

Executive Summary

For

“Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility”

At

Plot No. 27 & 28, TANSIDCO Industrial Park,

Village: Pellakuppam

Taluk: Tindivanam

District: Villupuram

State: Tamil Nadu

By:



Omexa Formulary Pvt. Ltd

M/S. OMEXA FORMULARY PVT LTD

Kalyani towers, 174c,

2nd Avenue, Ashok Nagar,

Chennai-600083,

Tamil Nadu.

[Project is termed under Schedule 5 (f)- Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates) shall be considered as a Category “B1” since it is located within TANSIDCO Industrial Park]

ToR Issued on F.No. 10894 dated:29/06/2024

Baseline Monitoring Period – March to May 2024

EIA Consultant



M/s. HUBERT ENVIRO CARE SYSTEMS (P) LTD

NABET/EIA/24-27/RA 0335 dated 25.06.2024 valid till 31.03.2027

July 2024

1. Project Description

M/s. Omexa Formulary Private Limited has proposing new manufacturing facility of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. The total project site area is 3.743 Acres.

According to the EIA Notification, 2006 and its amendment issued by MoEF & CC under Environmental Protection Act - units located inside the notified industrial area/estate are listed under schedule no. 5(f) Category 'B1'.

Accordingly ToR application was submitted vide Proposal No: **SIA/TN/IND3/472326/2024** dated: **06.06.2024** and ToR was issued vide F.No. **10894** dated:**29/06/2024**. Baseline monitoring for the proposed project was undertaken from March to May 2024. As per the issued ToR, Draft EIA report has been prepared and submitted for conducting Public Hearing (PH). After completion of Public Hearing, the Final EIA report along with action plan for Public concerns by the project proponent will be submitted to TNSEIAA for further appraisal of the project and obtaining the Environmental Clearance (EC).

The project site does not come under Comprehensive Environmental Pollution Index (CEPI) of Critically Polluted Area. Also, this project does not come under National Clean Air Programme.

2. Project Location

The proposed project has planned to establish new manufacturing facility of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. National Highway NH-77 (Tindivanam-Krishnagiri)/ NH179B (Chennai-Tindivanam-Harur)~0.37 km (S). Venmaniyattur village is located ~ 1.16 km, N. The nearest town is Tindivanam ~ 2.0 km, ESE.

2.1 Site Salient features

Table 1 Salient features of the project site and surrounding features

| S. No | Particulars | Details |
|--------------|-----------------------|--------------------------------------|
| 1 | Geographical Location | Centroid(12°15'10.79"N,79°37'5.11"E) |

| | | | | | |
|----|--|---|-------------------|--------------|-------------------|
| 2 | Present Land Use | Industrial use Zone as per site located in TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District | | | |
| 3 | Nearest Railway Station | Nearest Railway Station - Tindivanam ~4.31 km (ESE) | | | |
| 4 | Nearest Airport | Puducherry Airport ~37.48 km (SSE) | | | |
| 5 | Nearest Highway | NH-77(Tindivanam-Krishnagiri)/NH179B(Chennai-Tindivanam-Harur)~0.37 km (S) | | | |
| 6 | Nearest habitation /Village | Villages | ~Dist | Dire | Population |
| | | Hamlet(Periyar Ninaivu Samathuvapuram-Pattanam) | 0.74km | NE | 240 |
| | | Venmaniyattur | 1.16km | N | 1,350 |
| | | Pelakuppam | 1.39km | SSE | 1,610 |
| | | Vempundi | 1.47km | SSW | 1,843 |
| | | Pattanam | 1.53km | ENE | 2,896 |
| | | Tindivanam | 2km | ESE | 72,796 |
| 7 | Nearest Town/ City | Nearest Town: Tindivanam ~ 2 km (ESE) Nearest City: Puducherry ~ 38 km (SSE) | | | |
| 8 | Densely populated area | Tindivanam(Pop~72,796) ~2 km (ESE) | | | |
| 9 | Inland water bodies | Sensitive places | ~Dist (km) | Direc | |
| 10 | Reserved Forests/ Protected Forests | Waterbodies | | | |
| | | Pelakuppam Lake | 0.99 | ESE | |
| | | Pattanam Lake | 1.59 | NNE | |
| | | Buderi Lake | 2.13 | SSE | |
| | | Vempundi Lake | 2.26 | SW | |
| | | Melpakkam Lake | 4.31 | NE | |
| | | Avaiyurkuppam Lake | 7.36 | SW | |
| | | Kodiyam Lake | 7.5 | N | |
| | | Saram Lake | 7.97 | ENE | |
| | | Vilukkam Lake | 8.21 | W | |
| | | Elamangalam Lake | 8.6 | WNW | |
| | | Tondi Ar | 8.75 | SW | |
| | | Saram R | 8.91 | ENE | |

