1.0 Introduction:

M/s. Synergene Active Ingredients Pvt. Ltd., Unit-III proposed to establish Bulk Drugs and Intermediates manufacturing Unit at Plot No. 59 A, J.N. Pharmacity, Parawada Mandal, Vishakhapatnam District of Andhra Pradesh.

The industry proposes to manufacture 23 Products along with their intermediates and process development of R&D Products on regular basis based on the market demand. The Bulk Drugs proposed will either be manufactured till the final stage of the product or up to the corresponding quantities of the intermediates based on the market demand with a total production capacity of 2743.33 Kg/day (82.3 TPM).

1.1 About the Industry:

M/s. Synergene Active Ingredients Pvt. Ltd., Unit-III is promoted by a team of professionals having rich experience in the pharmaceutical industry and clear vision and is conscious about long term sustainable value added growth. M/s. Synergene Active ingredients Pvt. Ltd., has proposed to establish a Bulk Drug manufacturing facility in a 2.33 acres (0.94 hectares) site at Jawaharlal Nehru Pharmacity, Visakhapatnam, about 600 km from Hyderabad. The proposed gross investment in the project would be around Rs.1727.03 Lakhs. The manufacturing facility will be developed in future to meet the cGMP norms and US FDA approvable levels.

1.2 Site Location:

M/s. Synergene Active Ingredients Pvt. Ltd., is located at Plot No. 59 A, J.N. Pharmacity, Parawada Mandal, Vishakapatnam District, Andhra Pradesh. It is located at a distance of about 2 Km from National Highway NH-5 and about 25 Km from Airport, about 30 km from Port, about 8 Km from Duvvada Railway station and about 33 Km from Visakhapatnam.

2.0 Proposed Project:

M/s. Synergene Active Ingredients Pvt. Ltd., Unit-III has proposed to manufacture 23 Bulk Drugs & Intermediates along with their intermediates and process development of R&D Products on regular basis based on the market demand. The list and quantities of the proposed products are given in **Table 1**.

Table 1: List and Quantities of the Proposed Products

Sl. No	Product Name	Production Quantity (Kg/Day)	Starting Raw Material		Number of stages
			Name	Quantity (Kg/day)	
1.	Bilastine Hydrochloride	33.33	2-[1-(2-(4-(1-(4,4-Dimethyl-oxazoline-2-yl)-1-methyl ethyl) phenyl)piperidine-4-yl]-1H-benzimidazole	50.0	2
2.	Biperiden Hydrochloride	16.67	1-(Bicyclo[2.2.1]hept-5-en-2-yl) ethanone	13.33	3
3.	Dorzolamide Hydrochloride	33.33	N-[(4S,6S)-6-Methyl-7,7-dioxo-2-sulfamoyl-5,6-dihydro-4H-thieno[2,3-b]thiopyran-4-yl] acetamide	42.7	2
4.	Doxazosin Mesylate	333.33	2,3-Hydro-1,4-benzo dioxine-2-carboxyllic acid	180.0	3
5.	Efinaconazole	33.33	(2R,3R)-2-(2,4-Difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-2,3-butanediol	42.0	2
6.	Eletriptan Hydrobromide	333.33	5-Bromo-3-(1-methyl pyrrolidin-2(R)-yl-methyl-1H-indole	466.7	3
7.	Glipizide	166.67	5-Methyl pyrazine-2-carboxylic acid	75.0	2
8.	Lacosamide	16.67	D-Serine	11.7	3
9.	Luliconazole	16.67	(S)-1-(2,4-Dichloro-alpha-(chloromethyl)-benzene methanol	25.93	3
10.	Mebeverine Hydrochloride	66.67	Anisic Aldehyde	36.7	3
11.	Repaglinide	33.33	(S)-3-Methyl-1-(2-piperidino phenyl)- 1-butylamine	32.0	3
12.	Rivaroxaban	33.33	4-(4-Aminophenyl) morpholine-3-one	43.33	5
13.	Rupatadine Fumarate	33.33	5-Methyl pyridiine-3-methanol	16.0	3
14.	Sertaconazole Nitrate	333.33	1-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-yl)ethanone	250.0	2
15.	Sertraline Hydrochloride	333.33	N-[4-(3,4-Dichloro phenyl)-3,4-dihydro-1-(2H)-naphthalene ylidene] methanamine (Ketimine)	900.0	3
16.	Tapentadol Hydrochloride	33.33	3-Bromoanisole	61.33	5
17.	Taurolidine	16.67	CBZ Taurinamide	41.7	2
18.	Tioconazole	266.67	1-(2,4-Dichloro phenyl)-2-(1H-imidazol-1-yl)ethanol	314.7	2
19.	Tizanidine Hydrochloride	333.33	N-(5-Chloro-2,1,3-benzo thiadiazol-4-yl) thiourea	533.33	3

