

PIRAMAL ENTERPRISES LIMITED
SY. NO. 71, 77, 78, 79A TO 80A, 81A AND 82A, DIGWAL VILLAGE,
KOHIR MANDAL, SANGAREDDY DISTRICT, TELANGANA

EXECUTIVE SUMMARY

SUBMITTED TO
TELANGANA STATE POLLUTION CONTROL BOARD,
REGIONAL OFFICE, SANGAREDDY

CHAPTER 11.0 EXECUTIVE SUMMARY

Introduction

Active pharma ingredients are essential for maintaining both human and animal health. APIs are manufactured in smaller quantities compared to fine chemicals used in consumer products, dyes used in textiles and other large volume chemicals. Telangana state is the hub of major manufacturing facilities in pharma sector in India.

M/s. Piramal Enterprises Limited (and its group units) - (Unit -I, II & III) obtained Environment Clearance vide letter no.s Unit I: J-11011/392/2006-IA. II(I), Unit II: J-11011/393/2006-IA.II(I), Unit III: J-11011/394/2006-IA.II(I) dt. 21.02.2007. The unit has obtained the merged consent for operation vide letter no. APPCB/PTN/PTN/441/CFO/HO/2012 dt. 18.08.2012 and renewed the consent for operation vide order no. TSPCB/RCP/SRD/CFO/HO/2016-03 dated 26.03.2016 valid till 31.01.2021. It is proposed to expand the API manufacturing capacity from 363.16 TPM to 505.47 TPM in existing area of 79 acres. The capital cost for expansion is Rs. 250 crores, towards enhancement of zero liquid discharge facility, production blocks, utilities and debottlenecking and additional equipment to enhance the capacity, at Sy. No. 71, 77, 78, 79A to 80A, 81A & 82A, Digwal Village, Kohir Mandal, Sangareddy District, Telangana. Active pharma ingredients are classified under synthetic organic chemicals and the Ministry of Environment, Forest and climate change mandated prior environmental clearance vide SO 1533, dated September 14, 2006, for expansion projects also. The terms of reference for the environmental impact assessment studies was obtained from MoEF&CC vide letter no. F.No. J-11011/213/2014-IA II (I) dated 21.10.2014 and subsequently obtained extension of validity of TOR vide letter no. F.No. J-11011/213/2014-IA II (I) dated 19.02.2018 as part of environmental clearance process. The certified compliance letter from the regional office of MoEFCC, Chennai is obtained vide letter no. F. No. EP /12.1/519/AP/39 dated 23.02.2015.

Location of the Project:

The plant site is located at Sy. No. 71, 77, 78, 79A to 80A, 81A & 82A, Digwal Village, Kohir Mandal, Sangareddy District, Telangana. The site is located at the intersection of 17°39'57" (N) latitude and 77°43'02" (E) longitude. The plant site elevation above mean sea

level (MSL) is 635 m. The site is surrounded by open agricultural lands in north and east direction, National Highway No. 9 in south and road connecting Digwal village to Chillkeaply village in west direction. The nearest human settlement from the site is Digwal 0.15 km from the site in southwest direction. The nearest railway station is kohir at a distance of 6.2 km in south direction and Shamshabad airport is located at a distance of 90 km in southeast direction. Kotturu reservoir is at a distance of 7.2 km in northeast direction. Digwal RF is at a distance of 2.5 km in north direction from the site boundary. There is no national park, wildlife sanctuary, ecologically sensitive area, biosphere reserve, tiger reserve, elephant reserve, critically polluted areas and interstate boundary within 10 km radius of the site.