| | | | | | | | | | | |
|-------------------------|--|---|-------|-----|-----------------|--------------|--------------|-------------------------|--------|---|
| | | Kondamur Ar | 9.5 | SE | | | | | | |
| | | Olakkur Lake | 10.75 | NE | | | | | | |
| | | Sankaraparani R/Varaha N | 10.85 | WSW | | | | | | |
| | | Etanemali Lake | 10.98 | NW | | | | | | |
| | | Ongur Channel | 14.05 | ENE | | | | | | |
| | | Nallur Lake | 14.68 | N | | | | | | |
| | | Reserved Forest (RF) | | | | | | | | |
| | | Sevur RF | 12.39 | E | | | | | | |
| 11 | Defense Installations | Nil within 15 km radius | | | | | | | | |
| 12 | Archeologically Important places/sites | <table border="1" style="width: 100%; text-align: center;"> <tr> <td>Monument</td> <td>~Dist</td> <td>Direc</td> </tr> <tr> <td>Pallava Rock-cut shrine</td> <td>7.79km</td> <td>N</td> </tr> </table> | | | Monument | ~Dist | Direc | Pallava Rock-cut shrine | 7.79km | N |
| Monument | ~Dist | Direc | | | | | | | | |
| Pallava Rock-cut shrine | 7.79km | N | | | | | | | | |
| 13 | Interstate/ National Boundaries | Nil within 15 km radius | | | | | | | | |
| 14 | Notified Wildlife Sanctuary/ Notified national parks/ Ecologically sensitive areas | Nil within 15 km radius | | | | | | | | |

2.2 Magnitude of operation

The proposed project will involve manufacturing of Monoclonal antibodies with Capacity of 520 kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/**Month**. The list of proposed products and their respective quantities are given in **Table 2**.

Table-2. List of Proposed products with quantity

Monoclonal antibodies (drug substances)

| Sl.No | Product | CAS No. | Kg Per annum | Used to Treat |
|-------|---------------|--------------|--------------|---|
| 1 | Pembrolizumab | 1374853-91-4 | 100 | Lung cancer, head and neck cancer, melanoma and cervical cancer. |
| 2 | Denosumab | 615258-40-7 | 20 | Treatment of osteoporosis. It is also used to treat bone loss in men with prostate cancer and in women with breast cancer |
| 3 | Ustekinumab | 815610-63-0 | 20 | Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis, |

