearance before commencing the expansion. As unit is located in outside industrial estate of MIDC it is in category A and requires an EIA to be prepared to assess impacts due to proposal. Since the proposed project location is in outside MIDC the proposal public hearing is required to be conducted.

1.1 Purpose of Study

Purpose of the report is to identify environmental aspects, impacts arising out from proposed project in the category of API, prepare EIA and EMP report and get prior Environmental Clearance.

EIA report has been prepared as per Terms of References granted by MoEF & CC. As per the letter from MoEF & CC with Ref. No.IA-J-11011/258/2017-IA-II dated 24th August 2017, standard ToR for the purpose of preparing EIA and EMP for obtaining prior environmental clearance is prescribed with Public Consultation. ToR letter has been given as **below**

Acceptance Letter for TOR application

F.No.- IA-J-11011/258/2017-IA-II(I)

Ministry of Environment, Forests and Climate Change
Government of India

Indira Paryawaran Bhawan

Jor Bagh Road, Jor Bagh
New Delhi-110003
Dated: 24 Jul 2017

To,

MEHTA API PVT. LTD.
, Palghar
Maharashtra , 401506

Subject : Proposed Expansion of existing API manufacturing facility by Mehta API Pvt. Ltd.

Sir,

This has reference to your proposal No. IA/MH/IND2/64863/2017 dated 03 Jul 2017 regarding grant of TORs for the above mentioned proposal.

2.0 This is to acknowledge that the proposal has been received in the Ministry along with Form 1 and pre-feasibility report. You are requested to submit a hard copy (signed) of the documents in the Ministry(at the address given below) within a week, along with email alert generated by the system(through speed post).

Address:

Section Officer, 3rd floor, Vayu wing, Indira Paryawaran Bhawan, Jor Bagh Road, Jor Bagh, New Delhi-110003

3.0 The proposal shall be included in the agenda for its consideration by the EAC for grant of TORs after receipt of the hard copy along with email alert. The hard copy of the same can also be submitted by hand in the Ministry in between 3PM to 4PM on each working day. You are requested to visit website of the Ministry at <http://environmentclearance.nic.in> to check its inclusion in the agenda. Once the proposal is included in agenda for a meeting, you may circulate hard copies of documents to the Chairman and Members of EAC within a week of uploading of agenda on Ministry's portal.

1.2 Extent of Study and Study Covered

Environmental Impact Assessment report is prepared based on the studies carried out during October to December 2017. The Environmental parameters such as ambient air, water, soil, noise, are those which are likely to be affected by the project were selected for study. The study area is defined as an area within 10 kms radius around site.

1.3 Method of Study

The present environmental impact assessment report is prepared considering model ToRs for Synthetic Organic Chemical Industry. This Report is prepared based on 'General Structure of EIA' given in Appendix III of EIA Notification SO1533 dated 14th September 2006. The present environmental impact assessment report is prepared by Mahabal Enviro Engineers Pvt. Ltd. NABET accredited EIA consultant organization for this category (Synthetic Organic Chemicals sector) considering mainly the risk assessment and the impacts due to project proposals on surrounding environment.

2.0 Type of Project

Proposed project falls under the schedule "Manufacturing/fabrication", Project or Activity 5(f), Synthetic Organic chemicals Industries, Category "A" as per schedule in EIA notification, 2006 and amended till date.

2.1 Specific location and connectivity

Table 2.1- Location details

Name	Mehta API Pvt. Ltd.
Organizational Category	Private limited company
Legal Status	Private Limited company
Address	Gut No. 546, 571, 519 & 520 MIDC Tarapur (Boisar), Taluka & District Palghar, Maharashtra 401506
Area of the Project	26,940 m².
Website	-
Telephone	07030964120-29
Fax	-
Authorized Person	Mr. Yogin Mehta
Email Address	yogin@mehtaapi.com

2.1 Size or Magnitude of Operation

The proposed products and their capacities are shown in below table 2.2.

Table 2.2
Details of Proposed Production Capacity of product

Sr . No .	Therapeutic category	Name of product	Existing Quantity as per consent MT/A	proposed additional MT/A	Total quantity after expansion MT/A
1	Antibacterial	Erythromycin base	61.8	93.6	240
		Erythromycin Stearate			
		Erythromycin Estolate			
		Erythromycin Ethyl Succinate			
		Chloramphenicol	64.8		
		Chloramphenicol Palmitate			
		Azithromycin Dihydrate	19.8		
Clarithromycin	Nil				
2	Cardiovascular	Bisoprolol Fumarate	Nil	11.72	12.2
		Esmolol Hydrochloride	0.48		
		Landilol Hydrochloride	Nil		
		Neviblol	Nil		
3	Antiemetic	Droperidol	Nil	1.61	4.85
		Prochlorperazine maleate	3.0		
		Prochlorperazine mesylate	0.24		
		Aprepitant	Nil		
4	Antidiabetic	Linagliptin	Nil		
		Vildagliptin			
5	Antithrombotic & Antianaginal	Anagrilide HCL	Nil		
		Beraprost			