20.	Trazodone Hydrochloride	33.33	1-(3-Chlorophenyl)-piperazine Hydrochloride	33.33	3
21.	Vilazodone Hydrochloride	33.33	3-(4-Chloro-1-hydroxy butyl)-1-tosyl-indole-5-carbonitrile	100.0	5
22.	Ziprasidone Hydrochloride	166.67	5-(2-Chloroethyl)-6-chloro oxindole	126.7	3
23.	Zonisamide	33.33	1,2-Benzisoxazole-3-Acetic acid	46.7	3
24.	R&D Products	10.00	--	--	--
Total Production Capacity (All products at a time)		**2743.33**			

All products will be manufactured at a time either Bulk Drugs or corresponding quantities of intermediates based on the market demand.

The material balance including pollution load generated by way of solid waste, liquid effluent and gaseous emissions for the proposed products has been calculated. The product wise liquid effluent, solid waste and gaseous emissions including concentration of TDS and COD from the proposed products is presented in the report**.**

3.0 Environmental Management:

The environmental management plan (EMP) is delineated based on scientific assessment of pollution generation, its handling, treatment and disposal for gaseous, liquid, and solid wastes. Apart from the greenbelt development, safety of the workers, noise controls etc. are also included in it.

3.1 Liquid Waste:

The industry will be collected the effluents including domestic wastewater from all the sources by gravity into separate HTDS and LTDS collection sumps at production blocks / other generation areas. This effluent will be pumped separately to the above ground level collection tanks for storage, equalization and neutralization. The total HTDS and LTDS effluent after neutralization will be sent to Common Effluent Treatment Plant (CETP) provided by the J.N. Pharmacity for further treatment and disposal through separate pipelines. All the treatment tanks will be constructed above the ground level only with water proof lining.

The water requirement and wastewater generation for proposed products on regular basis is presented in **Table 2**.

Table 2: Details of Water Requirement and Wastewater generation

Sl No	Description	Water Requirement (KLD)	Wastewater Generation (KLD)	Disposal
1.	Process (LTDS + HTDS)	29.7	30.1 (20.06 + 10.04)	HTDS to CETP of Pharmacity for forced evaporation & LTDS to CETP of Pharmacity for Biological treatment
2.	Washings	6.0	6.0 (LTDS)	
3.	Boiler	48.0	2.4 (LTDS)	
4.	Cooling Tower	5.0	1.5 (LTDS)	
5.	DM Plant	1.0	1.0 (LTDS)	
6.	R&D, Q.C	1.0	1.0 (LTDS)	
7.	Scrubber	1.5	1.5 (HTDS)	
8.	Domestic	3.0	2.4 (LTDS)	
9.	Gardening	3.0	--	--
Total		**98.2**	**45.9**	
HTDS Maximum Effluent Permitted: 11.65			**11.54**	**2.33 Acres**
LTDS Maximum Effluent Permitted : 34.95			**34.36**	

The total water requirement for the proposed products is about 98.2 KLD and wastewater generated from the proposed products process is about 45.9 KLD. Out of this, maximum HTDS effluent will be about 11.54 KLD of which 10.04 KLD from process and 1.5 KLD from Scrubber. Maximum LTDS effluent will be about 34.36 KLD of which 20.06 KLD from process and 14.3 KLD from washing, utilities, R&D, Q.C and domestic wastewater etc., will be collected by gravity from all sources into a collection into individual collection sumps at Production Blocks / other generation areas. This wastewater will be pumped separately to the above ground level tanks for storage and neutralization then routed to Common Effluent Treatment Plant provided by the J.N. Pharmacity for further treatment and disposal through separate pipelines. Domestic wastewater will also route through separate pipelines to Centralized Sewage Treatment Plant (STP) provided by the J.N. Pharmacity for further treatment and disposal. All the treatment tanks will be constructed / installed above the ground only with water proof lining. Effluent Treatment Plant drawing is enclosed as Annexure.

High TDS concentration will be ranged from 12,000 to 80,000 mg/l and 8000 to 50000 mg/l of COD. Low TDS concentration will be < 12000 mg/l of TDS and < 8000 mg/l of COD.

3.2 Gaseous Emissions

The main source of emissions is from Process, Boiler, D.G. Set and fugitive emissions due to evaporation of solvents.

3.2.1 Process

The process emissions like HCl, H_2, CO_2, NH_3 and SO_2 are generated from proposed process reactions **(Table 3**). Emissions such as HCl, NH_3 and SO_2 will be scrubbed in a PP / FRP scrubber, and CO_2 will be routed through vents to disperse in the atmosphere. Hydrogen will be diffused with flame arrestor.