| | | | | |
|----|-----------------------|--------------|----|---|
| 4 | Bevacizumab | 216974-75-3 | 10 | Colon cancer, lung cancer, ovarian cancer, glioblastoma, and renal-cell carcinoma. |
| 5 | Adalimumab | 331731-18-1 | 20 | Spondylitis, rheumatoid arthritis, psoriasis, |
| 6 | Aflibercept | 862111-32-8 | 10 | Metastatic colorectal cancer. |
| 7 | Apixaban | 503612-47-3 | 50 | Stroke prevention · Deep vein thrombosis · Pulmonary embolism |
| 8 | Trastuzumab | 180288-69-1 | 20 | Breast and Stomach Cancer |
| 9 | Olaratumab | 1024603-93-7 | 10 | Solid Tumors |
| 10 | Omalizumab | 242138-07-4 | 10 | Moderate to severe asthma |
| 11 | Palivizumab | 188039-54-5 | 10 | Respiratory syncytial virus (RSV) infections |
| 12 | Panitumumab | 339177-26-3 | 10 | Colon and rectum Cancer |
| 13 | Tocilizumab | 375823-41-9 | 10 | Rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and other inflammatory disease |
| 14 | Trastuzumab emtansine | 1018448-65-1 | 10 | Breast Cancer |
| 15 | Infliximab | 170277-31-3 | 10 | Rheumatoid arthritis · Ankylosing spondylitis · Psoriasis |
| 16 | Eculizumab | 219685-50-4 | 10 | Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), |
| 17 | Etanercept | 185243-69-0 | 10 | Rheumatoid arthritis · spondylitis · Psoriasis |
| 18 | Ziv-aflibercept | 862111-32-8 | 10 | Colorectal Cancer |
| 19 | Rituximab | 174722-31-7 | 10 | Rheumatoid arthritis, blood cancer |
| 20 | Ramucirumab | 947687-13-0 | 10 | Lung Cancer, Stomach Cancer and Rectum |
| 21 | Raxibacumab | 5655451-13-0 | 10 | Prophylaxis and treatment of inhaled anthrax. |
| 22 | Sarilumab | 1189541-98-7 | 10 | Severely active rheumatoid arthritis |
| 23 | Inotuzumab ozogamicin | 635715-01-4 | 10 | Acute lymphoblastic leukemia |
| 24 | Brodalumab | 1174395-19-7 | 10 | Inflammatory diseases. |
| 25 | Abatacept | 332348-12-6 | 10 | Rheumatoid arthritis |
| 26 | Abciximab | 143653-53-6 | 10 | Blood Clots |
| 27 | Agalsidase beta | 104138-64-9 | 10 | Genetical Disorders |
| 28 | Alemtuzumab | 216503-57-0 | 10 | Blood cancer (Chronic lymphocytic leukemia) · Multiple sclerosis (MS) |
| 29 | Alglucosidase alfa | 420784-05-0 | 10 | Treatment of Pompe disease (Glycogen storage disease type II) |
| 30 | Alirocumab | 1245916-14-6 | 10 | High cholesterol in Adults |

| | | | | |
|--------------|--------------|-------------|------------|---|
| 31 | Cetuximab | 205923-56-4 | 10 | Meta static Colorectal Cancer, Head & Neck Cancer |
| 32 | Pertuzumab | 380710-27-5 | 10 | Metastatic HER2 positive Breast cancer |
| 33 | Somatropin | 12629-01-5 | 10 | Growth Factors |
| 34 | Tenecteplase | 191588-94-0 | 20 | Prevents Thrombosis |
| Total | | | 520 | |

Formulation products (drug products)

| Filling Format | Quantity (Numbers per Month) |
|--------------------|------------------------------|
| Prefilled Syringes | 1,00,000 |
| Vials | 40,000 |
| Lyophilised Vials | 24,000 |

2.2.1 Land Requirement

The total land area is 15147.40 Sq.m. The land area break-up details are provided in **Table 3** and builtup area is given in **Table 4**.

Table 3 Land Area Breakup

| Items | Area in Sq.m | Area in Acres | % |
|--------------------------|-----------------|---------------|------------|
| Ground coverage (plinth) | 6472.00 | 1.599 | 42.73 |
| Greenbelt | 5011.40 | 1.239 | 33.08 |
| Open Space | 144.00 | 0.036 | 0.95 |
| Road & Parking | 3520.00 | 0.869 | 23.24 |
| Total | 15147.40 | 3.743 | 100 |

Table 4 Tentative Builtup Area

| Items | Area in Sq.m |
|-----------------------------|-----------------|
| Manufacturing block | 13370.00 |
| R&D Block | 1950.00 |
| Admin/QC/QA block/reception | 2400.00 |
| Pilot plant + Dining | 3875.00 |
| Security Block | 42.00 |
| Creche, OHC & Utilities | 600.00 |
| Total | 22237.00 |

2.3 Raw materials

All the raw materials required in manufacturing are procured from local markets. The raw materials and finished products are transported by road. All chemicals used in the process were stored in a designated area with proper labels in the warehouse.

2.4 Water Requirement

2.4.1 Construction phase:

About 40 KLD of water (for labour 1.4 KLD & Construction activities 38.6 KLD) will be required during the peak construction phase and it will be sourced through Private tankers.

