

# **APPLICATION OF CONSENT FOR ESTABLISHMENT**

## **Along with ENVIRONMENT MANAGEMENT PLAN**



**Proposed by**

**M/s.TORRENT PHARMACEUTICALS LIMITED  
Plot No.77, Jawaharlal Nehru Pharmacy, Thanam Village,  
Parawada mandal, Visakhapatnam Dist-531021 A.P.  
[www.torrentpharma.com](http://www.torrentpharma.com)**

**(February, 2020)**

## **1.0 Introduction**

M/s.Torrent Pharmaceuticals Limited proposes to establish existing Bulk Drugs & Intermediates manufacturing unit at Sy.No. 36,37 & 46, Plot No 77, Thanam (V), Jawaharlal Nehru Pharmacy, Parawada (M), Visakhapatnam District of Andhra Pradesh in an area of 5.23 Acres.

The industry has obtained permission to manufacture 52 Bulk Drugs, Intermediates and API along with Validation batches/Research and development products with Total Production Capacity of 19.17 MT/Month from the Andhra Pradesh State Pollution Control Board vide Consent for Establishment Order No. 135/APPCB/CFE/RO-VSP/HO/2014 dated 26-04-2018. Now the Industry proposes new products and going for CFE (Consent for Establishment)-Change of product mix with production capacity of 19.17 MT/Month for 58 products in the existing production facility.

### **1.1 Local Scenario**

The Visakhapatnam is a global destiny for manufacturers of bulk drugs, active pharmaceutical ingredients, and intermediates. The Visakhapatnam has developed as a prestigious world class Pharma City. The Pharma City is furnished with all the requisite approvals like Environmental Clearance ref no: 12011/1/2004-IA (CIE), dated 10.03.2005 by Minister of Environment & Forest, Govt of India and operational amenities. The City is structured and developed to act as an exclusive hub for manufacturers of bulk drugs, active pharmaceutical ingredients, etc. The diverse range of available facilities viz., Common Effluent Treatment Plant, Secured Land fill, Hazardous Waste Management with incinerator, assured continuous potable water distribution, emergency medical center and central fire services.

### **1.2 Global Scenario**

Indian pharma stocks are performing better than their global counterparts. Their shares have surged on expectations of higher earnings driven by their expansion in the United States and India, faster drug approvals, and improved portfolio quality through acquisitions. Continued strength in the dollar when the Federal Reserve raises interest rates will also boost their income. More than 40 percent of over-the-counter and generic prescription drugs sold in the United States come from India.

The recent survey by World Bank has found Andhra Pradesh is India's best place for conducting business after Gujarat. The growth of business in India requires concerted action on several fronts - infrastructure, capital markets, trade facilitation and skills, the effort is part of the government's initiatives to improve India's position on the World Bank's 'Ease of Doing Business' ranking. Reforms that have changed the scenario are implemented reforms in online tax payments, construction, permits, electricity connections and environmental clearances in a specified time.

### **1.3 About the Industry**

M/s.Torrent Pharmaceuticals Limited., is operated by a team of professionals having rich experience in the pharmaceutical industry with a clear vision and is conscious about long term sustainable value added growth. M/s.Torrent Pharmaceuticals Limited., has acquired the established Plant in Sept 2016 and operating successfully and proposes for new products in the existing Bulk Drug & API manufacturing facility within the existing 5.23 Acres at Jawaharlal Nehru Pharma City, Visakhapatnam. The Existing Gross investment on the project is Rs 2376.93 Lakhs as the facility upgradation has taken up to the existing plant.

#### **ISO 14001-2015 & OHSAS 18001-2007 Certification**

The Industry has taken initiation to have Certification for ISO 14001- 2015 and OHSAS 18001-2007 and it has accorded with the certification on 29<sup>th</sup> November 2019. The ISO 14001- 2015 will insist to attain the requirements for an effective Environmental Management System (EMS). The EMS will gain competitive advantage in supply chain design, increase new business opportunities, meet legal obligations, increase stakeholder and customer trust, improve overall environmental impact and Manage environmental obligations with consistency. OHSAS 18001 -Occupational Health and Safety Management Certification is an international standard which provides a framework to identify, control and decrease the risks associated with health and safety within the workplace. Implementing the standard will send a clear signal to stakeholders that we view employee's health and safety as a priority within your organization. Improves corporate image and credibility among stakeholders, regulators, customers, prospective clients and the public. OHSAS 18001 will get benefit by adoption of international best practice in relation to risk management, ensures health and well-being of employees, sub-contractors and the public, minimization of liability of employers through adoption of proactive rather than reactive controls, ensures legislative awareness and compliance, reduces accident and incident rates by reducing or eliminating workplace hazards, improves the incident investigation process and increases employee motivation through the provision of a safer workplace and participation process.

The industry is planning to migrate into ISO- 45000 within the stipulated timeline.

### **1.4 Location & Its Advantages of the Unit:**

M/s. Torrent Pharmaceuticals Limited is a Bulk Drugs & Intermediates manufacturing facility in Sy.No. 36,37 & 46, Plot No 77, Thanam (V), Jawaharlal Nehru Pharmacity, Parawada (M), Visakhapatnam District of 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.

## 1.5 Introduction to J.N.Pharmacy :

J.N.Pharma city was incorporated as a Special purpose Company to develop India's first Sector specific industrial theme park exclusively to house Bulk Drug, Pharmaceutical & allied Fine Chemical Manufacturing Industries.

The Park is being developed in an extent of 2120 Acres by Ramky Group in association with Andhra Pradesh Industrial Infrastructure Corporation Limited (APIIC) on Public Private Partnership on Build Own Operate basis at Parawada, Visakhapatnam District, Andhra Pradesh.

JNPC is designed and Master Planned by JTC – Jurong Corporation, Singapore, achieving saleable area of 1420 Acres, balance 700 Acres is planned of Common facilities and utilities with green areas and open spaces in the park. 600 Acres is earmarked for setting up sector specific Pharma – SEZ.

The CETP with a capacity of 12 MLD is having with separate Low TDS and High TDS effluent conveyance pipe line network, Air stripper for removal of Volatile Organic Compounds, Incinerator/regenerative thermal Oxidizer for destruction of VOC's, fully automated cyclic biological activated sludge treatment plant, separate treatment facilities for handling cyanides, heavy metals and other wastes, powdered activated carbon treatment, guard ponds for toxicity check, marine outfall pipelines for disposal of treated effluent. M/s Ramky has gone for expansion of MEE to tackle the extra load of HTDS effluents. They have started the erection and commissioning work of MEE.

The Hazardous waste management facility provided with double composite geo-textile HDPE liners, meets USEPA specifications, secured engineered landfill of 2 Lakhs TPA. Incineration system with a capacity of 5.5 Mkcals/hr along with heat recovery system. An Emergency medical center with ambulance operating round the clock with doctors and supporting staff. Fire station is there with trained crew and fire tender to fight any chemical and hazardous calamities. JNPC member industries has developed centralized Mutual Aided Society for Risk Mitigation (MASRM) in case of any emergency under direction and guidance of District collector and Factory inspectorate. The mutual aided society is registered from Govt of Andhra Pradesh (Registration No 436 of 2016). The eminent roles of the society are listed below:

