

# **SMS PHARMACEUTICALS LIMITED, UNIT - VII**

**SY.NO. 160,161,163 TO 168 AND 170 (KANDIVALASA VILLAGE),  
SY. NO.72 (KOVVADA AGRAHARAM VILLAGE),  
PUSAPATIREGA MANDAL, VIZIANAGARAM DISTRICT,  
ANDHRA PRADESH**

## **EXECUTIVE SUMMARY**

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**SUBMITTED TO  
ANDHRA PRADESH POLLUTION CONTROL BOARD,  
REGIONAL OFFICE, VIZIANAGARAM**

## EXECUTIVE SUMMARY

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### Introduction

M/s. SMS Pharmaceuticals Limited, Unit VII obtained Environment Clearance Vide letter no. F. No. J-11011/361/2006-IA II (I) dated: 16.04.2007 and CRZ clearance vide letter no. 11-45/2007-IA III dated: 08.10.2007 for marine disposal of treated wastewater through dedicated pipeline to sea. It is now proposed to expand the API manufacturing capacity from 179.05 TPM to 740.76 TPM with inclusion of a captive power plant of 2 x 2 MW capacity in existing site area of 95.56 acres. The capital cost for expansion is Rs. 600 crores for additional production blocks, utilities, enhancement of treatment facilities, storages and additional equipment to increase manufacturing capacity, at Sy. Nos. 160, 161, 163 to 168 and 170 Kandivalasa Village, Sy. No. 72 Kovvada Agraharam Village, Pusapatirega Mandal, Vizianagaram District, Andhra Pradesh.

The terms of reference for the environmental impact assessment studies was obtained from MoEF&CC vide letter no. IA-J-11011/12/2018-IA II (I) dated 05.02.2018. The certified compliance letter from the regional office of MoEF&CC, Bangalore is obtained vide letter no. F.No. EP /12.1/526/AP/1864 dated 20.11.2017 and F.No. EP /12.1/604/AP/1863 dated 20.11.2017 for conditions mentioned in the environmental clearances and CRZ clearance obtained for marine outfall as mentioned above.

### Location of the Project:

The project site of 95.56 acres is located at Sy. Nos. 160, 161, 163 to 168 and 170, Kandivalasa Village, Sy. No. 72, Kovvada Agraharam Village, Pusapatirega Mandal, Vizianagaram District, Andhra Pradesh. There is no additional land acquisition for the proposed expansion and the available land of 96.56 acres is sufficient for expansion. The site is situated at the intersection of 18°06'02" (N) latitude and 83°35'22" (E) longitude. The site elevation above mean sea level (MSL) is in the range of 38-45 m. The plant site is surrounded by NH-5 to Chintapalli Road in North and East direction, open lands in south and west directions. The nearest village from the plant is Kovvada Agraharam village located at a distance of 1.7 km in southwest direction. The main approach road AH45 (NH-5) is at a distance of 1.9 km in north direction. The nearest Town Vizianagaram is at

a distance of 16 km in northwest direction and Nellimarla railway station is at a distance of 17 km in northwest direction and nearest airport is Visakhapatnam located at a distance of 56 km in southwest direction. Kandivalasagedda, a seasonal stream is flowing from northwest to southeast direction at a distance of 3.4 km in east direction, and Champavathigedda, a seasonal stream is flowing from northwest to southeast direction at a distance of 7.4 km in southwest direction. Bay of Bengal is at a distance of 6.7 km in SE direction. There are three reserve forests in the study area, Kumili RF is at a distance of 2.6 km in northeast direction, Konada RF is at a distance of 7.6 km in southwest direction, Damarasingi RF is at a distance of 8.2 km in northwest direction. There is no National Park, sanctuary, critically polluted area and interstate boundary within the impact area of 10 km surrounding the site. Pydibhimavaram industrial area, which has a number of pharmaceutical manufacturing industries is located at a distance of 4.5 km in northeast direction. There are few discreetly located active pharma ingredient manufacturing units, outside Pydibhimavaram industrial area, within the impact area.

### Product Profile

The manufacturing capacity both before and after expansion are presented in following table; and the list of by-products after expansion is presented in following table.