Product Profile

The manufacturing capacity of proposed products after expansion is mentioned below;

Manufacturing Capacity - After Expansion

S.No	Name of the Product	CAS No.	Capacity (TPM)
1	Abacavir Sulfate	188062-50-2	2
2	Diltiazem Hydrochloride	33286-22-5	25
3	Cis Hydroxy Lactam	42399-49-5	10
4	Ketoconazole	65277-42-1	17.5
5	Verapamil Hydrochloride	152-11-4	13.75
6	Halothane	151-67-7	25
7	Desflurane	57041-67-5	25
8	Isoflurane	26675-46-7	150
9	Sevoflurane (Bottling)	28523-86-6	72
10	Levobunolol Hydrochloride	27912-14-7	0.04
11	Brimonidine Tartrate	70359-46-5	0.04
12	Trazodone Hydrochloride	25332-39-2	5.57
13	FA (2,5-Bis (2,2,2-trifluoroethoxy)-2,2,2-trichloro acetophenone)	54143-56-5	2.9
14	Mebeverine Hydrochloride	2753-45-9	8.75
15	FC-4010 [5,6-Dihydro-(S)-6-methyl -4-oxo-thieno (2,3,6) thiopyram -7, 7- dioxide (Hydroxysulphane)	147086-81-5	0.42
16	Paroxetine	61869-08-7	4.5
17	Oxybutynin Hydrochloride	1508-65-2	0.05
18	Iodoaniline Methyltriazole	160194-26-3	0.3
19	Immiquimod	99011-02-6	0.1
20	Flecainide Acetate	54143-56-5	2.2
21	Vitamin A Palmitate	79-81-2	0.1
22	Vitamin E Alcohol	10191-41-0	12.5
23	Vitamin A Alcohol	68-26-8	6.67
24	Dry Vitamin A Acetate	127-47-9	25
25	Chloropurine	87-42-3	9.2

26	Sevoflurane	28523-86-6	25
27	Amiodarone Hydrochloride	19774-82-4	2.6
28	Sertraline Hydrochloride	79559-97-0	1
29	Quetiapine Hemifumarate	111974-72-2	2.3
30	Tolcapone	134308-13-7	0.4
31	Methyl-2-(2-methyl-1H-pyrrolo [2,3-b] Pyridin-3yl) acetate (FCI-1641)	1134327-80-2	0.03
32	Sodium Carboxymethyl Cellulose	9004-32-4	0.19
33	SSPP (4aS, 7aS)-Octahydro-1H-Pyrrolo[3,4-b] Pyridine	151213-40-0	0.9
34	Droxidopa	23651-95-8	0.4
35	Tramadol Hydrochloride	22204-88-2	5.47
36	Acyclovir	59277-89-3	1.3
37	Tafenoquine Succinate	106635-81-8	0.08
38	Spirapril Hydrochloride Dihydrate	83647-97-6	0.01
39	Clozapine	5786-21-0	2.08
40	Halofuginone Hydrobromide	64924-67-0	0.25
41	Donepezil Hydrochloride	120011-70-3	0.1
42	Irbesartan	138402-11-6	0.4
43	Telmisartan	144701-48-4	0.4
44	Sulindac	38194-50-2	0.2
45	Ziprasidone Hydrochloride	138982-67-9	0.05
46	Valacyclovir Hydrochloride	124832-27-5	2
47	Metaxalone	1665-48-1	0.8
48	Lisnopril Dihydrate	83915-83-7	0.2
49	Loratadine	79794-75-5	0.2
50	Netaglinide Hydrochloride	105816-04-4	0.1
51	Imipramine Hydrochloride	113-52-0	0.1
52	Opipramol Dihydrochloride	909-39-7	0.1
53	Clomipramie Hydrochloride	17321-77-6	0.1
54	Memantine Hydrochloride	41100-52-1	10
55	Itra 1330 (Cis -2-(2,4-Dichlorophenyl) -2- (1H-1,2,4 - triazol-1- yl-methyl) - 1,3- dioxolan -4-yl methylmethane sulfonate HCl	106461-41-0	0.1
56	Itra 1334 (2,4- Dihydro 4- [4-[4-(4- hydroxyphenyl) -1 - piperazinyl] phenyl] -2-(1- methyl propyl) -3H- 1,2,4 - triazol-2- N- isobutyl -3-one	67914-86-7	0.5
57	Aprepitant	170729-80-3	0.03
58	Candesartan Cilexetil	145040-37-5	3
59	Perindopril Erbumine	107133-36-8	12.54
60	Bittermelon	90063-94-8	1.4
61	Tinefcon		12.54
62	Allopurinal	315-30-0	0.01
	Total		505.47