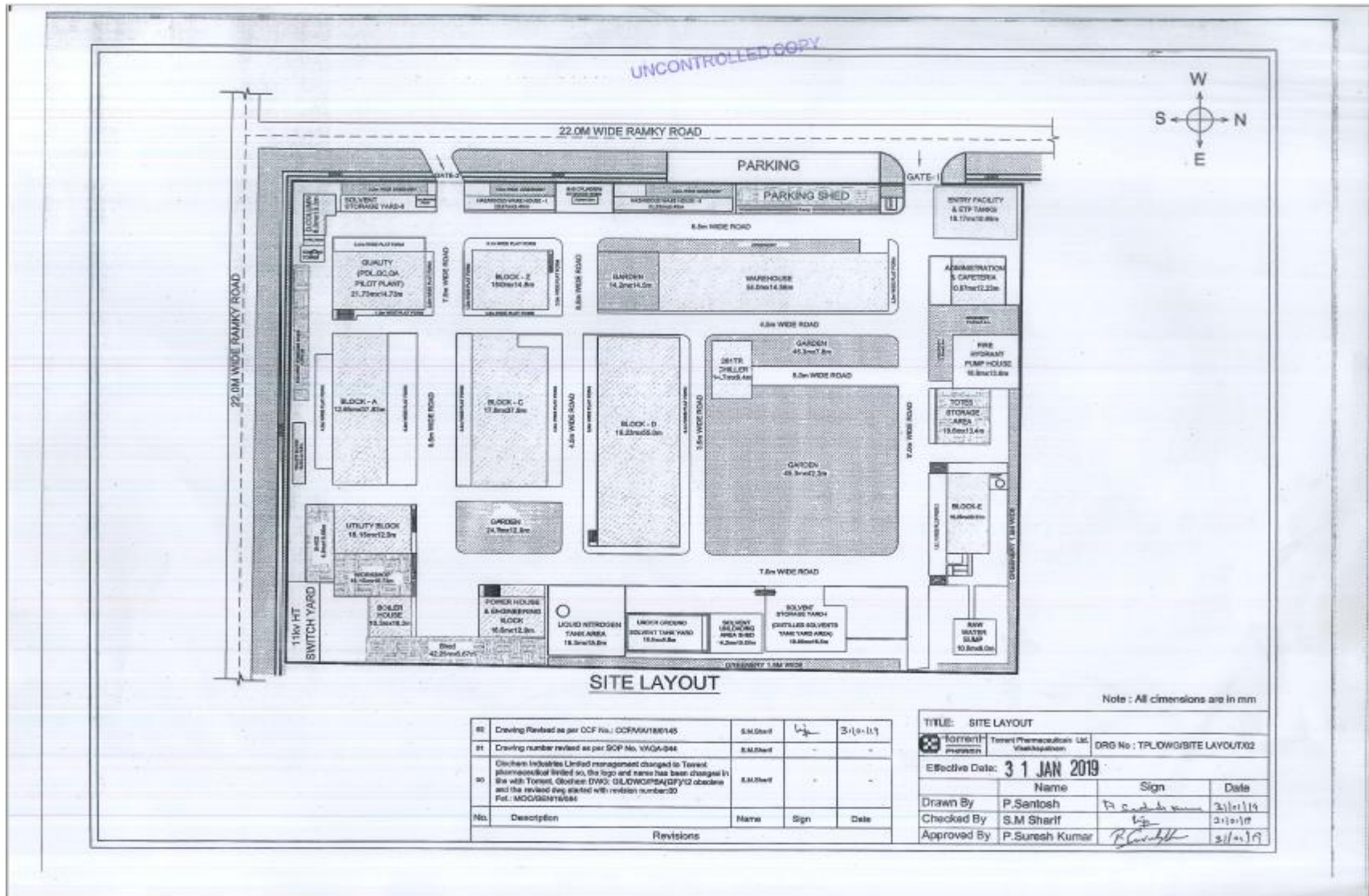
- Emergency response mechanism to be made available 24x7 and 365 days.
- Constitution of Emergency Response Group (ERG) to combat with emergency situation.
- Provision of HAZMAT VEHICLE with equipment loaded for handling any Emergency situations.
- Common facility shall be used for society members in case of any emergency

Emergency contacts (MASRM)-7997448448, 6301499442

## **2.0 About the Proposed Activity**

M/s.Torrent Pharmaceuticals Limited has proposed to manufacture 6 new products in existing facility and decided to drop Telmisartan with 5 stage and include Telmisartan with 2 stage to the existing 52 number of permitted product list. The proposed product list for change of product mix will be of 58 Nos of products.

A comparative list of quantities of the existing permitted products and proposed products are given in **table 1** and the list and quantities of the proposed products for CFE (Consent for Establishment) along quantities are given in **table 2**.



[Figure 1 Plant Layout]

table 1. A comparative list of quantities of the existing permitted products and proposed products

SI No	Name of Product	Existing CFE Product quantities		Proposes CFE Expansion quantities	
		Kgs/Year	Kgs/Month	Kgs/Year	Kgs/Month
1	ESOMEPRAZOLEMAGNESIUM AMORPHOUS (or) ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	6000	500	6000.00	500.00
2	TRC 150094	7200	600	7200.00	600.00
3	DULOXETINE HCL	6000	500	6000.00	500.00
4	TRC041266	7296	608	7296.00	608.00
5	Febuxostat API	3600	300	1000.0	83.33
6	TRC 160334	3600	300	500.00	41.67
7	ESOMEPRAZOLE INTERMEDIATE (STAGE-III)	35400	2950	21795.00	1816.25
8	TRC 240138	1092	91	500.00	41.67
9	RIVASTIGMINE HYDROGEN TARTARATE	3000	250	2000.00	166.67
10	CANDESARTAN CILEXETINE	8400	700	6000.00	500
11	OLANZAPINE	3648	304	3648.00	304.00
12	SILDENAFIL CITRATE	7200	600	7200.00	600.00
13	Silodosin	1824	152	1824.00	152.00
14	OLMESARTAN MEDOXOMIL	3648	304	9000.00	750.00
15	PRAMIPEXOLE	732	61	732.00	61
16	LAMOTRIGINE	30000	2500	25000.00	2083.33
17	RASAGILINE FUMARATE	1092	91	1092.00	91.00
18	Sitagliptin Tartrate	3648	304	500.00	41.67
19	RABEPRAZOLE SODIUM	6000	500	4000.00	333.33

SI No	Name of Product	Existing CFE Product quantities		Proposes CFE Expansion quantities	
		Kgs/Year	Kgs/Month	Kgs/Year	Kgs/Month
20	VENLAFAXINE HYDROCHLORIDE	16428	1369	16428.00	1369.00
21	Perampanel	1824	152	1824.00	152.00
22	LERCANIDIPINE	6000	500	4000.00	333.33
23	QUETIAPINE FUMARATE	3648	304	3648.00	304.00
24	TOPIRAMATE	3648	304	3648.00	304.00
25	Famotidine	12000	1000	2000.00	166.67
26	DONEPEZILE HCl	3648	304	3648.00	304.00
27	NIRCORANDIL	4800	400	4800.00	400.00
28	ALFUZOSIN HYDROCHLORIDE	732	61	733.65	61.14
29	RALOXIFINE HYDROCHLORIDE	1200	100	1200.85	100.07
30	Vilazodone Hydrochloride	3648	304	3646.35	303.86
31	OLANZAPINE PAMOATE	1092	91	1092.00	91
32	Sacubitril-Valsartan	1092	91	1091.35	90.95
33	Safinamide	1092	91	1092.00	91.00
34	Roflumilast	360	30	360.00	30.00
35	SERTRALINE HCL	3600	300	1000.00	83.33
36	Ferric Citrate Hydrate	5472	456	2000.00	166.67
37	Telmisartan (5 Stage)	<b>1092</b>	<b>91</b>	<b>dropped</b>	<b>dropped</b>
37	Telmisartan (2 stage)	1092	91	7200.00	600.00
38	CLOPIDOGREL BISULPHATE FORM-II	1092	91	1091.35	90.95
39	Apixaban	1092	91	1092.00	91
40	LEVODOPA	1824	152	1824.00	152.00