2.4.2 Operation phase:

Total water requirement for the project is 132.4 KLD. Fresh water is 70.4 KLD and Recycled water is 62 KLD. Source of fresh water is TANSIDCO. Details of water requirement for the proposed project are given in **Table 5**

Table 5 Water Requirements-Proposed

| Description | Fresh water (KLD) | Recycle water (KLD) | Total Water (KLD) |
|--|-------------------|---------------------|-------------------|
| Pre-Treatment System for process & Lab | 65 | 0 | 65 |
| Cooling tower | 0 | 37 | 37 |
| Boiler | 0 | 7 | 7 |
| Greenbelt | 0 | 18 | 18 |
| Domestic | 5.4 | 0 | 5.4 |
| Total (KLD) | 70.4 | 62 | 132.4 |

2.5 Power Requirement

Power requirement will be met from TANGEDCO. Two (2) DG set will be installed as back-up power requirement during power failure. The power and energy requirement details are provided below.

Table 6 Power and Energy Requirement

| Details | Quantity | Source |
|--------------------------|----------|------------------------------------|
| Power Requirement (kVA) | 1745.64 | TANGEDCO |
| Back-up (kVA) | 2x600 | DG Sets |
| Boiler (kg/hr) | 1x1500 | For steam |
| Fuel Requirement: | | |
| HSD (KLD) for Boiler | 2.509 | Local Supply such as HP, BHP & IOC |

| | | |
|------------------------|------|--|
| HSD for DG set (KL/Hr) | 0.12 | |
|------------------------|------|--|

Note: *In ToR application, DG sets capacity - 2x350 kVA.

2.6 Manpower Requirement

Total Manpower requirement Breakup is given below.

Table 7 Manpower Requirements

| S.No | Manpower | Construction Phase | Operation Phase |
|------|--------------|--------------------|-----------------|
| 1 | Contract | 30 | 30 |
| 2 | Permanent | 0 | 90 |
| | Total | 30 | 120 |

Additional employment opportunity for product dealers and distributors, and transport sectors for product movement will increase the employment opportunity indirectly.

2.7 Project Cost

Estimated project cost is INR. 95 Crores

2.8 Municipal Solid waste generation and management

Municipal Solid waste generation and management for the proposed project are given in **Table 8**

Table 8 Municipal Solid Waste Generation

| S.No | Waste | Proposed (kg/day) | Total (kg/day) | Method of disposal |
|--|------------|-------------------|----------------|---------------------------------|
| Operations Phase (120 Nos) | | | | |
| 1 | Organic | 32.4 | 32.4 | To Local TANSIDCO bins |
| 2 | Inorganic | 21.6 | 21.6 | To TNPCB Authorized Recyclers |
| 3 | STP Sludge | 0.6 | 0.6 | Used as a manure for greenbelt. |
| Total | | 54.6 | 54.6 | - |
| Construction Phase (30 Nos): 13.5 Kg/day (Disposal through local TANSIDCO bins) | | | | |

Note: As per CPHEEO norms - 0.45kg/capita/day

2.9 Hazardous Waste generation and management

The details of hazardous waste generation and handling/Management are given in **Table-9**.

Table 9 Hazardous waste details

| S.No | Description of Waste | Category as per HWM Rules 2016 | QTY/Annum | Storage method | Method of disposal |
|------|---|--------------------------------|----------------------|---|--|
| 1 | Used /Spent Oil | 5.1 | 1 KL | All the generated Hazardous waste will be stored on Concrete platform in leak Proof Barrels in designated areas | Will be collected and disposed through TNPCB Authorised recycler |
| 2 | Waste or residues containing oil | 5.2 | 1 Ton | | Will be collected and disposed through TNPCB Authorized TSDF |
| 3 | Discarded Containers/Bags | 33.2 | 4 Ton | | Will be collected and disposed through TNPCB Authorised recycler |
| 4 | MEE salt | 37.3 | 16.5 Ton (50 kg/day) | | Will be collected and disposed through TNPCB Authorized TSDF |
| 5 | ETP Sludge | 35.3 | 3.3 Ton (10 kg/day) | | |
| 6 | Off Specification Products (Doesn't Met by Specifications or standards) | 28.3 | 2 Ton | | |
| 7 | Expiry Products/Chemicals | 28.5 | 1.5 Ton | | |

3. Description of the Environment

3.1 Meteorological Environment

The baseline study was carried out during March to May 2024.