**Manufacturing Capacity**

S.No	Name of Product	Capacity (TPM)	
		Permitted	After Expansion
1	Efavirenz	16	120
2	Lopinavir	3	5
3	Emtricitabine	1.5	20
4	Tenofavir	5	60
5	Atazanavir	0.5	15
6	Valcyclovir	10	30
7	Ritonavir	1	5
8	Zidovudine	7	20
9	Lamivudine	2	75
10	Valsartan	13	13
11	Abacavir	5	10
12	TPN Base	3	3
13	Pantoprazole	2	5
14	Ranitidine	90	90
15	Levetiracetam	10	20
16	Temisartan	0.5	2
17	Olmisartan	0.5	5

18	Candesartan	0.3	2
19	Ibresartan	0.25	2
20	Itraconazole	1.5	3
21	L-Carbocystiene	2	10
22	Sulfamide	3	3
23	Gabapentin	1	40
24	Valganciclovir	1	5
25	Sitagliptin		10
26	Vildagliptin		2
27	Briviracetam		10
28	Amlodipine		5
29	Penciclovir		1
30	Arpiprazole		2
31	Rosiglitazone		0.5
32	Canagliflozin		2
33	Dapagliflozin		2
34	Empagliflozin		20
35	Ranolazine		10
36	Lanconazole		0.05
37	Paliperidone Palmitate		0.1
38	Mirabegron		0.5
39	Solefinacin		1
40	Lamotrazine		5
41	Sumatriptan		0.5
42	Famotidine		5
43	Almotriptan		0.1
44	Ondansertan		0.5
45	Zolmitriptan		0.5
46	Rizatriptan		0.5
47	Elitriptan		0.25
48	Tadalafil		0.5
49	Sildenafilcitrate		2
50	Lanthanum Carbonate		2
51	Luliconazole		0.01
52	Verdinafil		0.25
53	Raltegravir		5
54	Dolutegravir		25
55	Darunavir		15
56	Linagliptin		0.5
57	Rivaroxaban		3
58	Apixaban		1
59	Sofosbuvir		30
60	Trazadone		15
	<b>Total</b>	<b>179.05</b>	<b>740.76</b>
61	Co-generation Power Plant	---	2 x 2 MW

**List of By-Products - After expansion**

S.No	Name of Product	Stage	Name of By-product	Quantity	
				Kg/day	TPM
1	Atazanavir Sulphate	III	Triethylamine HCl	521.2	15.6
2	Dapagliflozin Propanediol	I	N-Methylmorpholine HCl	121.7	3.6
3	Darunavir	II	1-Hydroxy pyrrolidine-2,5-dione	210.2	6.3
4	Dolutegravir Sodium	III	Toluene	175.8	5.3
5	Efavirenz	V	Trichloro methanol	3430.9	102.9
6	Emitricitabine	I	Menthol	438.7	13.2
			Isopropyl Alcohol	168.7	5.1
		II	Triethyl amine HCl	377.2	11.3
7	Leviteracetam	II	Potassium Chloride	876.0	26.3
8	Sofosobuvir	I	Triethyl amine HCl	821.4	24.6
		III	4-Trifluoromethyl phenol	306.2	9.2
9	Tenofovir disoproxil fumarate	I	p-Toulene sulfonic acid	555.1	16.7
			Ethanol	296.9	8.9
10	TPN Base	II	Ammonium chloride	43.7	1.3
11	Valacyclovir HCl	III	Benzoyl formate	377.3	11.3
12	Zidovudine	I	Trityl chloride	695.4	20.86

### Manufacturing Process

Chemical synthesis produces majority of API's currently in the market. Chemical synthesis consists of four steps - reaction, separation, purification, and drying. Large volumes of solvents are used during chemical syntheses, extractions, and solvent interchanges. The manufacturing process of the above-mentioned molecules involve various types of reactions like acetylyzation, protection, deprotection, hydrolysis etc. The manufacturing process of all the compounds, reactions involved, material balance are presented in annexure of EIA report.

The cogeneration plants shall use steam turbines, and the steam is generated by using a 20 TPH @ 67 bar (a) pressure coal fired boilers for 2 x 2 MW co-generation power plants. Step down pressure of about 9.5 TPH of steam is extracted at 10 to 15 bar pressure to meet process heating requirements and also effluent treatment system.

