

**1. Case No. - 5064/2016 Shri Ravindra Ramakant Gulgule, Joint Managing Director, M/s Thing Pharma – CRO Pvt. Ltd., A/30, Thing House, Road No. 10, MIDC Wagle Estate, Thane West (MH)-400604 Prior Environment Clearance for Proposed Active Pharma Ingredients for M/s Thing Pharma- CRO Pvt. Ltd., Bulk Drug & Drug Intermediate Manufacturing Plant at M 40 & 42 Industrial State Dector-3, Village-Pithampur, Tehsil-Pithampur, District-Dhar (MP) Case forwarded to SEIAA letter No. 11808 dtd. 14-03-16 rec. dt 17/03/16 Env. Consultant: Not discosed. For- ToR**

- The company is planning to set up a new unit as Thing Pharma CRO ltd. at Plot No. M40-42,Pithampur industrial estate-3, Bugdoon, Dhar,Madhya Pradesh. M.P. Audyogik Kendria Vikas Nigam (Indore) LTD allotted above plot no. vide letter no. AKVN/IND/INFRA/2016/18917 dtd. 03/03/2016. The land for the project admeasuring 21794 Sq. meters is allotted by MPAKVN on lease to the company.
- The company is putting up a project to manufacture intermediates and APIs. Theses intermediates are primarily for contrast media APIs. These are iodine based. Currently, these products are imported. Producing within India should save valuable foreign exchange and also ensure un-interrupted supply of good quality of higher intermediates to API and formulation manufacturers.
- Project Land is situated within the designated notified industrial area of MPAKVN.
- No wildlife sanctuary/National Park/Tiger Reserve falls within 10 km radius.
- No critically polluted area falls within 10 km radius of project site.

|                     |   |
|---------------------|---|
| Site Address        | Plot No. M40 & 42, Pithampur Indsutria Estate-3, Budgoon, Dhar (MP) |
| Production Capacity | Given below   |
| Cost of Project     | 20 Crore  |
| Boiler capacity     | 3 T   |

|                             |                      |
|-----------------------------|----------------------|
| Power Requirement           | 500 KVA              |
| Area of plantation          | 3268 sqmt (0.8 acre) |
| Alternative Source of Power | DG set of 250 KVA    |
| Land acquired               | 21794square meter    |

### **PROPOSED FACILITIES;**

- Separate Raw Materials and Finished Goods Storage area.
- Comprehensive Chemical Management Plan and Waste Management Plan will be implemented.
- Solvent Recovery Plant to manage Solvents
- Effluent Treatment Plant to manage Wastewater
- Installation of scrubber for fugitive emissions.
- Provision of Adequate Stack height and vents for Boiler and DG sets
- Plantation (Pollution Specific green belt development).
- Membership of TSDF Facility to manage generated wastes.

### **ENVIRONMENTAL SETTING OF THE PROJECT**

| <b>S. No.</b> | <b>Particulars</b> | <b>Details</b>  |
|---------------|--------------------|---|
| 1             | Co-ordinate        | 1. 22°38'46"N- 75°34'49"E (NE)<br>2. 22°38'46"N- 75°34'49"E (SE)<br>3. 22°38'46"N - 75°34'51"E (SW)<br>4. 22°38'46"N- 75°34'49"E (NW) |
| 4             | Nearest Town       | Town – Pithampur – Distance – 5 KM<br>City – Indore – Distance – 25 KM<br>District Head quarter – Dhar – Distanc                      |

|    |                                 |  |
|----|---------------------------------|--|
|    |                                 | 25 KM  |
| 5  | Nearest Railway Station/Town    | Rau Railway Station approx – 20 KM   |
| 6  | Nearest Airport                 | Indore Domestic Airport approx - 30 KM   |
| 7  | Nearest Highway/Road            | Mhow- Ghatabillod Road   |
| 8  | Hills/Valley                    | Narmada Valley   |
| 9  | Ecological Sensitive Zone       | None   |
| 10 | Reserve Forest                  | None   |
| 11 | Nearest Village                 | Budgoon -0.12 km - W   |
| 12 | Nearest River/ Nalla            | Local Nalla - 0.15km - W<br>Angrer Nadi – 5.0km - SE   |
| 13 | Other industries in 5 km radius | DivyaJyoti, Indorama, Avtec Hindustan Moto<br>Bridgestone  |
| 14 | Surrounding Features            | North : Agricultural Land<br>South : Industries and village<br>East : Agricultural land<br>West : Village road |

### AREA STATEMENT

| Particulars   | Total Area (Sq. mt.) |
|---------------|----------------------|
| Total Land    | 21794                |
| Built up area | 13500                |
| Open Land     | 8294                 |

| Particulars              | Total Area (Sq. mt.) |
|--------------------------|----------------------|
| Proposed roof area       | 13500                |
| Utilities area           | 750                  |
| ETP area                 | 750                  |
| AHU Area                 | 250                  |
| Plant and machinery area | 8000                 |
| Admin office             | 2000                 |
| Plantation               | 3268                 |