List of By-products - After Expansion

S.No	Name of Byproduct	Quantity (Kg/day)	Name of Product
1	Sodium Bromide (16%)	2716.2	Halothane
2	Aluminium Chloride (50%)	3460	Flecainide Acetate
3	p-Toluene Sulfonyl Sodium	213.1	Ketoconazole
4	Spent Sulfuric Acid (40%)	5921.4	Memantine Hydrochloride
5	Spent HCl (20%)	4945.8	Isoflurane

Manufacturing Process

Chemical synthesis produces majority of API's currently in the market. Chemical synthesis consists of four process steps - reaction, separation, purification, and drying. Large volumes of solvents are used during chemical syntheses as medium, extractions, and solvent interchanges. The manufacturing process of all the compounds, reactions involved, material balance are presented in chapter 2 of EIA report.

Utilities

The proposed expansion requires additional steam for both process and effluent treatment system. It is proposed to establish a 16 TPH coal fired boiler and a 6 TPH Oil fired boiler in addition to existing 1 x 16TPH , 2 x 4TPH and 3 x 6TPH coal fired boilers. It is proposed to dismantle 1 x 4 TPH and 1 x 6TPH coal fired boilers after expansion. The DG sets required for emergency power during load shut down is estimated at 3380 kVA and accordingly 4 x 750 kVA and 3 x 725 kVA DG sets are proposed in addition to the existing 2 x 1000, 3 x 500, 2 x 380 kVA, 2 x 250 and 1 x 225 kVA DG sets. The list of utilities is mentioned below;

List of Utilities

S.No	Utility	Permitted	Proposed	Total after expansion
1	Coal Fired Boiler	2 x 4 TPH* 3 x 6 TPH * 1 x 16 TPH	1 x 16 TPH	2 x 16 TPH 1 x 4 TPH 2 x 6 TPH
2	Oil Fired Boilers	1 x 6 TPH	1 x 6TPH	2x6TPH
3	DG Set**	2x1000 kVA 3x500 kVA 2x380 kVA 2x250 kVA 1x225 kVA	4 x 750 kVA 3 x 725 kVA	2 x 1000 kVA 3 x 500 kVA 2 x 380 kVA 2 x 250 kVA 1 x 225 kVA 4 x 750 kVA 3 x 725 kVA

*1x 4TPH and 1x 6TPH coal fired boilers will be dismantled after expansion.

** DG sets will be used during load shutdown.

Water Requirement

Water is required for process, scrubbers, washing, cooling tower makeup, steam generation and domestic purposes. The total water requirement after the proposed expansion shall increase from 1161.9 KLD to 2306.4 KLD, wherein fresh water requirement shall be 1291.4 KLD and the remaining will be treated wastewater in the order of 1015 KLD. The required fresh water shall be drawn from ground water. The unit obtained permission to abstract ground water of 1300 KLD. The water balance for daily consumption after expansion is mentioned below;

Water Balance after Expansion

Purpose	INPUT KLD		OUTPUT KLD	
	Fresh Water	Recycled Water	Loss	Effluent
Process	472.4			528.16*
Washings	50			50
Lab Washings	10			10
Scrubber	30	20		50
Boiler	147	20	152	15
Cooling Tower	172	975	1052	95
RO/DM Rejects	225			225
Domestic	95		11	84
Water for gardening	90		90	
Gross Total	1291.4	1015	1305	1057.16
Total	2306.4		2362.16	

* Process Effluents contains unreacted raw materials, water formed during reaction, soluble solvents, by-products etc

Baseline Environmental Data

The baseline data was collected in the study area during October to December 2017. The baseline data includes collection of Samples of ground water, surface water and soil, monitoring of ambient air quality, noise levels, ecological status and meteorological parameters. The analytical results show that the values are within the prescribed limits for air quality. The ground water quality is observed to be above the limits for potable purpose when compared to the prescribed standards of IS: 10500 – 2012 at few locations.