SI No	Name of Product	Existing CFE Product quantities		Proposes CFE Expansion quantities	
		Kgs/Year	Kgs/Month	Kgs/Year	Kgs/Month
41	TRC04186	1824	152	1824.00	152.00
42	Prucalopride Succinate	1824	152	1825.00	152.08
43	CLOPIDOGREL BISULPHATE FORM-I	1092	91	1091.35	90.95
44	Teneligliptin hemipentahydro bromide hydrate	1092	91	1091.35	90.95
45	DARIFENACIN HYDROBROMIDE	360	30	360.00	30.00
46	TAPENTADOL HEMIPAMOATE	360	30	50.00	4.17
47	Aripiprazole Lauroxil	360	30	360.00	30.00
48	PALIPERIDONE	1092	91	1092.00	91.00
49	ORMELOXIFENE HCl	1824	152	1824.00	152.00
50	ESOMEPRAZOLEMAGNESIUM TRIHYDRATE	1824	152	1825.00	152.08
51	Validation batches/Research and development	3600	300	3600.00	300.00
52	Montelukast Sodium	0	0	4800.00	400.00
53	Zolpidem Hemitartrate	0	0	10000.00	833.33
54	Pantoprazole sodium sesquihydrate	0	0	19800.00	1,650.00
55	Rosuvastatin Calcium	0	0	6000.00	500.00
56	Ropinirole	0	0	99.96	8.33
57	Levocetirizine HCl	3040.35	253.37	500.00	41.67
58	Pencyclovir	0	0	100.00	8.33

table 2 : List and Quantities of the proposed Products

SI No	Name of Product	No of Stages	Proposed Products	
			Kgs/Year	Kgs/Month
1	ESOMEPRAZOLEMAGNESIUM AMORPHOUS (or) ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	5	6000.00	500.00
2	TRC 150094	7	7200.00	600.00
3	DULOXETINE HCL	3	6000.00	500.00
4	TRC041266	3	7296.00	608.00
5	Febuxostat API	3	1000.0	83.33
6	TRC 160334	2	500.00	41.67
7	ESOMEPRAZOLE INTERMEDIATE (STAGE-III)	3	21795.00	1816.25
8	TRC 240138	12	500.00	41.67
9	RIVASTIGMINE HYDROGEN TARTARATE	5	2000.00	166.67
10	CANDESARTAN CILEXETINE	5	6000.00	500
11	OLANZAPINE	5	3648.00	304.00
12	SILDENAFIL CITRATE	4	7200.00	600.00
13	Silodosin	4	1824.00	152.00
14	OLMESARTAN MEDOXOMIL	3	9000.00	750.00
15	PRAMIPEXOLE	4	732.00	61
16	LAMOTRIGINE	2	25000.00	2083.33
17	RASAGILINE FUMARATE	3	1092.00	91.00
18	Sitagliptin Tartrate	2	500.00	41.67
19	RABEPRAZOLE SODIUM	3	4000.00	333.33
20	VENLAFAXINE HYDROCHLORIDE	2	16428.00	1369.00
21	Perampanel	2	1824.00	152.00

SI No	Name of Product	No of Stages	Proposed Products	
			Kgs/Year	Kgs/Month
22	LERCANIDIPINE	2	4000.00	333.33
23	QUETIAPINE FUMARATE	2	3648.00	304.00
24	TOPIRAMATE	2	3648.00	304.00
25	Famotidine	2	2000.00	166.67
26	DONEPEZILE HCl	3	3648.00	304.00
27	NIRCORANDIL	3	4800.00	400.00
28	ALFUZOSIN HYDROCHLORIDE	3	733.65	61.14
29	RALOXIFINE HYDROCHLORIDE	6	1200.85	100.07
30	Vilazodone Hydrochloride	2	3646.35	303.86
31	OLANZAPINE PAMOATE	1	1092.00	91
32	Sacubitril-Valsartan	3	1091.35	90.95
33	Safinamide	3	1092.00	91.00
34	Roflumilast	2	360.00	30.00
35	SERTRALINE HCL	4	1000.00	83.33
36	Ferric Citrate Hydrate	2	2000.00	166.67
37	Telmisartan	2	7200.00	600.00
38	CLOPIDOGREL BISULPHATE FORM-II	6	1091.35	90.95
39	Apixaban	3	1092.00	91
40	LEVODOPA	3	1824.00	152.00
41	TRC04186	2	1824.00	152.00
42	Prucalopride Succinate	3	1825.00	152.08
43	CLOPIDOGREL BISULPHATE FORM-I	2	1091.35	90.95

SI No	Name of Product	No of Stages	Proposed Products	
			Kgs/Year	Kgs/Month
44	Teneligliptin hemipentahydro bromide hydrate	2	1091.35	90.95
45	DARIFENACIN HYDROBROMIDE	2	360.00	30.00
46	TAPENTADOL HEMIPAMOATE	1	50.00	4.17
47	Aripiprazole Lauroxil	2	360.00	30.00
48	PALIPERIDONE	4	1092.00	91.00
49	ORMELOXIFENE HCl	1	1824.00	152.00
50	ESOMEPRAZOLEMAGNESIUM TRIHYDRATE	3	1825.00	152.08
51	Validation batches/Research and development	-	3600.00	300.00
52	Montelukast Sodium	2	4800.00	400.00
53	Zolpidem Hemitartrate	3	10000.00	833.33
54	Pantoprazole sodium sesquihydrate	1	19800.00	1,650.00
55	Rosuvastatin Calcium	2	6000.00	500.00
56	Ropinirole	2	99.96	8.33
57	Levocetirizine HCl	3	500.00	41.67
58	Pencyclovir	5	100.00	8.33
<b>Total</b>		-	<b>230797.21</b>	<b>19233.10</b>

## 2.1 Raw Material Requirement

Bulk Drugs & Intermediate manufacturing involves the use of various chemicals and organic solvents either directly as reactant or for extraction of a product of interest from the reaction mixture. Such reactions, which are taking place under varied physical conditions like temperature and pressure lead to evaporative losses. All such losses are recovered by condensing the vapors. There would however still be some quantity of unrecovered solvents. These solvents find way out of the reactor sheds through designed vents.

The production blocks will be provided with very efficient ventilation in order to maintain healthy workroom environment ensuring minimal residual solvent concentrations, which would be many times less than the threshold limits defined by OSHA.

The raw materials of the plant are the chemicals and the fuel. The chemicals required for the process are mostly bought from the local (indigenous) markets. Coal/biomass briquettes are used in the Existing Boiler of 2.0 TPH. Diesel will be used in the Existing 2 Nos. of 380 KVA DG Set (380 KVA Stand By), which will be about 100Ltrs/hr at full operation load and the DG sets will be used as power backup during power failure.

The biomass briquettes using as an alternate to conventional fuel a Non-renewable resource (Coal).

The total power requirement of the plant is 3061 HP and is met from A.P.TRANSOCO. DG sets are used only as standby during power failures.

All solvent will be stored in HDPE drums on raised platform with roof, in underground Licensed (PESO) solvent tanks and above ground storage tanks. The spent and recovered solvents will be stored in above ground storage tanks and intermediate bulk containers (Totes). The other raw materials will be stored in the Store room as per the safety norms.

## 2.2 By Products

The details of by products produced during the manufacturing process are given in the **table 3**

**table 3 List of by-products**

S.No	Type of By-Product	Quantity Kg/Day
1	Spent solvent	9803.87
2	Mixed solvent	4977.6
3	Spent acids	2739.8

### 3.0 Environmental Management:

EMP includes scheme for proper, scientific assessment of pollution generation, its handling, treatment and disposal mechanism for liquid, air and solid pollutants. Apart from this green belt development, Safety aspect of the workers, noise controls etc are also included in it. The following is the Environmental status at M/s. Torrent Pharmaceuticals Limited.

#### 3.1 Water Pollution

The Industry has been collecting the effluents including domestic waste water 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 send to Common effluent Treatment Plant provided by the J.N. Pharmacy (Ramky) for further treatment and disposal through separate pipelines. All the treatment tanks are constructed above the ground only with HDPE inner lining.

The total water requirement of the plant is 165.76 KLD. The water needs for the industry will be met from the J.N. Pharmacy which in sourcing it from APIIC. The sources of effluent from the plant are from the Process, Floor & reactor washes, Utilities, Scrubber, Boiler and plant domestic waste. Total water consumption after expansion is given in **table no 4** Total effluent expected from the proposed products and its treatment details are presented in the below **table no 5**. The per acre maximum limit of the effluent is given in **table 6**.