Table 10 Micrometeorological data during study period

| S. No | Parameter | Observation |
|-------|---------------------------|---|
| 1 | Temperature | Max. Temperature: 41°C Min. Temperature: 24°C Avg. Temperature: 31.15°C |
| 2 | Average Relative Humidity | 73.36% |
| 3 | Average Wind Speed | 3.61m/s |

| | | |
|---|----------------------------|------------|
| 4 | Predominant Wind Direction | South East |
|---|----------------------------|------------|

3.2 Ambient Air Quality

The ambient air quality has been monitored at 8 locations as per NAAQS, 2009 within the study area. The results obtained are summarized as below:

- The average baseline levels of PM₁₀ vary from 36.27 to 50.05 µg/m³.
- The average baseline levels of PM_{2.5} vary from 21.42 µg/m³ to 27.88 µg/m³.
- The average baseline levels of SO₂ vary from 8.50µg/m³ to 10.49 µg/m³.
- The average baseline levels of NO₂ vary from 19.42 µg/m³ to 21.81 µg/m³

3.3 Noise Environment

8 locations under the study constitute of 7 locations in residential areas and 1 in industrial area. It was observed that within the Residential areas, noise levels (Day and Night) are well within the standards prescribed by CPCB.

- In Industrial area (Project site), day time noise level was about 54.6 dB (A) and 49.3 dB(A) during night time, which is within prescribed limit by CPCB for Industrial area (75 dB(A) Day time & 70 dB(A)Night time).
- In Residential area day time noise levels varied from 45.4 dB (A) to 54.6 dB (A) and night time noise levels varied from 40.4 dB(A) to 43.6 dB(A) across the sampling stations. The field observations during the study period indicate that the ambient noise levels in Residential area are within the limit prescribed by CPCB for Residential area (55 dB (A) Day time & 45 dB(A) Night time).

3.4 Surface water quality

Surface water sample results are discussed below:

- Water sampling results are compared with Surface water standards IS 2296:1992.
- pH in the collected surface water samples varies between 7.34to7.74which is within the limit of IS 2296:1992.
- The Total Dissolved Solids (TDS) value of collected surface water sample ranges from 395mg/l to 473mg/l.
- The Total hardness value of the collected surface water sample ranges between 175 mg/l to 265 mg/l.
- BOD value of surface water varies from 2 mg/l to 5 mg/L
- COD value of surface water varies from 10 to 22 mg/l.

3.5 Ground water quality

A summary of analytical results are presented below:

- The pH of the collected ground water sample ranges from 6.91-7.6
- The concentrations of Chloride in the collected ground water sample ranges from 146 to 206 mg/l.
- Total Dissolved Solids (TDS) value of the collected ground water sample varies from 650 mg/l to 750 mg/l.
- Total hardness of the collected ground water sample ranges from 226 mg/l to 243 mg/l.

3.6 Soil quality

Summary of analytical results

- The pH of the soil samples ranged from 6.55 to 7.56.
- Conductivity of the soil samples ranged from 276 to 346 $\mu\text{S}/\text{cm}$.
- Nitrogen content ranged from 83.5 to 116.8 mg/kg.
- Phosphorous ranged from 3.6 to 5.3 mg/kg.
- Potassium content ranges from 37.5 to 50.3 mg/kg.

3.7 Biological Environment

A detailed biological survey of the core zone (Project site) and 10 km radius (Buffer zone) from periphery of the proposed project) was carried out based on secondary sources giving details of flora and fauna.

As Per Indian Wild Life (Protection) Act, 1972 as amended on 17th January 2003 is an Act to provide for the protection of wild animals, birds and plants and for matters connected therewith or ancillary or incidental thereto with a view to ensuring the ecological & environmental security. Indian Wild Life (Protection) Act, 1972 protects some of the sighted fauna.

While many birds are included in Schedule IV except Brahminy Kite (*Haliastur indu*) which comes under in Schedule I. Suitable measures and conservation plan was prepared for Brahminy Kite.

3.8 Socio economic status

The Socioeconomic profile of the study area shows that the majority of people in the study area work in non-agricultural sector, however in rural area majority of the people in the rural area depends on agricultural sector. They have good educational infrastructures and the people in the study area are well connected to the educational infrastructures. The average literacy rate of the study area is 71.54 %. The people in the study area are well connected to Government primary health centres and Primary health sub-centres.