		Limaprost		36.062	36.062
		Dypiridamol			
		Dabigatran			
		CLOPIDOGREL			
		Rivaroxaban			
6	Antidepressant & antipsychotic	Fluoxetine Maleate	Nil	5.601	5.601
		Agomelatine			
7	Urinary system related	Cinacalcet HCL	Nil		
		Mirabegron			
8	Others	Bazedoxifene Acetate	Nil		
		Lupbiprostone	Nil		

2.2 Requirement of Resources

Water Requirement and Source

Fresh water requirement of the project for domestic and industrial activity during operation phase will be 50 CMD after recycling. The water requirement will be sourced from MIDC.

Power Requirement

The proposed project is expected to require electricity as below

Connection Load: present connected load is 550 KW

Sanctioned load: 554 KW

600kW power will be required for proposed project.

MSEDCL will supply required power for the project. Two no. of DG set of capacity 320 KVA and 50 KVA being used to meet emergency power requirement of the plant. No extra DG set will require for proposed expansion.

Steam Requirement

The proposed unit will require following units in order to meet its process steam requirement and process heating requirements:

Details of Boilers and Thermopac

Sr.No	Source	Capacity	Type of Fuel	Utilization	Quantity	Air Pollution Control Equipment's
1	Boiler (Demolished)	0.6 TPH x 1 no.	Briquette	Regular	1 TPD	Stack- 20 m from ground
2	Boiler (Existing)	0.6 TPH x 1 no.	LDO FO	Regular	200 Lit/D	Stack- 30 m from ground
	Boiler (Proposed)	2 TPH x 1 No.	Briquette	Regular	6 TPD	
3	Thermopack (Existing)	1 lac Kcal/Hr x 1 no	LDO	Regular	21.16 Kg/hr	Stack- 20 m from ground

Man Power requirement

The project will need manpower in different categories as below:

Existing Manpower Details

Sr. no.	Particulars	No. of personnel
1.	Management	14
2.	Supervisory	66
3.	Skilled	11
4.	Unskilled	19
5.	Others(Indirect)	43

The existing manpower of the project is about 153 Nos. &30 extra manpower is required For proposed expansion project.

Waste Generation:

Effluent Generation

The quantity of total effluent generated and expected from proposed project is as below:

Table: Water Budget

Particulars	Consumption (CMD)			Loss/Gain (CMD)			Effluent (CMD)		
	Existing	Proposed additional	Total	Existing	Proposed additional	Total	Existing	Proposed additional	Total
Domestic	10	02	12	2	0.5	2.5	8	1.5	9.5
Industrial Process	06	02	08	1	1	2	5	1	6
Boiler and cooling tower make up	15	15	30	10	10	20	5	5	10
Gardening	10	7	17	10	7	17			
Total	41	29	67	23	18.5	41.5	18	7.5	25.5
Recycled Water (RO permeate + waste water from STP)			7.5+9.5 =17						
Total Fresh water required			50						

Waste water from utility will be treated in RO and RO permeate 7.5 CMD will be reused for utilities. RO reject 2.5 CMD along with high TDS stream(1.8 CMD) will be treated separately in Evaporator. Low TDS stream along with condensate from evaporator will be treated in conventional effluent treatment plant having Primary Secondary and tertiary treatment. 7 CMD effluent will dispo seto CETP as per consent

Solid waste generation

The hazardous waste generation from the existing as well as proposed project and procedure of its disposal, are elaborated in the following table:

Table: Hazardous Waste

Sr. No.	Resource	Category	Existing	Proposed additional	Total	Unit	Disposal
1.	Spent Solvent	28.6	-	2	2	MT/M	Sale to authorized recycler
2.	Chemical sludge from waste water treatment	35.3	0.185	0.22	0.405	MT/M	CHWTSDF
3.	Process Residue & Wastes (Activated Carbon)	28.1	-	0.075	0.075	MT/M	CHWTSDF
4.	Process Waste	28.1	0.025	0.01	0.035	MT/M	CHWTSDF
5.	Empty Drums & plastic bags	33.3	500	100	600	No./M	Sale to authorized recycler
6.	Off specs products	28.2	0.19	-	0.19	MT/M	CHWTSDF
7.	Expired Chemicals	28.3	0.1	-	0.1	MT/M	CHWTSDF

3.0 Baseline Environment

Baseline environment studies were carried out to incorporate the description of the various existing environmental settings within the area encompassed by a circle of 10 km radius around the proposed project site.