### Utilities

The proposed expansion requires additional steam for both process and effluent treatment system. It is proposed to establish coal fired boilers of 1 x 20 TPH, 1 x 12 TPH, and 2 x 10 TPH capacity and 1 x 10 lac k.cal/hr and 1 x 2 lac. K.cal/hr coal fired thermic fluid heaters

for process requirement in addition to the existing 1 x 6 TPH, and 1 x 3 TPH coal fired boilers. It is proposed to keep proposed 1 x 12 TPH coal fired boiler and the existing 1 x 6 TPH and 1 x 3 TPH coal fired boilers as standby after expansion. The DG sets required for emergency power during load shut down is estimated at 12000 kVA and accordingly 7 x 1500 kVA DG sets are proposed in place of exiting 1 x 125kVA. The list of utilities is presented in following table;

**List of Utilities**

S. No	Description	Unit	Capacity			
			Existing	Proposed	Total after expansion	
1	Coal Fired Boilers	TPH	1 x 6	1 x 20	1 x 20	
			1 x 3	1 x 12	1 x 12*	
				2 x 10	2 x 10	2 x 10
					1 x 6*	1 x 3*
2	Themic Fluid Heater	K. Cal/hr		1 x 2 Lac	1 x 2 Lac	
				1 x 10 Lac	1 x 10 Lac	
3	DG Set**	KVA	1 x 125	7 x 1500	7 x 1500	
					1 x 125	

\* Standby

\*\*DG sets will be used during load shut down by AP TRANSCO.

### Water Requirement

Water is required for process, scrubbers, washing, cooling tower makeup, steam generation and domestic purposes. The total water requirement after expansion increased from 324 KLD to 2035 KLD. The required water shall be drawn from ground water supply by APIIC from Thota palli reservoir. The water balance for daily consumption is presented in following table;

**Water Balance**

Purpose	INPUT (KLD)		OUTPUT (KLD)	
	Fresh Water	Loss	Loss	Effluent
Process	400.2			430.7*
Washings	60			60
Scrubber	40			40
Boiler Feed	300	255		45
Cooling Tower	1100	890		210
DM Regeneration	80			80
Domestic	35	7		32
Gardening	20	20		
<b>Gross Total</b>	<b>2035</b>	<b>1172</b>		<b>897</b>

\* Includes water formed during reaction and water in raw material

### **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 the mitigation and control of the same. 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 the emissions from, Coal Fired Boilers and standby DG sets. The incremental concentrations are quantified using ISC-AERMOD model based on ISCST3 Algorithm. The results indicate marginal increase in ambient air quality concentration. The predicted values for PM, PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub> and NO<sub>x</sub> are 4.08, 1.66, 0.73, 8.06 and 15.72µg/m<sup>3</sup> respectively and the maximum values are observed at a distance of 1.0 km from the center of plant site in northeast direction, and 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 mitigative and control measures of 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 essentially used for process and utilities and domestic purposes. The total fresh water required of quantity 2035 KLD after expansion. No impact

on water quality is expected due to the discharge of effluents, as treated effluent will be disposed to sea by using marine outfall system.

**Impacts on Noise quality:** The noise levels may increase due to turbines, motors, compressors, DG set and other activities. The major source of noise generation is turbine which emit noise levels of above 100 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 62 to 185m. 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 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 PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub> and NO<sub>x</sub>, work room for VOC concentrations, stack emissions for boiler and DG sets, noise levels on quarterly basis. Water, treated wastewater on daily basis, Soil analysis will be done once in a year.

### **Additional Studies**

Risk assessment was conducted and the heat radiation damage distances of pool fire in the tank farm was limited to 12 m for a heat radiation of 4 KW/m<sup>2</sup>, and the same was within the plant premises.



### Project Benefits

The proposed expansion will provide employment to 300 people. The proposed project will also generate indirect employment to the locals during construction phase in the order of 150 people for a period of 18-24 months. The project shall have positive impact on socioeconomic environment due to provision of employment both direct and indirect in addition to proposed corporate environmental responsibility activities and taxes accrued to local body and state government.