Table 11 Socio- economic indicators of study area

| S.No | Particulars | Study area | Unit |
|------|--------------------------------------|------------|------|
| 1 | Number of villages in the Study Area | 59 | Nos. |
| 2 | Total Households | 38642 | Nos. |
| 3 | Total Population | 162540 | Nos. |
| 4 | Children Population (<6 Years Old) | 17309 | Nos. |
| 5 | SC Population | 46608 | Nos. |
| 6 | ST Population | 1971 | Nos. |
| 7 | Total Working Population | 70465 | Nos. |
| 8 | Main Workers | 56966 | Nos. |
| 9 | Marginal Workers | 13499 | Nos. |
| 10 | Cultivators | 10205 | Nos. |
| 11 | Agricultural labours | 25509 | Nos. |
| 12 | Household Industries | 1479 | Nos. |
| 13 | Other Workers | 33272 | Nos. |
| 14 | Literates | 116282 | Nos. |

Source: census 2011

4. Impact on Air environment

Air quality modelling was done using AERMOD software to identify the ground level concentration due to operation of proposed industries. The details on the type of fuel proposed, emissions are given in Chapter-4 of the EIA report. Based on the modelling done, the total ground level concentrations from point source and line source are given in below:

Table 12 Total Maximum GLCs from the Stack Emissions

| Pollutant | Max. Base line Conc. (µg/m3) | Estimated Incremental Conc. (µg/m3) | Total Conc. (µg/m3) | NAAQ standard (µg/m3) |
|-----------------|------------------------------|-------------------------------------|---------------------|-----------------------|
| PM | 59.48 | 0.056 | 59.536 | 100 |
| SO ₂ | 12.46 | 0.048 | 12.508 | 80 |
| NO _x | 25.92 | 0.832 | 26.752 | 80 |
| CO | 720 | 1.497 | 721.497 | 4000 |

Table 13 Total Maximum GLCs from the Vehicular Emissions

| Pollutant | Max. Base line Conc. (µg/m3) | Estimated Incremental Conc. (µg/m3) | Total Conc. (µg/m3) | NAAQ standard (µg/m3) |
|-----------------|------------------------------|-------------------------------------|---------------------|-----------------------|
| PM | 59.48 | 0.03 | 59.51 | 100 |
| NO _x | 25.92 | 0.87 | 26.79 | 80 |

| | | | | |
|----|-----|-------|--------|------|
| CO | 720 | 22.16 | 742.16 | 4000 |
|----|-----|-------|--------|------|

Table 14 Total Maximum GLCs from the cumulative Emissions

| Pollutant | Max. Base line Conc. (µg/m³) | Estimated Incremental Conc. (µg/m³) | Total Conc. (µg/m³) | NAAQ standard (µg/m³) |
|------------------|--|---|---------------------------------------|---|
| PM10 | 59.48 | 0.05 | 59.53 | 100 |
| SO ₂ | 12.46 | 0.04 | 12.5 | 80 |
| NO _x | 25.92 | 0.87 | 26.79 | 80 |
| CO | 720 | 22.16 | 742.16 | 4000 |

Air pollution control measures will be taken and the following will be adopted:

1. There are no process emissions from the proposed manufacturing facility.
2. Wet scrubber with stack height of 3.0 m (AGL) will be provided for QC lab vent.
3. Utilities stacks are provided with adequate height for DG Sets-30m for 2x600 KVA and also 30m for 1x1.5TPH boiler.
4. Adequate Green belt area will be provided

5. Alternate site consideration

No Alternative site was selected since the Omexa selected the plot at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State

Specific Site Selection Criteria of the Unit have been given below:

1. It is allocated within Notified TANSIDCO industrial Park.
2. Site is well connected by road (~0.37km, S), railways (~4.31 Km, ESE) and Airway (~37.48 km,SSE)
3. Sufficient land is available within the TANSIDCO IP.
4. 100% assurance of water & power supply by TANSIDCO.

6. Environmental Monitoring Programme

A monitoring schedule with respect to Ambient Air Quality, Water & Wastewater Quality and Noise as per CPCB/MoEF&CC/Tamil Nadu Pollution Control Board (TNPCB) shall be maintained.

7. Public Hearing

The Draft EIA report is being submitted to TNPCB for conducting Public hearing.