Identification and Quantification of Impacts

The impact assessment report has identified various sources of pollution and quantified the pollution loads due to proposed expansion. It has also identified the technologies to be adopted for impact mitigation and control. The sources of pollution are air emissions from utilities and process; liquid effluents from process, utilities and domestic usage; solid

wastes from process, treatment systems and utilities; and noise pollution from utilities, and process equipment.

Impacts on Air quality: The impacts on air quality shall be due to emissions from coal fired boilers and standby DG sets. The incremental concentrations are quantified using ISC-AERMOD model. The results indicate marginal increase in ambient air quality concentration. The predicted values for SPM, PM₁₀, PM_{2.5}, SO₂ and NO_x are 4.47, 1.78, 0.80, 6.96 and 3.32 µg/m³ respectively and the maximum values are observed at a distance of 0.5 km from the center of plant site in northwest direction. The cumulative values of baseline air quality combined with predicted values are found to be within the prescribed limits of national ambient air quality standards. The proposed mitigation and control measures for air pollution shall ensure that the impact on air quality is local – within the site area and its surroundings. The fugitive and diffuse emissions were quantified and a box model was used to predict air borne concentrations, and the results indicate the work room concentrations less than threshold limit values (TLV) for various solvents.

Impacts on Water: Water is used for process, utilities and domestic purposes. Ground water is abstracted to obtain the required fresh water in the order of 1291.4 KLD. Treated wastewater is reused in the order of 1015 KLD in addition to fresh water usage. No impact on water quality is expected due to discharge of effluents as zero liquid discharge is envisaged, which ensures reuse of treated wastewater for cooling towers, boiler makeup and scrubbers. There is no usage of treated wastewater for on land irrigation.

Impacts on Noise quality: The noise levels may increase due to motors, compressors, DG set and other activities. The major source of noise generation is DG sets which emit noise levels of above 90 dB (A) at a reference distance of 1m from the source. The predicted cumulative noise levels (as calculated by the logarithmic model without noise attenuation) ranged between 55 and 75 dB (A) at distances of 70 to 150 m. The increase in noise levels shall have neutral impact, restricted to within site area.

Impacts on Soil: The solid wastes generated from process, utilities and effluent treatment plant may have significant negative impacts if disposed indiscriminately. The total solid waste will be stored separately in Hazardous waste storage area. Solid waste will be sent

to cements plants for co-incineration based on calorific value or sent to TSDF. The operational phase impacts shall be neutral due to effective implementation of mitigative measures in handling, storing and transferring of solid wastes, effluents and chemicals, and development of green belt.

Impacts on Ecology: There are no endangered species of flora and fauna in the impact area. The impact on biological environment is neutral with the effect confined mainly to the site area.

Environmental Monitoring Programme

It is proposed to monitor Ambient Air Quality (AAQ) for PM₁₀, PM_{2.5}, SO₂ and NO_x, work room for VOC concentrations, stack emissions for boiler and DG sets, noise levels on quarterly basis. Ground water, treated wastewater are monitored on daily basis, while Soil analysis is conducted once a year.

Additional Studies

Risk assessment was conducted and the heat radiation damage distances of pool fire in the tank farm was limited to 12m for a heat radiation of 4 KW/m², and the same was within the plant premises.

Project Benefits

The proposed expansion will provide employment to 400 people. The proposed project will also generate indirect employment to the locals during construction phase in the order of 105 people for a period of 12-18 months. The project shall have positive impact on socioeconomic environment due to provision of employment both direct and indirect and proposed CSR activities.