**table 4: Water Consumption Details**

S.No	Purpose	Water Consumption in KLD	
		Permitted	Proposed
1	Potable water system	85.22	85.22
2	Boiler	16.28	16.28
3	Water for Cooling Towers	16	16
4	Scrubbers	0.94	0.94
5	Domestic	16.22	16.22
6	Green belt	15.62	15.62

S.No	Purpose	Water Consumption in KLD	Water Consumption in KLD
		Permitted	Proposed
7	Periodical Equipment Cleaning	1.86	1.86
8	Detoxification of containers	13.46	13.46
9	Floor Washings	0.16	0.16
<b>Total</b>		<b>165.76</b>	<b>165.76</b>

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table 5: Waste Water Generation and Disposal Method

S.No	Purpose	Effluent generation in KLD			Effluent generation in KLD			Disposal Option
		Permitted			Proposed			
		HTDS & LTDS		Total Effluent	HTDS & LTDS		Total Effluent	
		HTDS	LTDS	KLD	HTDS	LTDS	KLD	
1	Potable water system	25.05	27.015	52.07	25.05	27.015	52.07	After segregation (HTDS/LTDS) of waste water and preliminary treatment sent to CETP-J.N.Pharmacy for further treatment and safe disposal.
2	Boiler	0.20	14.88	15.08	0.20	14.88	15.08	
3	Cooling tower	0	10	10	0	10	10	
4	Scrubbers	0.90	0	0.90	0.90	0	0.90	
5	Domestic	0	13.07	13.07	0	13.07	13.07	Septic tank and over flow to LTDS of CETP provided by J.N.Pharmacy.
6	Floor washings	0	0.16	0.16	0	0.16	0.16	After segregation (HTDS/LTDS) of waste water and preliminary treatment sent to CETP-J.N.Pharmacy for further treatment and safe disposal.
7	Periodical Equipment cleaning	0	1.86	1.86	0	1.86	1.86	
8	Detoxification of containers	0	11.47	11.47	0	11.47	11.47	
<b>Total</b>		<b>26.15</b>	<b>78.45</b>	<b>104.60</b>	<b>26.15</b>	<b>78.45</b>	<b>104.60</b>	-



**table 6: HTDS & LTDS Effluent Maximum Permission**

Effluent Maximum Permitted as per JNPC		Proposed Effluent Maximum Quantities	
HTDS	LTDS	HTDS	LTDS
26150 Ltrs (1 Acre 5000 Ltrs)	78450 Ltrs (1Acre 15000 Ltrs)	26150 Ltrs	78450 Ltrs

**Note:**

The Total permitted water requirement is about 165.76 KLD and waste water generated from the plant will be about 104.6 KLD. Out of this HTDS effluent will be about 26.15 KLD & LTDS effluent will be 78.45 KLD, will be collected by gravity from all sources into a collection tank of ETP.

The proposed total water requirement for the CFE new and existing products is about 165.76 KLD and waste water generated from the proposed expansion process is about 104.6 KLD. Out of this HTDS effluent will be about 26.15 KLD (24.00 KLD from process & washings 1.05 KLD from regeneration of potable water system, 0.20 KLD from regeneration of softener and 0.90 KLD from Scrubber blow down). Maximum LTDS effluent on various combinations will be about 78.45 KLD (18.49 KLD from Process & Washings and 10.00 KLD from cooling tower, 8.525 KLD from backwash of potable water system, 0.16 KLD from floor washings, 1.86 KLD from Periodical equipment cleaning, 1.06 from boiler blow down, 13.82 KLD condensate from equipment, 13.07 KLD from domestic Waste water and 11.465 KLD from detoxification of containers) will be collected by gravity from all sources into individual collection sumps at Production Blocks/ other generation areas. This waste water will be pumped separately to the above ground level tanks for storage and neutralization at ETP then routed to Common Effluent Treatment Plant provided by J.N.Pharma City for further treatment and disposal through separate pipelines.

Domestic waste water will be sent to LTDS of CETP at J.N.Pharma City for further treatment and disposal. All effluent treatment tanks are constructed above the ground with HDPE inner lining.

HTDS concentration will be more than 12,000 mg/l TDS and Above 8,000 mg/l of COD. LTDS concentration will be less than 12,000 mg/l of TDS and below 8,000 mg/l of COD. The quality failed LTDS effluent shall be treated as HTDS and sent to CETP for disposal. Old ETP 20x4 tanks are being used as

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intermittent storage tanks. It adds the extra storage capacity during rainy season when CETP occasionally could not provide conveyance for disposal of effluent.

### **3.1.1. Hydrogeology**

No major effect on the level of water table is envisaged as water requirement is about 165.76 KLD only and will be met through J.N. Pharamacity. Trade effluent will be segregate in HTDS and LTDS Effluent.

After Primary treatment sent to CETP J.N.Pharma city for further treatment and disposal for which Industry has already entered into agreement with J.N. Pharamacity for further treatment and safe disposal of Effluent and Solid Waste.

### **3.1.2 Pollution Loads**

Product wise pollution generation in terms of Effluent, Solid Waste, Emissions are given in the **table 7**.

## 3.1.3 Waste Water generation and details

table 7: Waste Water and Pollution Load Details – Product Wise

Name of Product	No of batches per month	Quantity Kg/Batch	Quantity in Kg/Year	Quantity Proposed in Kg/Month	Qty Kg per day	Input Water Kg/day	LTDS Kg/day	HTDS Kg/day	Inorganic S/W Kg/day	Organic S/W Kg/day	Emissions Kg/day	Spent Carbon Kg/day
ESOMEPRAZOLEMAGNESIUM AMORPHOUS	7.55	66.22	6000.00	500.00	16.44	3095.13	942.19	1392.26	0.93	50.63	811.82	0.00
TRC 150094	29.60	20.27	7200.00	600.00	19.73	6788.20	1989.82	1660.88	35.44	77.59	2611.35	14.09
DULOXETINE HCL	11.62	43.04	6000.00	500.00	16.44	1585.79	674.69	514.97	6.18	116.18	471.59	5.25
TRC041266	9.01	67.50	7296.00	608.00	19.99	2116.74	816.97	990.81	0.00	60.05	750.62	7.76
Febuxostat API	2.08	40.00	1000.0	83.33	2.74	188.72	84.66	107.37	6.65	0.00	85.99	0.00
TRC 160334	9.90	4.21	500.00	41.67	1.37	148.46	32.70	123.03	1.40	2.95	44.28	0.00
ESOMEPRAZOLE INTERMEDIATE (STAGE-III)	5.82	312.00	21795.00	1816.25	60	688.86	57.83	573.40	0.58	55.30	149.81	0.00
TRC 240138	1.50	27.76	500.00	41.67	1.37	249.14	63.30	288.10	10.76	23.69	0.00	0.00
RIVASTIGMINE HYDROGEN TARTARATE	6.44	25.87	2000.00	166.67	5.48	523.06	268.57	254.14	14.32	0.00	131.03	0.70
CANDESARTAN CILEXETINE	8.54	58.58	6000.00	500	16.44	1424.00	842.72	442.51	12.91	30.93	356.28	6.90
OLANZAPINE	21.57	14.09	3648.00	304.00	9.99	1484.59	990.09	474.80	0.00	0.00	282.73	1.56
SILDENAFIL CITRATE	7.14	84.00	7200.00	600.00	19.73	4583.36	755.24	2310.33	22.22	260.10	562.81	0.00
Silodosin	4.71	32.24	1824.00	152.00	5.00	1008.09	347.57	798.87	4.74	26.40	121.60	0.00
OLMESARTAN MEDOXOMIL	9.34	80.32	9000.00	750.00	24.66	3237.28	1207.33	1967.56	50.66	290.26	885.03	8.30
PRAMIPEXOLE	2.78	21.92	732.00	61	2.01	1027.55	257.82	688.49	24.60	15.49	42.98	5.31
LAMOTRIGINE	24.51	85.00	25000.00	2083.33	68.49	5425.09	1225.55	612.77	0.00	0.00	612.77	9.80
RASAGILINE FUMARATE	13.58	6.70	1092.00	91.00	2.99	421.53	20.37	461.41	0.41	11.39	116.70	0.00
Sitagliptin Tartrate	1.39	30.00	500.00	41.67	1.37	123.26	75.23	61.46	0.28	3.48	14.45	0.71
RABEPRAZOLE SODIUM	3.94	84.68	4000.00	333.33	10.96	1102.05	420.84	681.21	15.17	53.14	32.74	5.99