8. Rehabilitation and Resettlement

R&R is not applicable; since site is located within TANSIDCO industrial area

9. Environmental Management Plan

9.1 Air Environment

1. There are no process emissions from the proposed manufacturing facility.
2. Wet scrubber with stack height of 3.0 m (AGL) will be provided for QC lab vent.
3. Utilities stacks are provided with adequate height for DG Sets-30m for 2x600kVA and also 30m for 1x1.5TPH boiler.
4. Adequate Green belt area will be provided.

9.2 Noise Environment

As a preventive measure for the noise reduction the following will be adopted:

1. Acoustic measure for all the DG set, air compressor and feed water pumps etc.
2. Greenbelt development and maintenance will attenuate the noise levels.
3. The designed equipment with noise levels not exceeding beyond the requirements of Occupational Health and Safety Administration Standard will be employed.
4. Personal protective Equipments (PPE) will be provided to the workers who are working in high noise areas.
5. Speed restrictions will be provided to the vehicles in the plant premises.

9.3 Water Environment

Total waste water is separated into sewage and Trade effluent.

Table 12 Liquid waste management

| S. No | Description | Proposed Quantity KLD) | Final Disposal Points |
|---------------------------|--------------------|-------------------------------|---|
| Construction Phase | | | |
| 1 | Sewage | 1.22 | Will be treated in mobile STP (3 KLD) and treated sewage will be reused for greenbelt development |
| Operation Phase | | | |
| 1 | Effluent | 59.5 | Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. |

| | | | |
|---|--------|-----|--|
| 2 | Sewage | 4.6 | Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge will be used as a manure for greenbelt. |
|---|--------|-----|--|

No disposal of wastewater outside the plant premises and Zero Liquid Discharge (ZLD) concepts will be implemented. Technical Specification of STP and ETP is attached as an **Annexure-5a** and **Annexure-5b**.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as ‘biologically contaminated’ or ‘regular’ waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as ‘liquid waste’ at the source point, from the process equipment drain point is led to a common drain network made fromStainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- 1 No. Collection tank
- 2 Nos of Treatment vessels – 1 working +1 standby
- Chemical dosing system
- Transfer pumps – 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste. As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste.

Online monitoring System: All pollution generating stream will be connected to server of OCMS, TNPCB. So it will be continuously monitored.

9.4 Solid & Hazardous waste:

- STP is proposed for treating the sewage generated and treated sewage will be used for green belt development within the industry.
- ETP with ZLD scheme is proposed to treat the effluent. Hence there will be no discharge of treated/ untreated wastewater outside the project premises.
- Municipal Solid Wastes generated will be segregated to organic and inorganic wastes. The organic wastes (33 kg/day) will be disposed to TANSIDCO Bins and inorganic waste (21.6 kg/day) will sell to TNPCB authorized vendors.
- Hazardous waste will be segregated and stored under roofshed on raised platform. Proper leachate collection system and roof. Leachate, if any will be collected and treated in effluent treatment plant.
- Unit will take membership with TSDF and also Authorization from TNPCB after getting Environmental Clearance from SEIAA, Tamil Nadu.

9.5 Greenbelt Development

The total land area is 15147.40 Sq.m and Greenbelt area is 5011.40 Sq.m (33.08%). Around 1503 numbers of tree (2mx2m spacing for each tress) will be planted as calculated below:

| S.No | Description | Unit | Proposed Greenbelt within project site |
|---|----------------------------------|-------|--|
| 1 | Total area of project site | Ha | 1.5147 |
| 2 | Total Area of Green Belt | Ha | 0.5011 |
| 3 | Percentage of total project area | % | 33.08 |
| As per the MoEF&CC Requirement, No. of tree saplings to be planted as per guidelines(2500 tree/Ha) considering 80% survival rate | | | |
| 4 | As per MoEF&CC requirement | Nos | 1503 |
| 5 | Actual No. of plants present | Nos. | - |
| 5 | No of plants to be planted | Nos. | 1503 |
| 6 | Fund Allotted | Lakhs | 6.00 |
| 7 | Status of Implementation | - | Within 3 year |