Air Environment

Air sampling was done in 8 locations in and around the project site. Air monitoring has been done at selected locations upwind, downwind as well as cross wind direction.

Micro Meteorological Data

From the meteorological data of the study area, the months of October, November & December are considered to be post monsoon season. It is referred that minimum and maximum temperatures was 20.8°C and 37.4°C respectively. Predominant wind direction was from South – West – to North East in study period. Wind speeds during study period

varied 0.5 Km/h to more than 28.6 Km/h.

Particulate Matter

The average concentration of among all the locations varied between 83 and 90 $\mu\text{g}/\text{m}^3$. The highest 24-hourly concentration was recorded at sampling location A5. At the same time minimum average 24-hourly concentration was observed at location A6. The average concentration of PM_{10} at all locations was observed to be ranging between $74\mu\text{ g}/\text{m}^3$ to $85\mu\text{g}/\text{m}^3$. The high concentration of particulate matter recorded at A5, may be due to fugitive emissions and vehicular traffic flow in near sampling location.

The PM_{10} concentrations for all locations were observed to be below stipulated standards for NAAQS (**24 hourly $\text{PM}_{10} = 100 \mu\text{g}/\text{m}^3$**).

The major source of $\text{PM}_{2.5}$ is due to the anthropogenic activities such as combustion of fossil fuel, firewood, biomass burning, etc. The maximum 24 hourly concentration of $\text{PM}_{2.5}$ ($46 \mu\text{g}/\text{m}^3$) during the study period was recorded at location A1, whereas the minimum $14 \mu\text{g}/\text{m}^3$ concentration was recorded at A6 location which is a remote area. The minimum concentration indicates that the residential area experiences minimal combustion and vehicular activity. On the other hand high concentration at location A1 indicates that the area experiences high emissions from combustion of fossil fuel and vehicular movement in the surroundings. The average 24 hourly concentration of $\text{PM}_{2.5}$ during the study period was computed to be in the range of $20\text{-}38 \mu\text{g}/\text{m}^3$.

The $\text{PM}_{2.5}$ concentration for all the locations were observed within stipulated standards for NAAQS (**24 hourly $\text{PM}_{2.5} = 60 \mu\text{g}/\text{m}^3$**)

Gaseous Pollutants

The ambient air monitoring results indicate that the highest average concentration of SO_2 is experienced at the project site, i.e. location A1. High levels concentration of SO_2 at A1 can be attributed to the traffic of vehicles which are diesel driven. The average concentration of SO_2 recorded at all the monitoring locations during the study period ranged between 16 & $27 \mu\text{g}/\text{m}^3$ respectively.

The average concentrations of NO_x were in the range of $23 - 40 \mu\text{g}/\text{m}^3$. The maximum 24 hourly value of NO_x was recorded at the monitoring location A1 ($49 \mu\text{g}/\text{m}^3$) whereas the minimum concentration of NO_x was recorded at location A6 ($15\mu\text{g}/\text{m}^3$).The levels of the gaseous pollutants were below stipulated National Ambient Air Quality Standards. (**24-hourly is $\text{SO}_2\&\text{NO}_x$ is $80 \mu\text{g}/\text{m}^3$**).

Noise Environment

The ambient noise scenario within the study area was monitored at 8 locations up to 3km from the project site. The maximum noise levels during the daytime were noted to be 66.4 db (A) at project site, while the minimum levels were noted to be 48.6 db (A). The highest level during the night time was observed to be 60.8 db (A) at project site and the lowest level of noise during the night time was recorded to be 40.8 db (A). Results shows that noise level in the study area was within stipulated standards prescribed by CPCB for industrial and residential sectors.

Water Environment

Surface Water

In order to assess the present water quality of the region, 8 surface water samples were collected and analyzed for selected environmental parameters viz. physical, inorganic, organic and nutrient parameters and heavy metals. Surface water samples were taken from Banganga river, Gundalelake, Bandhara lake, Arabian Sea, Nandgaon lake, Banganga river (near tarapur atomic plant, Vikasnagar lake, Navapur lake.

The values of nitrate and phosphates indicate that domestic sewage can be a major source of pollution in the selected water bodies.

Ground Water

Groundwater samples were collected from 8 different locations namely Project site, Agawan Sarawali, Salawad, Pam, Tembhi, Gundali, Kumbhwali These locations were selected as per the expertise of FAE and guidelines in standard ToR. The results of analysis reveal that the values for all the parameters were within the acceptable limits prescribed in 'IS Standards for Drinking Water (IS1050:2012).