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Name of Product	No of batches per month	Quantity Kg/Batch	Quantity in Kg/Year	Quantity Proposed in Kg/Month	Qty Kg per day	Input Water Kg/day	LTDS Kg/day	HTDS Kg/day	Inorganic S/W Kg/day	Organic S/W Kg/day	Emissions Kg/day	Spent Carbon Kg/day
VENLAFAXINE HYDROCHLORIDE	11.16	122.72	16428.00	1369.00	45.01	1301.48	312.36	434.17	0.00	0.00	583.70	6.69
Perampanel	2.18	69.70	1824.00	152.00	5.00	349.72	3.28	364.26	10.01	10.01	29.95	1.37
LERCANIDIPINE	7.57	44.02	4000.00	333.33	10.96	1633.79	504.82	536.37	0.00	0.00	0.00	13.06
QUETIAPINE FUMARATE	1.08	281.00	3648.00	304.00	9.99	658.49	302.09	356.39	18.39	18.39	23.92	0.37
TOPIRAMATE	3.94	77.09	3648.00	304.00	9.99	521.41	199.36	322.06	63.75	23.14	15.20	1.31
Famotidine	2.61	63.91	2000.00	166.67	5.48	99.47	47.61	59.18	0.00	0.00	0.00	0.00
DONEPEZILE HCl	10.31	29.50	3648.00	304.00	9.99	930.69	679.02	251.67	33.81	0.00	189.48	0.55
NIRCORANDIL	8.24	48.55	4800.00	400.00	13.15	420.18	140.06	307.48	6.59	0.00	196.89	10.06
ALFUZOSIN HYDROCHLORIDE	1.01	60.52	733.65	61.14	2.01	239.91	113.99	197.87	8.54	13.53	7.52	0.36
RALOXIFINE HYDROCHLORIDE	2.08	48.00	1200.85	100.07	3.29	527.11	213.98	300.91	38.22	74.15	9.38	0.00
Vilazodone Hydrochloride	3.02	100.49	3646.35	303.86	9.99	362.89	201.59	161.30	0.00	41.85	90.95	1.06
OLANZAPINE PAMOATE	1.77	51.43	1092.00	91	2.99	0.00	63.43	0.00	0.00	0.00	6.78	0.00
Sacubitril-Valsartan	5.29	17.18	1091.35	90.95	2.99	102.91	4.54	140.39	65.54	70.57	194.44	0.00
Safinamide	0.84	108.36	1092.00	91.00	2.99	91.11	16.38	85.72	1.45	10.11	26.47	0.25
Roflumilast	0.33	90.20	360.00	30.00	0.99	58.20	0.03	77.64	0.00	3.80	9.26	0.73
SERTRALINE HCL	2.16	38.59	1000.00	83.33	2.74	302.27	196.75	105.52	14.99	73.10	28.01	2.52
Ferric Citrate Hydrate	2.08	80.00	2000.00	166.67	5.48	24.31	0.00	27.39	0.00	41.04	0.00	0.00
CLOPIDOGREL BISULPHATE FORM-II	1.10	82.58	1091.35	90.95	2.99	431.44	165.19	253.05	14.27	25.96	10.20	2.25
Apixaban	1.37	66.66	1092.00	91	2.99	98.34	45.71	66.49	17.29	11.10	59.36	0.04
LEVODOPA	3.04	50.00	1824.00	152.00	5.00	81.07	30.40	50.67	2.03	0.00	0.00	1.01
TRC04186	1.01	149.99	1824.00	152.00	5.00	56.16	25.33	30.82	38.42	38.42	84.44	0.70
Prucalopride Succinate	1.26	120.38	1825.00	152.08	5.00	42.32	0.00	42.32	0.00	6.03	16.71	0.00

## Torrent Pharmaceuticals Limited, Visakhapatnam

Name of Product	No of batches per month	Quantity Kg/Batch	Quantity in Kg/Year	Quantity Proposed in Kg/Month	Qty Kg per day	Input Water Kg/day	LTDS Kg/day	HTDS Kg/day	Inorganic S/W Kg/day	Organic S/W Kg/day	Emissions Kg/day	Spent Carbon Kg/day
CLOPIDOGREL BISULPHATE FORM-I	2.16	42.04	1091.35	90.95	2.99	715.17	251.94	417.15	25.44	20.18	39.75	3.33
Teneligliptin hemipentahydro bromide hydrate	0.50	183.12	1091.35	90.95	2.99	30.16	0.00	34.93	0.00	8.28	6.62	0.00
DARIFENACIN HYDROBROMIDE	9.68	3.10	360.00	30.00	0.99	105.48	68.39	34.28	0.63	1.09	6.95	2.02
TAPENTADOL HEMIPAMOATE	0.93	4.50	50.00	4.17	0.14	4.63	0.02	4.63	0.00	0.24	1.61	0.00
Aripiprazole Lauroxil	0.34	88.20	360.00	30.00	0.99	22.68	9.07	17.01	0.00	0.99	1.33	0.74
PALIPERIDONE	1.81	50.22	1092.00	91.00	2.99	0.00	0.00	2.72	0.00	0.00	18.97	2.38
ORMELOXIFENE HCl	3.53	43.00	1824.00	152.00	5.00	70.70	70.70	0.00	0.00	0.00	3.00	1.18
ESOMEPRAZOLEMAGNESIUM TRIHYDRATE	1.93	78.90	1825.00	152.08	3.00	386.73	115.69	202.20	0.56	3.02	32.90	0.00
Validation batches/Research and development	-	-	3600.00	300.00	9.86	4622.94	294.67	1762.29	14.50	42.13	5.00	17.53
Montelukast Sodium	8.89	45.00	4800.00	400.00	13.15	1511.11	622.22	961.15	22.22	0.00	162.67	7.11
Telmisartan	8.00	75.00	7200.00	600.00	19.73	1775.20	242.67	1553.16	0.00	41.11	112.42	7.28
Zolpidem Hemitartrate	4.11	203.00	10000.00	833.33	27.40	673.37	665.57	103.85	2.73	26.59	72.20	0.00
Pantoprazole sodium sesquihydrate	6.45	256.00	19800.00	1,650.00	54.25	1420.03	1420.03	198.69	0.00	26.27	78.82	0.00
Rosuvastatin Calcium	3.91	128.00	6000.00	500.00	16.44	192.71	103.42	107.89	47.44	32.77	38.16	0.00
Ropinirole	0.50	16.50	99.96	8.33	0.27	44.49	40.46	0.00	0.00	0.00	8.25	1.15
Levocetirizine HCl	0.74	56.35	500.00	41.67	1.37	39.90	16.74	23.17	0.46	5.69	3.50	0.15
Pencyclovir	2.85	2.92	100.00	8.33	0.273972	218.10	226.68	1.99	6.26	10.81	30.77	6.70
<b>Total</b>			<b>230949.21</b>	<b>19245.77</b>	<b>630.74</b>	<b>55387.60</b>	<b>18487.67</b>	<b>24001.15</b>	<b>660.80</b>	<b>1757.95</b>	<b>10290.17</b>	<b>158.28</b>
<b>Proposed</b>						<b>55.39</b>	<b>18.49</b>	<b>24.00</b>	<b>241.19TPA</b>	<b>641.65TPA</b>	<b>3755.91TPA</b>	<b>57.77TPA</b>

The wastewater generated from the plant is about 104.6 KLD. Out of this about 88.38 KLD will be trade effluent generating from Process, Washings, Potable water system, cooling tower, floor washings, periodical equipment cleaning, Boiler, Scrubbers and Detoxification of containers. Trade effluent will be collected by gravity from all sources into a collection tank (SS inner lined with HDPE tank of 1KL capacity) at production blocks for each HTDS & LTDS.