Table 3: Process emissions and Treatment methods

Sl. No.	Name of the Process Emission	Quantity (Kg/day)	Treatment Method
1.	HCl	222.92	Scrubber with water / Caustic sol.
2.	SO_2	10.4	Scrubbed with Caustic sol.
3.	NH_3	9.61	Scrubber with water
4.	CO_2	82.41	Dispersed into atmosphere
5.	H_2	10.22	Diffused with flame arrestor

3.2.2 Boiler:

Industry is proposing one 4 TPH Coal fired Boiler for steam requirements of the Process, Pollution Control equipments and solvent recovery systems. The Coal fired boiler will be connected with Cyclone separator, Bag filter followed by stacks height of 30 Mtrs. The emissions will be regularly analyzed on monthly basis by recognized laboratories.

About 16.0 TPD Coal will be used as fuel at full production and about 6.4 TPD Boiler ash will be generated which will be send to Brick Manufacturers.

3.2.3 D.G. Set:

Industry is proposing to install 2 no's of 320 KVA D.G. Sets to meet 100 % stand-by power generation in case of power supply failure. The D.G Sets will be silent power (with acoustic enclosures). The emissions from the D.G Sets will be very nominal as it will operate on an average only for 1 to 2 hr's a day. About average 130 lit/hr of Diesel will be used. The stack height will be provided as per the norms of the Board.

3.2.4 Emissions from Solvent Vapour:

The solvents from the proposed products will be transferred in a closed system. Solvent recovery facility like fractional distillation column will be provided for efficient recovery upto 95%. The evaporation losses in solvents will be controlled by various measures like

- Chilled brine circulation will be carried out to effectively reduce the solvent losses into the atmosphere.
- Transfer of solvents using pumps instead of manual handling.
- Insulation and vent condensers will be provided to the solvent storage tanks etc.,
- Closed centrifuges and ANFD will be used due to which solvent losses will be reduced drastically.
- Installation of secondary condensers will further reduce the solvent losses during operations.

Product wise solvent details of the proposed products i.e., Type of solvents used in the product, solvent loss in effluent, solvent loss in organic residue, solvent evaporation losses and solvent recovery are given in the report (Material Balance of each product).

3.3 Hazardous / Solid Wastes:

Solid waste is generated from proposed process where organic residues, isolated inorganic salts and spent carbon are produced, Pollution control facilities like neutralization tanks where sludge will be generated, Stores where waste paper, cartons, wooden crates, plastic bags etc. are generated. The organic residues and spent carbon from the process will be sent to TSDF for incineration provided by the J.N. Pharmacity / APPCB Authorized cement industries. Inorganic salts from process and sludge from

neutralization tanks will be collected and disposed to TSDF provided by the J.N. Pharmacity for secured landfill. Wastes from stores will be segregated and disposed off to the authorized agents as scrap.

3.3.1 Process:

a) Process residues mainly consists of organic residues and spent carbon which will be collected and stored for disposal to TSDF for incineration / Authorized cement industries as alternate fuel.
b) Inorganic solid wastes from proposed process and ETP sludge from neutralization tanks will be disposed to TSDF after isolating and drying. These salts will be collected in bags and stored on a dedicated raised platform under a shed prior to disposal to TSDF.

Hazardous / Solid waste generated from the proposed products will be to the tune of 12.27 TPD including 6.4 TPD Boiler Ash. The details of the solid waste generation are presented in **Table 4**.

Table 4: Hazardous / Solid Waste generation form the Plant

Sl. No.	Source	Stream	Quantity (Kg/day)	Disposal
1.	Organic residue	36.4 of Schedule-I	4731	TSDF / Cement Industries
2.	Spent Carbon	28.2 of Schedule-I	199	
3.	Inorganic Solid Waste	28.1 of Schedule-I	842	TSDF
4.	ETP Sludge	34.3 of Schedule-I	100	
5.	Boiler Ash	--	6400	Sold to Brick Manufactures
Total			**12272**	

3.3.2 Stores:

a) The solid waste generated in the form of empty drums, containers / liners, HDPE liners etc., will be disposed off to the Authorized parties identified by APPCB.
b) Other paper waste will be disposed off to scrap venders.
c) Metal scrap disposed off to the scrap vendors.