Based on the analysis it can be concluded that the ground water can be considered for use for drinking, domestic & irrigation purposes after a basic primary treatment.

Land Environment

The land use analyses show that the area is of predominantly Crop Land. Industrial area is included in built up land.

Land use details around 10 km radius from the project site

Class	Area (Hectares)	Area (%)
Water body	7551.09	24.04
Wet land	1607.49	5.12
Vegetation	5879.19	18.71
Settlement	1546.39	4.92
Agriculture	6640.76	21.14
Scrub	6879.34	21.89
Salt Pan	540.23	1.72
Mangrove	771.51	2.46
Total	31416	100.00

Baseline Status of Soil

Soil samples were taken from 6 locations namely Banganga river, Gundale lake, Bandhara lake, Arabian Sea, Nandgaon lake, Banganga river (near tarapur atomic plant), Vikasnagar lakeNavapur lake. The findings of the study reveal that pH of the soil in the study area ranged between 7.1 to 7.8. This is indicative of the neutral to slightly alkaline nature of soil. The values for Nitrogen at all locations varied between 276.9 to 460.2 Kg/ha. Maximum concentration of nitrogen was observed at location Gundalelake.

As the land selected for proposed expansion unit is located near to MIDC area and not a prime agricultural land, quality of soil interpreted only to explore existing base line status of soil of the selected study area. Care has been taken by Proponent that due to operation of the project soil quality of the study area will not get adversely affected.

Biological Environment

The field studies conducted in the inner 5 km radial study area in and around the MIDC area and the wetlands/ marshes along the Navapur & Murbe Creeks resulted in recording 51 floral species comprising of 24 trees, 6 shrubs, 10 climbers and 11 herbs. As a virtue of green belt developmental activities in and around the industrial area though the tree diversity was more, the vegetation stature observed in the core study area was mostly of scurb dominant flora such as Chromolena, Hyptis, Lantana, Alternanthera, Amaranthus etc. and 4 species of true mangrove were alsoobserved.

Socio-Economic Effect

Socio- economic study indicate that the people in the study area is somewhere satisfied with the accessibility of public recourses and the activity of the industry Mehta API Pvt. Ltd. will not hamper or impact in any way to them. Hence, the attitude towards industrial activity is also found to be favorable.

4.0 Description of Investigated Impacts & Mitigation Measures

Air Environment

The impacts on air environment due to emission of gaseous from stacks depend on the type of fuel used and may extend to far distances depending on meteorological conditions. Quantity of SO₂ and NO_x generated from the proposed project is expected to be around 0.00327 gram/sec and 0.01705 gram/sec respectively at full load conditions from boiler in case of FO use. In case of briquette, the ash emitted from the proposed expansion shall be around 0.112 gram/sec. at full load conditions. 0.190 gram/sec CO will be generated from burning of briquette and FO.

Water Environment

Water is essentially used for process, utilities and domestic purposes. Generation of trade effluent will be 7CMD and domestic sewage will be 9.5-CMD. Which will be used for gardening after treatment in STP.

Waste water from utility will be treated in RO and RO permeate 7.5 CMD will be reused for utilities. RO reject 2.5 CMD along with high TDS stream (1.8 CMD) will be treated separately in Evaporator. Low TDS stream along with condensate from evaporator will be treated in conventional effluent treatment plant having Primary Secondary and tertiary treatment.

Tertiary treated water after meeting MPCB norms (7 CMD) will be dispose to CETP as per consent .

There will not be any disposal of treated or untreated water either into the aquatic body or on land; therefore the impact on water quality is negligible.

Soil Environment

The main source of hazardous waste generation will be ETP sludge and salts from evaporator. Other sources will be discarded drums and containers. The Hazardous Wastes

generated will be sent for further treatment and disposal i.e. incineration and secured land filling to CHWTSDF. Whereas discarded drums and containers will be properly cleaned and sold to approve end users. Thus, after taking adequate steps for the hazardous waste storage, there will be minor impact on the environment due to proposed project activities.

Socio Economic Aspects

As there are no visible and reported negative impacts due to the operations of the company; no mitigation measures are recommended.

Under each category the company had already chosen focus areas like healthcare, education, infrastructure development, livelihood and skill building, women empowerment, child care, intervention for senior citizens, environment conservation and protection, etc. as per Corporate Social Responsibility Notification (Schedule VII, Company Act), the Company has earmarked Rs. 70.72 lacs (2.5% of proposed expansion cost 28.29 Cr.) for undertaking the CSR activities.