The Quantities of Effluent generating from process will be segregated in HTDS & LTDS Effluent. After Primary treatment HTDS Effluent will be sent to MEE of CETP, J.N.Pharmacy for further treatment and safe disposal through pipelines. The domestic waste water will be sent to the LTDS of CETP at JNPC Pharmacy.

After Segregation the LTDS Effluent will be sent to CETP for biological treatment at J.N. Pharmacy for further treatment and safe disposal through pipelines.

Domestic wastewater will be about 13.07 KLD will be sent to septic tank and overflow to LTDS of CETP provided by J.N. Pharmacy.

### **3.1.4 ETP Tank Details**

**HTDS:** Total Effluent Handling Capacity: 256 KL

Industry has constructed 2 No's of Settling tanks of the Capacity 35 KL each.

1 No of Tanks (reactor with stirrer) of the capacity 2 KL for Homogenization

1 No of Tanks (reactor with stirrer) of the capacity 2 KL for Neutralization

1 No of Tanks of the capacity 182 KL treated effluent for Disposal to M/s. Ramky

**LTDS:** Total Effluent Handling Capacity: 169 KL

Industry is constructing 2 No's of Settling tanks of the Capacity 35 KL each.

1 No of Tanks (reactor with stirrer) of the capacity 2 KL for Homogenization

1 No of Tanks (reactor with stirrer) of the capacity 2 KL for Neutralization

1 No of Tanks of the capacity 95 KL treated effluent for Disposal to M/s. Ramky

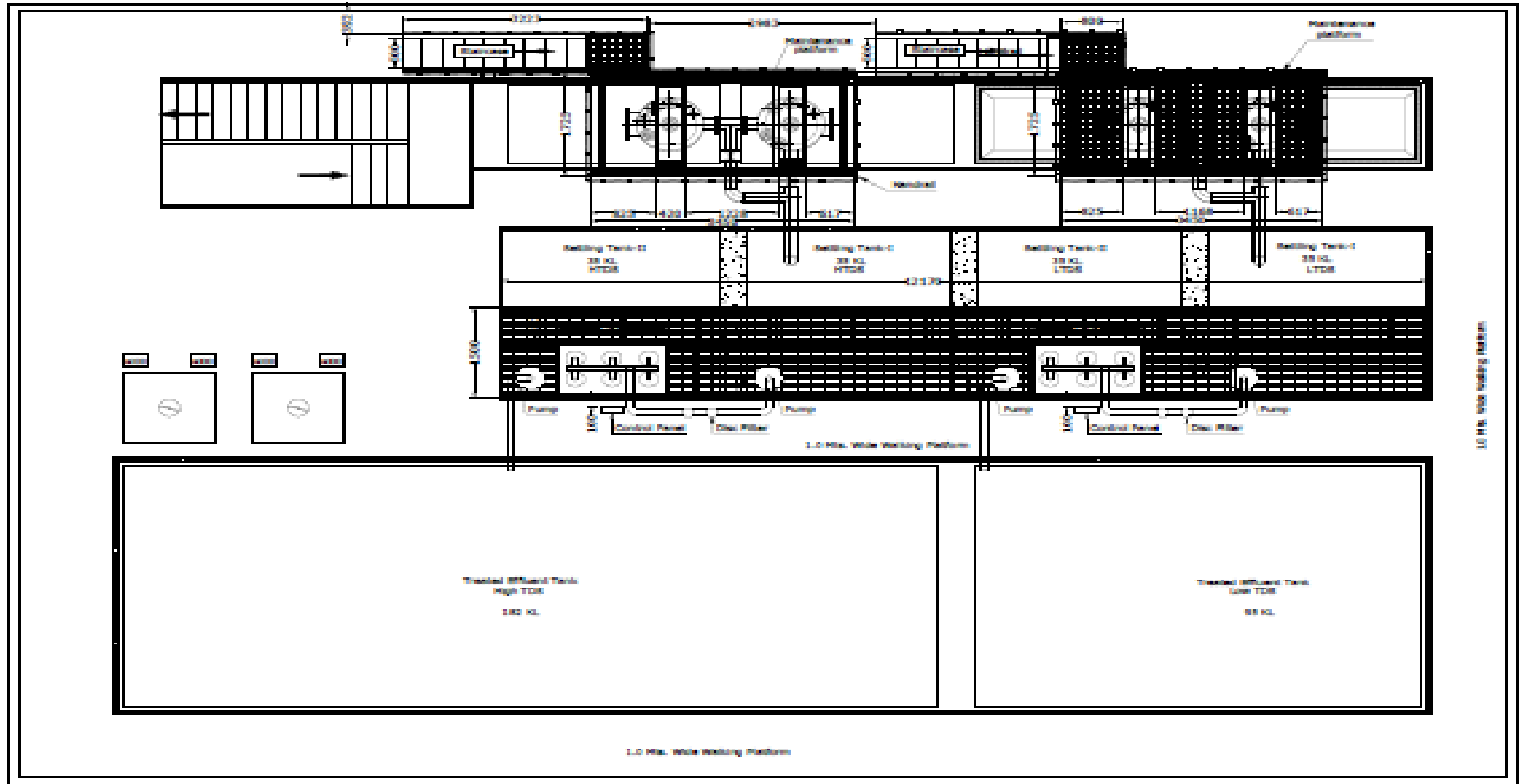
All Effluent Storage Tanks are constructed above the ground having 12 mm thick Acid /Alkali proof tiles.

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The above said tank will cater for storage of 256 KLD & 169 KLD of Effluent

The above said tank is partitioned into 4 tanks which are useful for Collection of HTDS and LTDS effluents and for Equalization and neutralization. The HTDS effluent will be sent to CETP to fed in MEE for further treatment. The effluent tanks constructed 5.0 mtrs above the ground level.

The effluent tank is lined with acid proof tiles.



[Figure 2 ETP Design]



## 3.2 Solid Waste

Solid waste is generated from Process where Organic solid waste and isolated Inorganic salts 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 residue from the process and sludge from neutralization tanks will be sent to TSDf for incineration (provided by the J.N.Pharmacy). Inorganic salts will be collected and disposed off to TSDf (provided by the J.N.Pharmacy) for secured land fill. Wastes from stores will be segregated and disposed off to the authorized agents as scrap. Apart from regular waste as in existing authorization we have identified some other waste which are hazardous in nature are listed in the **table 8** along with disposal method.

### 3.2.1 Process

a) Process residues mainly consists of organic residues which are collected and stored for disposal to TSDf / Authorized Parties for Incineration / Recovery

b) Inorganic solid wastes from process are disposed off to TSDf after isolating and drying it. These salts are collected in bags and stored on a dedicated raised platform under a shed prior to disposal to TSDf.

Solid waste generation from the plant is given in **table 8**.