Table 13 Recommended Species for Proposed Green Belt Development in project site

| S.No | Scientific Name | Common Name | No of Trees | Yearwise |
|--------------|------------------------------|-------------|-------------|----------------------|
| 1 | <i>Pongamia pinnata</i> | Pungai | 300 | 1 st Year |
| 2 | <i>Thespesia populnea</i> | Poovarasu | 300 | 2 nd Year |
| 3 | <i>Albizis lebback</i> | Vaagai | 150 | |
| 4 | <i>Cassia fistula</i> | Sarakondai | 150 | 3 rd Year |
| 5 | <i>Lagestroemia Speciosa</i> | Poo marudhu | 150 | |
| 6 | <i>Pterocarpus Marsupium</i> | Vengai | 150 | 4 th Year |
| 7 | <i>Aegle Marmelos</i> | Vilvam | 150 | |
| 8 | <i>Madhuca longifolia</i> | Iluppai | 153 | |
| Total | | | 1503 | |

9.6 Risk Assessment

Risk assessment is an indispensable part of Process Safety Management (PSM). PSM must be invariably invoked when involved in handling, using, storing, moving, or manufacturing of highly hazardous chemicals. The M/s.Omexa Formulary Pvt Ltd is planning to manufacture of bulk drugs & intermediates & formulation products, handles some solvents which pose health and flammability hazard. Thus, the risk associated with production facility was assessed and to be elaborated in this report. The Risk Assessment study has been performed as dictated by the IS15656:2006 “HAZARD IDENTIFICATION AND RISK ANALYSIS - CODE OF PRACTICE” to give crucial insights on the hazards involved in the facility line of production.

Based on the available studies & plant layout, the potential scenarios which can cause significant consequences like Dispersion of vapour cloud, fire and explosion scenarios were identified. The purpose of the study includes the following:

- To identify those hazards that pose health and flammability risks as per NFPA rating.
- To eliminate or reduce to As Low As Reasonably Practicable (ALARP) the risk to human health, risk of injury, risk of damage to plant, equipment and environment, business interruption or loss etc.
- To Suggest On-site Mitigation Measures

9.7 Budgetary provisions for EMP

The capital cost of EMS is Rs 456.0 lakhs and recurring cost will be Rs. 42.2 Lakhs, this includes cost of APCM, ETP, STP, Solid and Hazardous waste management, Safety equipments and greenbelt development as well third party monitoring, maintainace and membership cost

Table 14 Budget for Environmental Management Plan

| S. No | Particulars | Proposed Capital Investment (Rs in lakhs) | Recurring Cost per Annum (Rs in Lakhs) |
|---|--|---|--|
| Environment Management Plan | | | |
| Water Pollution Control | | | |
| 1 | ETP | 350 | 20 |
| 2 | MEE/ATFD and RO | | |
| 3 | STP | 8.5 | 2 |
| Air Pollution Control | | | |
| 4 | DG & Boiler Stack/ Wet scrubber | 60 | 3 |
| Environmental Monitoring | | | |
| 5 | Environmental Monitoring by third party | 0 | 4.4 |
| Solid Waste Management | | | |
| 6 | Solid Waste Management | 2 | 3 |
| Greenbelt | | | |
| 7 | Greenbelt Development | 7 | 2 |
| Hazardous Waste Management | | | |
| 8 | Hazardous Waste Management | 2 | 5 |
| Storm Water and Rain water harvesting management | | | |
| 9 | Storm Water and Rain water harvesting management | 26 | 2.6 |
| 10 | OHC Expenses | 1.5 | 0.2 |
| | Total | 456.0 | 42.2 |

10. CER Cost:

As per OM.F.No.22-65/2017-IA.III Dated: 1st May 2018, 2.0% of the total project cost ie., (INR 1.9 crores) will be used for CER activities. This will be used for nearest village water tank sustainability development and other environmental related activities in nearby villages as per the observation made in public hearing

11. Project Benefits

- Presently, 120 persons are expected to be employed for the skilled, semi skilled and unskilled category for the proposed project.

- The preference will be given to local populations for employment in the semi skilled and unskilled category, this will increase the employment opportunity in the surrounding area.
- Secondary jobs and indirect employment are also bound to be generated to provide day to day needs and services to the work force and industrial activity.
- This will also increase the demand for essential daily utilities in the local market.
- The employed people will be benefited financially. This financial gain will fulfill their monetary requirements which in turn will increase their standard of living.