5.0 Risk Assessment and Disaster Management Plan

The proposed project of Mehta is also complying statutory requirements under section 7A & B and chapter IV A of Factories Act, 1987 and manufacture, storage and import of hazardous Chemicals Rules Under Environment (Protection) Act, 1986. Risk mitigation suggested is as follows;

1. Provision of fire hydrant system and manual call points.
2. Provide Dyke for accidental spill containment for above ground storage tanks.
3. Provide mobile pump arrangement to transfer the accidental spill contained in Dyke to emergency spare tank.
4. Store chemicals considering the compatibility and reactivity hazards at store/warehouse.
5. Prepare Safe Operating Procedure (SOP) for handling of flammable chemicals in particular water reactive chemicals.
6. Provide wind direction socks.
7. Provide smoke detector at warehouses.
8. Provide suitable arrangement at storm drain to avoid any organic contaminated water/ spill/ fire water going out of the site.
9. Revise "DMP" based on MCLS Analysis for the site with dove tailing data for offsite disaster control plan.

6.0 Environmental Monitoring Program

EMP is planned such that the mitigation measures should be put in place to reduce the adverse impacts likely to result from the implementation of the project. Apart from the regular monitoring, Post – Project Monitoring Plan (PPMP) is proposed to monitor the ambient environmental quality after the commissioning of the project. The frequency of monitoring of various parameters will be increased as per the requirement after the project goes on schedule.

7.0 Environmental Management Plan

Environmental Management Plan (EMP) includes the protection, mitigation and environmental enhancement measures to be implemented to nullify the adverse impact on the environment.

Sr. No.	Particulars	Proposed Equipment , Method
1.	Air Pollution Control	<ul style="list-style-type: none"> • Stacks of Height provided as per CPCB recommendations. • Scrubbers provided for process vents with 5 m high vents.
2.	Water Pollution Control	<ul style="list-style-type: none"> • The effluent will be treated as per MPCB norms and will be discharged to CETP.
3.	Noise Pollution Control	<ul style="list-style-type: none"> • No Demolition involved. Construction for short duration and Fabrication part is more. • Acoustic enclosures to D G set as per manufacturers design.
4.	Environment Monitoring and Management	<p>For the effective implementation of the EMP, an Environmental Management System (EMS) will be established at the proposed project. The EMS will include-</p> <ul style="list-style-type: none"> • An Environmental Management cell • Environmental Monitoring Program • Personnel Training • Regular Environmental Audits and Corrective Action • Documentation – Standard operating procedures • Environmental Management Plans and other records
5.	Occupational Health	<p>Cleanliness of all workplaces will be emphasized upon. Sufficient and suitable lighting arrangements will be provided in all working areas. Effective provisions of drinking water at convenient places will be made for the work force.</p> <p>Apart from the above provisions, the health of all personnel will be consistently monitored for occupational diseases through medical check-up at regular intervals carried out by a registered medical practitioner. Regular Work Place monitoring will be done to take care of work environment in turn safety of persons working in it.</p>
6	Green Belt	No impact. 9000 m2 area of Green belt will be provided.
7	Hazardous Waste Management	<ul style="list-style-type: none"> • Segregation category wise and disposed to CHWTSDF. • Disposal of Hazardous Waste: Shall be sent to CHWTSDF, • Disposal of biodegradable Waste: Shall be used as manure for Gardening.

The capital cost of Environmental Management Cost will be around **Rs. 1 Cr. and 22 Lacs** and extrapolated values of recurring expenditure will be **Rs.7 lacs 75 thousand/Annum.**

8.0 Conclusion

The industry proposes to manufacture APIs & Advance Drug Intermediates which are in good demand in Indian and Global market. Project activity is not expected to disturb the environmental setting because Mehta has proposed necessary preventive and mitigation measures required for pollution prevention. The risk associated has been identified, risk assessment has been carried out, HAZOP study is also done and recommendations of the same will be implemented to ensure safety. Moreover on site emergency plan will be prepared to tackle the emergency when it arises.

Land selected is in notified Industrial estate. Trees will be planted and existing will be maintained. No Rehabilitation issue is involved. There will not be problematic waste materials as all will be safely disposed. Socio-economic benefits are expected due to creation of direct/indirect employment. Moreover due to project other direct and indirect business will be benefited.

Mehta API Pvt Ltd. will take care that there should not be any kind of pollution from operation of this project. It can be concluded on a positive note that after the implementation of the Mitigation Measures and Environmental Management Plan, the normal operation of proposed unit of Mehta, will have no negative impact on environment and the proposed project merits grant of environment clearance.