**table 8: Solid Waste generation from the Plant**

Permitted				Proposed			Method Of Disposal
S.No.	Description	Units	Quantity	Description	Units	Quantity	
1	Process residue	TPA	641.65	Process residue	TPA	641.65	Sent to TSDf/CWMP, Parawada, Visakhapatnam District for incineration/ Authorised Cement plants for co-processing.
2	Organic Residue(Distillation bottom residue)	TPA		Organic Residue(Distillation bottom residue)	TPA		
3	Spent Carbon + Hyflow	TPA	62.18	Spent Carbon + Hyflow	TPA	57.77	
4	Inorganic Process Salts	TPA	241.19	Inorganic Process Salts	TPA	241.19	Sent to TSDf/CWMP, Parawada, Visakhapatnam District for secured land filling.
5	ETP Sludge	TPA	25.0	ETP Sludge	TPA	25.0	Sent to TSDf/CWMP, Parawada, Visakhapatnam District for incineration/ Authorised Cement plants for co-processing.
6	Spent Solvents	Kgs/day	9803.87	Spent Solvents	Kgs/day	9803.87	Shall be sent to APPCB authorized agency

Permitted				Proposed			Method Of Disposal
S.No.	Description	Units	Quantity	Description	Units	Quantity	
7	Used Oils	LPA	5000	Used Oils	LPA	5000	Authorized reprocessors/recyclers
8	Container and container liners of hazardous waste	NOs Per Annum	20,000	Container and container liners of hazardous waste	NOs Per Annum	20,000	After complete detoxification shall be disposed to authorized agencies for recycling.
9	Lead acid batteries	NOs Per Annum	150	Lead acid batteries	NOs Per Annum	150	Shall be sent back to suppliers on buy back basis.
10	Mixed solvent	Kgs/day	4977.6	Mixed solvent	Kgs/day	4977.6	Shall be sent to APPCB authorized agency
11	Spent acids	Kgs/day	2739.8	Spent acids	Kgs/day	2739.8	Shall be sent to APPCB authorized agency
12	Contaminated Sand (used for spill collection & control)	TPA	2.0	Contaminated Sand (used for spill collection & control)	TPA	2.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for secured land filling.
13	Rejected raw material	TPA	Actuals	Rejected raw material	TPA	Actuals	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for disposal
14	Rejected Products	TPA	Actuals	Rejected Products	TPA	Actuals	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for disposal
15	Hepa Filters	TPA	3.0	Hepa Filters	TPA	3.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for disposal
16	Insulation wool	TPA	0.99	Insulation wool	TPA	0.99	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
17	Thermocol	TPA	0.5	Thermocol	TPA	0.5	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
18	Contaminated glassware	NOs Per Annum	20,000	Contaminated glassware	NOs Per Annum	20,000	After complete detoxification shall be disposed to outside agencies.
19	Used PPEs	TPA	3.5	Used PPEs	TPA	3.5	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
20	Sodium Hydride bags	TPA	0.5	Sodium borohydride bags	TPA	0.5	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
21	LDPE Bags	TPA	8.78	LDPE Bags	TPA	8.78	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration/for recycling to authorized recyclers.
22	Expired Laboratory Chemicals	TPA	1.0	Expired Laboratory Chemicals	TPA	1.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for disposal
23	Filtration bags	Nos per Annum	500	Filtration bags	Nos per Annum	500	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for

Permitted				Proposed			Method Of Disposal
S.No.	Description	Units	Quantity	Description	Units	Quantity	
							incineration.
24	Coal Ash	TPA	251	Coal Ash	TPA	251	Disposed to local Ash Bricks manufacturers.
25	Cooling Tower Sludge	TPA	10	Cooling Tower Sludge	TPA	10	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
26	Cooling Tower Packing material	TPA	2.0	Cooling Tower Packing material	TPA	2.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
27	Foam	TPA	1.0	Foam	TPA	1.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
28	Discarded Samples (Products and raw materials)	TPA	2.0	Discarded Samples (Products and raw materials)	TPA	2.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
29	Oil Contaminated Waste(DG Set oil filters)	TPA	1.0	Oil Contaminated Waste(DG Set oil filters)	TPA	1.0	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
30	General Waste	TPA	25	General Waste	TPA	25	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.

Solid waste will be segregated, detoxified and collected in HDPE Drums/ Bags and will be stored in the Covered and raised Platform with Leachate Collection System.

### 3.2.2 Stores

- 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.
- Other paper waste will be disposed off to scrap vendors.
- Metal scrap disposed off to the scrap vendors.

Container & Container liners will be detoxified at the specified covered platform with dyke walls and the wash waste water is routed to LTDS collection tank.

### 3.3 Gaseous Emissions

The main sources of emissions in the unit are from Process, Boiler, D.G.Sets and fugitive emissions due to evaporation of Solvents. The industry is having Online VOC analyzer to measure the volatile Organic compound in the plant premises.

#### 3.3.1 Process Emissions

Manufacturing of Bulk Drugs could result in gaseous emissions. Proposed gaseous emissions, quantity and handling methods are given in following **table-9**. The scrubber system details are given in **table 10**.

**table 9: Process Emission Details**

S.No.	Emission by solvent loss	Quantity Kg/Day	Control equipment	Efficiency	Scrubbers
1	Solvent loss	10290.17	Two stage condensers followed by Wet Scrubber (Double stage)	90%	Absorption

**table 10: Scrubber System Details**

All the scrubbers are 2 stages Scrubbers

Evacuation Capacity	750 M <sup>3</sup> /Hr at Room Temperature
Acid Fume Capacity	25 Kg/Hr
Scrubbing Media	Caustic Solution/Chilled water
MOC	PP + FRP, Body made of 3mm PP and 5mm FRP
Packings	12mm Honeycomb Packings in PVC
Operating Temperature	Less than 35 <sup>o</sup> C
Blower Capacity	750 M <sup>3</sup> /Hr, 2HP Motor

### 3.3.2 Boiler

Coal being used to 2.0 TPH Existing Boiler Connected with Bag Filter and 30 m height chimney for steam generation, Suspended Particulate Matter (SPM) and Sulphur dioxide (SO<sub>2</sub>) and Oxides of Nitrogen (NO<sub>x</sub>) will be the important pollutants. The various measures proposed to minimize the pollution from the boiler are as follows. The particulate matter (PM) emitted from coal fired boiler within statutory limit of 100 mg/Nm<sup>3</sup> to facilitate wider dispersion of pollutants; stack will be installed 30 Mtrs height. The replacement of old chimney with new one is under progress.

Fugitive dust will be controlled by adopting dust extraction and dust suppression measures and development of green belt along the periphery of the plant. Stack emission details of boiler is given in **table 11**.

**table 11: Stack Emission Details of Boiler**

Particulars	Units	2.0 TPH Coal fired Boiler	
		Indian Coal	biomass briquette
Type of Fuel	--	Indian Coal	biomass briquette
Coal Consumption	TPD	2.5	2.5
Ash Content	%	47	5.10
Sulphur Content	%	0.8	0.048
Nitrogen Content	%	1.07	-
No. of Stacks	No	1	1
Height of the Stack	m	30	30
Diameter of Stack	M	0.60	0.60
Temperature of Flue Gas	°C	96	83
Velocity of Flue Gas	m/s	3.65	3.46
Particulate Matter at outlet of Bag filter (Based on 100 mg/Nm <sup>3</sup> at outlet)	gm/sec	0.087	80
Sulphur dioxide emission	gm/sec	0.138	124
Oxides of Nitrogen emission	gm/sec	0.06	52

### 3.3.3 D.G.Set

The Industry using Existing D.G. Set Capacity of 2 x 380 KVA to provide standby Power supply in case of failure of supply by A.P.C.P.D.C through Ramky Pharma city. Which are installed in a separate room with proper acoustic enclosures and silencers so as to reduce the noise levels and proper rubber padding is also provided to curtail the vibrations. About 100 Liters/hr of diesel will be used for the D.G.set.

The Emissions from the D.G.Set are very nominal as it is operated on an average only for 1 to 2 hours a day. Stack emission details of D.G. Set-1 and D.G. Set-2 are given in **table 12** and **table 13**.