3.3.3 Other Hazardous Wastes

Table 5: Other Hazardous Waste generation from the Plant

Sl. No.	Source	Stream	Proposed Quantity	Disposal
1.	Used oils / Waste lubricating oil (lit/Annum)	5.1 of Schedule-I	300	APPCB Authorized Agencies for reprocessing / recycling
2.	Detoxified Containers / drum liners (No's/Annum) a) HDPE carboys (No's/Annum) b) Fiber drums (No's/ Annum) c) PP Bags (Kg/Annum)	33.3 of Schedule-I	3000 1200 1200 1200	Disposed off after complete detoxification
3.	Used Lead acid batteries (No's/year)	17 of Schedule-IV	10	Send back to suppliers
4.	Spent Mixed distilled solvents (KLD)	28.5 of Schedule-I	6	APPCB authorized Solvent recovery units

* Container & Container liners will be detoxified at the specified covered platform with dyke walls and the wash wastewater is routed to Low TDS Collection tank.

3.4 Noise Levels:

The main source of Noise will be from the D.G. Sets. These D.G. Sets will be silent powers and installed in a separate rooms with silencers and acoustic enclosures for reduction of the noise levels. The operators will be provided with ear muffs and ear plugs. Proper rubber padding will be provided to avoid vibrations.

3.5 Storage and Handling of Hazardous Raw materials:

Details of Storage and Handling of Hazardous Raw materials will be as per the safety guideline given in the MSDS. The MSDS of these Hazardous Raw materials are given in report as Annexure.

3.6 Safety practices:

The Environment and Safety Department in M/s. Synergene Active Ingredients Pvt. Ltd., Unit-III is keen on implementing the best of the safety gadgets within the premises and will be developed certain awareness programs for its employees. The employees will be trained in safety and environment protection regulations, chemical safety aspects. Industry will strictly follow the safety norms as per the guidelines of the National Safety Council and provided all the necessary safety equipment for the protection of the Industrial establishment as well as the personnel working in the plant premises. Industry will provide the personnel protective equipment to all its employees who are involved in the handling of hazardous chemicals / activities. The storage and handling of hazardous chemicals, solvents, etc., is according to the norms of PCB and the Inspector of Factories. Personnel involved in the production will be provided with protective clothing, helmets, goggles, masks, gloves, etc. These handling operations will be carried out under the strict supervision of the trained and highly skilled personnel. Supervision will be provided to ensure the usage of these PPE's. Necessary fire-fighting facilities like fire hydrant system, fire extinguishers, sand buckets, etc., will be provided to meet the on-site emergencies.

3.7 Greenbelt:

Out of a total area of 0.943 hectares i.e., 9434 Sq Mtrs and the break up of area is given in the table.

Table 6: Break-up of Plant area

Sl.No.	Description	Area in Sq.m
1.	Building area	3867.8
2.	Roads & Open area	2053.0
3.	Pollution Control facilities area (Storage of wastewater, solid waste storage platform etc.,)	153.0
4.	Greenbelt area	3360.2
Total		**9434.0**

3.8 PCB Compliance:

M/s. Synergene Active Ingredients Pvt. Ltd., Unit-III will respond positively to all the Norms, Regulations and Directions of the Board.

4.0 Post Project Monitoring:

The industry has defined environmental monitoring program to monitor the Ambient Air Quality as well as Stack Emissions. The industry will engage recognized laboratories to carry out all necessary monitoring parameters. The wastewater is regularly analyzed and sent to CETP. Qualified staff will be employed for the purpose of operation and maintenance of the pollution control facilities. Stand-by facilities will be provided to all the facilities so as to ensure fail proof treatment.

5.0 Conclusion:

M/s. Synergene Active Ingredients Pvt. Ltd., has proposed to establish a Bulk Drugs and Intermediates manufacturing industry at JN Pharmacity, Parawada, Vishakhapatnam Dist. of A.P. The industry proposes to manufacture 23 Products along with their intermediates and process development of R&D Products on regular basis based on the market demand. The Bulk Drugs proposed will either be manufactured till the final stage of the product or up to the corresponding quantities of the intermediates based on the market demand with a total production capacity of 2743.33 Kg/day (82.3 TPM).

The industry will be fully equipped with all the pollution control facilities to handle the pollution load generated due to its proposed operations. The industry will also provide the primary treatment facility for treating its Low TDS effluent and HTDS effluent and entered into agreement with CETP for further treatment of its effluent before final disposal. Industry will also entered into agreement with TSDF for safe disposal of solid waste. The Coal fired boiler will be equipped with Bag filter and a stack of 30 m. D.G. Sets will be attached with silencers and install in a separate room for controlling the noise levels.

In view of the above, it is requested to kindly consider the proposed application and arrange to issue the CFE for establishment of an proposed project for manufacturing 23 products and process development of R&D products on regular basis with a total maximum production capacity of 2743.33 Kg/day (82.3 TPM).

The report has been prepared based on the information and clarifications provided by the project proponent.