### 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 effluents generated in the process, separation techniques and during purification contain organic and inorganic soluble raw materials, adducts, solvents, and products. Hence the effluents contain both organic and inorganic salts and chemicals in various quantities. Effluents from process, washings, scrubbing media, garment washings and utility blow downs will be sent to the effluent treatment system. The treated effluent will be disposed to sea by using marine outfall system. Domestic wastewater is sent to sewage treatment plant and treated wastewater is reused for greenbelt development. Total Effluent generated and mode of treatment before and after expansion is presented in following table;

**Total Effluent Generated and Mode of Treatment**

S.No	Description	Quantity (KLD)		Mode of Treatment/Disposal
		Permitted	After Expansion	
<b>I</b>	<b>High TDS Effluents</b>			
1	Process	71.91	430.7	Effluent is stripped in a steam stripper to remove organics and then concentrated in multiple effect evaporators (MEE) followed by drying in agitated thin film dryer (ATFD). Stripper condensate will be sent to cement plants for Co-
2	Washings	20	60	
3	Scrubber	---	40	

				Incineration. Salt from ATFD is sent to TSDF. Distillate from MEE and ATFD is sent for further treatment in biological treatment plant.
	<b>Total - I</b>	<b>91.91</b>	<b>530.7</b>	
<b>II</b>	<b>Low TDS Effluents</b>			
1	Process	3.6	--	Sent to biological treatment plant and disposed to sea from guard ponds on site, through Marine Outfall system after bioassay, only when it meets the disposal standards.
2	Boiler Blow downs	16	45	
3	Cooling tower blow downs	12.5	210	
4	Domestic wastewater	16	31.5	
5	RO/DM Rejects	53.5	80	
	<b>Total - II</b>	<b>101.6</b>	<b>366.5</b>	
<b>Grand Total (I+II)</b>		<b>193.51</b>	<b>897.2</b>	

### Effluent Treatment System

The effluents are segregated into two streams; high TDS/ COD and Low TDS/COD stream. The segregation is at source and is stream wise. Effluent from process, washings and scrubbers are considered as high TDS and high COD streams. Effluent from Boiler, cooling tower blow downs, DM/softener rejects and domestic wastewater are considered as Low TDS and low COD streams. The effluent treatment system shall be developed in modules at the same location for ease of operation.

#### I. 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 based on biological treatment. Salts from ATFD are disposed to TSDF.

#### II. 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 will be stored in Guard ponds and sent to marine disposal after meeting the standards in bioassay test.

## **Air Pollution**

The sources of air pollution are boilers, and thermic fluid heaters which use coal as fuel and DG sets which use HSD as fuel. Bag filters are proposed as air pollution control equipment for 1 x 20 TPH, 1 x 12 TPH (standby) and 2 x 10 TPH coal fired boilers. DG sets shall be provided with required stack height based on CPCB formula. Process emissions contain ammonia, carbondioxide, carbon monoxide, hydrogen, nitrogen, nitrous oxide, oxygen, isobutylene, hydrogen chloride, hydrogen bromide and sulfur dioxide. Ammonia, hydrogen chloride, hydrogen bromide and sulphur dioxide are sent to scrubber in series. The resultant solutions after scrubbing i.e., Sodium chloride solution from Hydrogen chloride gas scrubbing, ammonium bicarbonate solution from carbon monoxide, sodium bromide solution from hydrogen bromide scrubbing, ammonium bicarbonate solution from carbon monoxide scrubbing, ammonium chloride solution from ammonia scrubbing, sodium bisulphite solution from sulfur dioxide scrubbing are sent to ETP. Carbon dioxide, Nitrogen, nitrous oxide and oxygen are let out into atmosphere following a standard operating procedure, isobutylene gas let out into atmosphere safely through a flare stack, while Hydrogen gas is let out into atmosphere through a water column.

Emissions are also released from various operations of manufacturing like centrifuge, drying, distillation, extraction etc. 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 turbines, motors, compressors, centrifuges and DG sets. DG set shall be provided with acoustic enclosure. Noise absorbing walls are proposed for turbine room and the control room shall be acoustically enclosed. 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 the effluent treatment system is monitored periodically to estimate 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 12-15 truck trip per day to the factory for transporting raw materials and products. Traffic signs 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. Treated wastewater from sewage treatment plant is reused for greenbelt development. 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 32 acres and proposed to increase density 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**

The Environment Management Cell of the project is headed by the President, Senior vice president, vice president operations, DGM- EHS, followed by manager, assistant manager, Dy. Manager and technicians/fitters.