**table 12: Stack Emission Details of D.G. Set-1**

Capacity In KVA	Emission of PM in g/kw-hr	Emission of NO <sub>x</sub> +HC in g/kw-hr	Carbon Monoxide in g/kw-hr	Stack dia. In m	Flue Gas Temp. in °C	Stack Height in (m)	Flue gas Velocity In m/sec.
380 KVA	0.06	2.28	0.39	0.11	217.0	14.5	17.05

**table 13: Stack Emission Details of D.G. Set-2**

Capacity In KVA	Emission of PM in g/kw-hr	Emission of NO <sub>x</sub> +HC in g/kw-hr	Carbon Monoxide in g/kw-hr	Stack dia. In m	Flue Gas Temp. in °C	Stack Height in (m)	Flue gas Velocity In m/sec.
380 KVA	0.09	2.36	0.31	0.11	213	14.5	16.86

### 3.4 Fugitive Emissions

The Solvents will be transferred in a closed system. Solvent recovery facility like distillation column will be provided for efficient recovery up to 95 % Purity. The evaporation losses in solvents will be control by various measures like.

- a) Chilled brine circulation will be carried out to effectively reduce the solvent losses into the atmosphere.
- b) Transfer of solvents using pumps instead of manual handling.
- c) Vent condensers to the storage tanks etc.,
- d) Closed centrifuges will be used due to which solvent losses will be reduced drastically.
- e) Installation of secondary condensers will further reduce the solvent losses during operations.
- f) The height of the solvent receiver tank vent is above production block roof level and the diameter is 20mm. The maximum solvent loss is 3-7% depending on the boiling point of the solvent.

### 3.5 Noise Levels

The main source of noise is D.G.Set. This D.G.Sets is silent powers and installed in a separate room with silencers and acoustic enclosures for reduction of the Noise levels. The operator will be provided with ear plugs. Proper rubber padding will be provided to avoid vibrations.

### 4.0 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.

### 5.0 General Safety Measures

- a) All the personnel at the plant will be made aware about the manufacturing process and details of the products, their proximity of its exposure and risks associated with them.
- b) Personnel engaged in handling of hazardous chemicals will be trained to respond in an unlikely event of emergency.
- c) Safe work practices will be developed to provide for the control of hazardous during operation and maintenance.
- d) Firefighting facilities will be provided at the plant, including dry chemical powder type, water CO<sub>2</sub> type, mechanical foam type, CO<sub>2</sub> type of fire extinguishers and sand bucket. Personnel will be trained to combat the fire in various hazardous chemicals.
- e) The Firefighting system and equipment will be tested and maintained as per relevant standards.
- f) The required PPE's for each area/ operation should be identified and the necessary PPE's like Helmets, Goggles, Hand gloves, Mask, PVC Suit, Self-contained Breathing apparatus, PAPR, Organic vapor masks, safety belts, ear muff and plug etc., will be provided to the personnel.
- g) Centralized fire alarm system has installed to the entire plant including coverage of unmanned areas to alert immediately in case of any fire/smoke occurs/releases.

### 5.1 Safety Precautions

- a) The unit will provide special precautions for storage and handling of Chemicals within the premises
- b) Acid storage tanks will be placed into the separate storage area within the premises with all sign boards stating the proximity of danger to the personnel

- c) The proper collection system will be provided for the leakage and spillage collection of both the acids by preparing dyke wall and acid proof RRC Flooring with spillage collection tank and will be transferred to the emergency storage tank.
- d) Proper vent will be provided to each storage tank. Moreover, weather shed and water sprinkling system will be provided.

## **6.0 Greenbelt Development**

### **6.1 Objective**

The purpose of a green belt around the plant site is to capture the fugitive emissions, attenuate the noise generated and improve the aesthetics.

The unit has been proposed in a total area about 21159.32 SMT. The green belt developed in an area of 4068.4 sq m.

The proposed green belt at the project site will form a barrier between the plant and the surroundings. Open spaces, where tree plantation may not be possible, will be covered with shrubs and grass to prevent erosion of topsoil. Adequate attention has been paid to plantation of trees, their maintenance and protection.

### **6.2 Plant Species for Green Belt**

A wide range of plant species will be planted in and around the premises to help capture the fugitive emissions and noise levels from the plant premises. This wide range covers plants of Fast growing type

- With thick canopy cover
- Perennial green nature
- Native origin
- A large leaf area index

A specialist in horticulture may be appointed to identify any other native species and also supervise greenbelt development.

### **6.3 Design of Green Belt**

As far as possible the following guidelines will be considered in proposed green belt development. Shrubs and trees will be planted in encircling rows around the project site.



The short trees (< 10m height) will be planted in the first two rows (towards plant side) of the green belt. The tall trees (>10m height) will be planted in the outer three rows (away from plant side).

- Planting of trees in each row will be in staggered orientation.
- In the front row, shrubs consisting of Callistemon, Prosopis etc. will be grown.
- Since the trunks of the tall trees are generally devoid of foliage, it will be useful to have shrubs in front of the trees so as to give coverage to this portion.
- The spacing between the trees will be maintained slightly less than the normal spaces, so that the trees may grow vertically and slightly increase the effective height of the green belt.

#### 6.4 Green Visakha Plantation Programme

4500 No of Saplings has been planted under Green Visakha Plantation Programme at JNPC. The details of the link is given below

<http://greenvisakha.co.in>

#### 7.0 Plant and Machinery

Apart from list of plant and machinery given in **Enclosure 3** there is thermic fluid system at E-Block the details are given in **table 14**.

**Table 14 Details of thermic fluid system which was located at E-block**

S.No	Specification	Capacity
1.	Design Capacity of tank	1.5 KL
2.	Fuel type	Electricity
3.	Capacity of heaters	54 KW
4.	No.of Heaters	6 No's
5.	Capacity of Each Heater	9 KW
6.	Capacity interms of heat Energy	1,84,256 Btu/hr
7.	Quantity of Oil to be charged in Liters	1000 Liters

S.No	Specification	Capacity
8.	Oil Used	<b>Sigma Therm-K</b> Used at Or below 300 OC for continuous operation
9.	Frequency of Oil Changing/yr	2 times (Whenever the Oil Viscosity increases or formation of Sludge.)

## 8.0 Public Relations:

M/s.Torrent Pharmaceuticals Limited will maintain very good Public Relations with one and all and will continue to do so in future.

## 9.0 Handling of Raw materials and Finished materials

The Industry is proposed to store the raw materials (maximum seven days' storage capacity). These raw materials and finished goods will be stored in the ware house as per safety norms.

## 10.0 Hazardous Chemicals, waste and Risk Assessment

Bulk Drugs & Intermediates manufacturing industry has to handle many such chemicals that are hazardous in nature. Once these chemicals are used for some reactions, some hazardous wastes are generated. The Industry will provide special training to the workers handling hazardous chemicals / Wastes. The industry will engage safety consultants to prepare a risk assessment and suggest safe handling and safe storage of Hazardous waste for the proposed project. Only highly trained person with proper personal protective equipment will be allowed to handle such chemicals or waste under strict super vision.

## 11.0 Recycle / Reuse

All efforts will be made by the industry to carryout R&D on the isolated by-products / wastes to recycle / reuse wherever possible. However, R&D is a continuous process, where improvements in the processes adopted by the industry, waste minimization etc can be worked out as the project progresses.

## **12.0 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 Waste Water is regularly analyzed and sends to CETP. Qualified staff will be employed for the purpose of operation and maintenance of the Pollution Control facilities. Stand-by facilities will be providing to all the facilities so as to ensure fail proof treatment.

## **13.0 Conclusion**

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 LTDS effluent and HTDS effluent and entered into agreement with CETP for further treatment of its effluent before final disposal. It has also entered into agreement with TSDF for disposal of solid waste. The Coal fired Boiler has been equipped with Cyclone dust collector followed by Bag filter and a stack of 30 m. D.G.Set will be attached with silencers, acoustic enclosures and install in a separate room for controlling the noise levels.

In view of above it is requested to kindly consider the application of the industry and arrange to issue the CFE (Consent for Establishment) for manufacturing of 58 products (52 Permitted + 06 New proposed products) with a total Production Capacity of 19.23 MT/Month.