Environment Management Plan

The management plan is drawn in consultation with project proponents and technical consultants after evaluating various mitigation and control measures to address the impacts identified, predicted and monitored. The impacts during construction stage are temporary and less significant, the management plan for impacts identified during operation stage is described as follows;

Liquid Effluents

The sources of effluents both before and after expansion are process, washings, scrubbers, utility blowdowns, RO/DM rejects from pre-treatment of water and domestic wastewater. The total effluents are segregated into two streams High COD/ TDS and Low COD/ TDS streams. The effluents are segregated stream wise based on the characteristics of effluents, i.e., less than 15000 mg/l of TDS and COD are considered as low COD/TDS effluents, while the others are considered as high COD/TDS effluents. The effluent treatment system shall be developed in modules for ease of operation for ease of operation. The treated wastewater is used for cooling towers, boilers as make up, scrubbers and washings. Total Effluent generated and mode of treatment before and after expansion is mentioned below;

Total Effluent Generated and Mode of Treatment

Description	Quantity (KLD)		Mode of Treatment
	Permitted	After Expansion	
HTDS Effluents			
Process	207	277.02	Sent to Stripper. Stripper condensate shall be disposed to cement industries for co-processing/TSDF. Stripper bottom is sent to MEE followed by AFTD. Condensate from MEE shall be sent to biological treatment plant followed by RO. RO rejects are sent to MEE and permeate is reused in cooling towers, boiler make-up, and scrubbers .
Washings		50	
Scrubber Effluent	5	50	
Total - I	212	377.02	
LTDS Effluents			
Process	97.7	251.14	Sent to biological treatment system followed by RO. RO permeates reused for cooling towers, boiler make-up, and scrubbers. RO rejects are sent to MEE.
Washings	59		
Lab Washings		10	
Boiler Blow downs	95.78	15	
DM/RO Rejects		225	
Cooling Tower Blow downs	70	95	
Domestic	28	84	
Total - II	350.48	680.14	
Grand Total (I+II)	562.48	1057.16	

Effluent Treatment System

The Effluent management system is developed to ensure 'Zero Liquid Discharge'. The total effluents are segregated into two streams High COD/ TDS and Low COD/ TDS

streams. The effluents are segregated stream wise based on the characteristics of effluents, i.e., less than 15000 mg/l of TDS and COD are considered as low COD/TDS effluents, while the others are considered as high COD/TDS effluents. The effluent treatment system shall be developed in modules for ease of operation.

The High TDS/ COD Effluents

The treatment system for treating High TDS/ COD effluents consists of Equalization, Neutralization, Settling tank, Stripper, Multiple Effect Evaporator (MEE) followed by Agitated Thin Film Dryer (ATFD). The organic distillate from the stripper is sent to cement plants for co-incineration and aqueous bottom from stripper is sent to MEE followed by ATFD for evaporation. The condensate from the MEE and ATFD are sent to effluent treatment plant (Biological). Salts from ATFD are disposed to TSDF.

The Low TDS/ COD Effluents:

These effluents along with the condensate from MEE and ATFD are treated in primary treatment consisting of equalization, neutralization, and primary sedimentation followed by secondary biological treatment consisting of aeration tank and clarifier.

The treated effluents after biological treatment are subjected to tertiary treatment in a reverse osmosis (RO) system. Permeate from RO is reused for cooling tower, boiler make-up, and scrubbers, while rejects are sent to MEE followed by ATFD. Sludge from various units of Biological treatment are thickened in sludge handling system and sent to TSDF.

Air Pollution

The sources of air pollution from utilities are coal fired boilers, oil fired boilers and DG sets. DG sets shall be used during load shut down only. The proposed air pollution control equipment for coal fired boiler is bag filters and multi-cone cyclone separators. DG sets shall be provided with stack heights based on the CPCB formula for stack height.

The process emissions contain Ammonia, Hydrogen Chloride, Sulfur dioxide, Hydrogen sulfide, Carbondioxide, Nitrogen, Oxygen, Nitrogen and Hydrogen. Ammonia, Hydrogen Chloride, Sulfur dioxide, Hydrogen fluoride emissions are sent to a scrubber with dilute caustic medium and the resultant scrubbing effluent is sent to ETP. The other gases are Carbon dioxide, Nitrogen, Oxygen, which are let out into atmosphere following a

standard operating procedure while Hydrogen gas is let out into atmosphere through water column.

The process operations of centrifuging, drying, distillation, extraction etc are also source of diffuse emissions. These emissions mainly contain volatile contents of the material used for processing. It is proposed to provide vent condensers in series to reactors, distillation columns, driers and centrifuge etc. to mitigate VOC emissions release. Other vents are connected to common headers and scrubbers.

Solvent Use and Recycle

Solvents are used for extraction of products and as reaction medium. Used solvents are recovered by distillation for reuse. Residues from distillation columns and mixed solvents shall be sent to TSDF for incineration or cement plants for co-incineration. If any of the distilled spent solvents are not reused due to statutory reasons the same shall be sold to end users.

Solid Waste

Solid wastes are generated from process, solvent distillation, effluent treatment system, DG sets and boilers. Stripper distillate, process residue and solvent residue are sent to cement plants for co-incineration based on acceptability as the same contain significant calorific value and are predominantly organic in nature. If these wastes are not suitable for co-incineration, the same are sent to TSDF facility. The evaporation salts from ATFD, and sludge from ETP are sent to TSDF for landfill. Waste oil and used batteries from the DG sets are sent to authorized recyclers. Other solid wastes expected from the unit are containers, empty drums which are returned to the product seller or sold to authorized buyers after detoxification. Coal ash from boiler is sold to brick manufacturers.

Noise Pollution

Noise is anticipated from motors, compressors, centrifuges and DG sets. DG sets shall be provided with acoustic enclosure. Engineering controls like acoustic enclosures, barriers, shields, and anti vibrating pads are provided to ensure reduction of noise levels and vibration. Employees working in noise generating areas shall be provided with appropriate personnel protective equipment.

Occupational Safety and Health

Direct exposure to chemicals or its raw materials may affect health of employees. Direct exposure to hazardous materials is eliminated by providing closed handling facilities. Personal Protective Equipment (PPE) i.e., hand gloves, safety goggles, safety shoes, safety helmets, respiratory masks etc. are provided to all the employees working in the plant. Company has a policy of providing PPEs to all personnel including contract workers. Periodic medical checkup in addition to checkup during recruitment is adopted to monitor health status of employees.

Prevention, maintenance and operation of Environment Control Systems

The pollution control equipment and effluent treatment system are monitored periodically to assess their efficiency and performance potential as part of adoptive management. Proactive maintenance and monitoring program for all equipment and machinery is adopted to identify the problems/under performance of the equipment. Necessary measures will be adopted to rectify the identified problems/defects. The management agrees that the results of monitoring will be reviewed periodically to adopt new measures if necessary, for efficient pollution control.

Transport systems

All the raw materials and finished products are transported by road. Dedicated parking facility is provided for transport vehicles. There will be 15-20 additional truck trip per day to the factory due to expansion, for transporting raw materials and products. Traffic signage will be placed in the battery limit. The drivers of vehicles will be provided with TREM cards of chemicals and materials to be transported, and will be explained the measure to be adopted during various emergencies

Reduce, Recycle and Reuse

A number of measures are proposed to achieve high yields and reduce generation of wastes. It shall be endeavor of the R&D team to improve yields through constant research and development activities. The solvents shall be recycled for reuse in the process after distillation. Mother liquors from the first crop shall be reused for process. The steam condensate shall be reused for boiler feed. Wherever possible all products of reactions are

extracted and sold. It is also proposed to explore recovery of various salts from MEE salts, and from process effluents to reduce effluent loads, and quantity of solid waste.

Green Belt Development

The management developed green belt in a total area of 27 acres and proposed to enhance the greenbelt area covering the boundary of the site as part of environment management plan to enhance environmental quality through mitigation of fugitive emissions, attenuation of noise levels, balancing eco-environment, prevention of soil erosion, and creation of aesthetic environment

Post Project Monitoring

Environmental monitoring for water, air, noise and solid waste quality will be conducted periodically either by proponent or third party. The frequency of monitoring and the quality parameters shall be as suggested by the Ministry of Environment and Forests and Climate Change, Government of India.

Environment Management Department

Vice President operations, GM (Head- EHS), President EHS corporate and chief manager - EHS will take the final responsibility for environmental Management and Safety control.