### PRODUCTS AND PRODUCTION CAPACITY

| Sr. No. | Product  | Qty MT/PA |
|---------|--|-----------|
| 1       | (2S)-1- {[3,5-bis(chlorocarbonyl)-2,4,6-triiodophenyl]amino}-1-oxopropan-2-yl acetate(Iopamidol stage-III) | 82.71     |
| 2       | 5-amino-2,4,6-triiodobenzene-1,3-dicarbonyl dichloride(Iopamidol stage-II)                                 | 80.29     |
| 3       | Paroxetine Hydrochloride   | 0.4       |
| 4       | QuetiapineFumatate   | 0.8       |
| 5       | Valacyclovir hydrochloride   | 0.2       |
| 6       | Ractopamine hydrochloride  | 6         |
| 7       | OctopamineHydrochloride  | 6         |

|    |   |      |
|----|---|------|
| 8  | Benzocaine  | 10   |
| 9  | Benfothiamine   | 2    |
| 10 | 5-Phenyl valariac acid methyl ester (5-PVM)                         | 3    |
| 11 | trans Retinoic acid, 1-hydroxy-3,3-dimethyl-2-butanone ester(G-101) | 0.2  |
| 12 | Chlorothymol  | 0.3  |
| 13 | N-Boc-4-Hydroxy-L-Proline   | 3    |
| 14 | 2-Nitro benzene sulfanyl chloride(NSC)                              | 0.2  |
| 15 | Sharpless catalyst  | 0.02 |

### RAW MATERIAL

| <b>Sr. No.</b> | <b>Key Raw materials Solvents</b> | <b>Quantity<br/>MT</b> |
|----------------|-----------------------------------|------------------------|
| 1              | Iodine                            | 218.39                 |
| 2              | 5-amino isophthalic acid          | 102.37                 |
| 3              | L-Lactic acid                     | 68.62                  |
| 4              | Acetyl chloride                   | 89.3                   |
| 5              | Thionyl chloride                  | 385.35                 |
| 6              | S-Carbinol                        | 0.492                  |
| 7              | Tosyl chloride                    | 0.524                  |
| 8              | Sesamol                           | 0.284                  |
| 9              | Phenyl chloroformate              | 0.26                   |

|    |   |       |
|----|---|-------|
|    |   |       |
| 10 | Dibenzo [ b,f] [ 1,4] thiazepine-11(10H) one (DBTO) | 0.776 |
| 11 | Piperazine  | 0.584 |
| 12 | Dimethyl aniline                                    | 0.312 |
| 13 | 2-chloro ethoxy ethanol                             | 0.424 |
| 14 | Fumaric acid  | 0.2   |
| 15 | POCl3   | 0.52  |
| 16 | Acyclovir   | 0.278 |
| 17 | Cbz-L-Valine  | 0.388 |
| 18 | Dicyclohexyl carbodiimide (DCC)                     | 0.59  |
| 19 | 2'-amino-4-hydroxyacetophenone                      | 24.74 |
| 20 | Raspberry ketone                                    | 5.42  |
| 21 | 4-Nitro benzoic acid                                | 14.7  |
| 22 | Thiamine HCl  | 4     |
| 23 | Benzoyl chloride                                    | 1.34  |
| 24 | Phosphoric acid                                     | 31.71 |
| 25 | Phosphorous pentoxide                               | 4     |
| 26 | Benzene   | 13.16 |
| 27 | Delta valaralactone                                 | 4.18  |
| 28 | Aluminium chloride                                  | 10.44 |
| 29 | All trans retinoic acid                             | 0.18  |
| 30 | 1-chloro picolone                                   | 0.18  |
| 31 | Cesium carbonate                                    | 0.21  |

|    |   |         |
|----|---|---------|
| 32 | Thymol  | 0.42    |
| 33 | Sulfuryl chloride   | 0.45    |
| 34 | Carbon tetachloride   | 0.96    |
| 35 | 4-Hydroxy L-Proline   | 4.17    |
| 36 | BOC anhydride   | 8.34    |
| 37 | Sodium periodate  | 24.46   |
| 38 | Ruthenium chloride  | 0.01    |
| 39 | 2-chloro nitro benzene  | 0.57    |
| 40 | Sodium sulfide  | 0.43    |
| 41 | Sulfur  | 0.09    |
| 42 | Trichloro ethylene  | 0.51    |
| 43 | (S)-(6-methoxyquinolin-4-yl) (2R,4S,5R)-5-ethyl-1-azabicyclo 2.2.2 oct-2-yl methanol. HCl | 0.035   |
| 44 | Dichloro Phthalyl hydrazine   | 0.00871 |

|    |                    |         |
|----|--------------------|---------|
| 45 | Toluene            | 59.2243 |
| 46 | Methanol           | 24.826  |
| 47 | Dichloromethane    | 480.872 |
| 48 | Acetone            | 2.79918 |
| 49 | Isopropanol        | 54.741  |
| 50 | Ethyl acetate      | 753.01  |
| 51 | Dimethyl formamide | 3.342   |
| 52 | Pet ether/hexane   | 6.36    |

|    |                    |       |
|----|--------------------|-------|
| 53 | Dimethyl acetamide | 75.27 |
| 55 | Tetrahydrofuran    | 24.69 |
| 55 | Triethyl amine     | 92.54 |

### WATER CONSUMPTION AND WASTE WATER GENERATION

| Sr.No | Heads     | Consumption KLD | Generation of waste water KLD | Treatment and Disposal           |
|-------|-----------|-----------------|-------------------------------|----------------------------------|
| 1     | Process   | 50              | 45                            | To ETP                           |
| 2     | Domestic  | 5               | 4                             | To ETP – Aeration Tank           |
| 3     | Cooling   | 1               | 1                             | Neutralization and use Gardening |
| 4     | Boiler    | 5               | 3                             | Neutralization and use Gardening |
| 5     | Washing   | 5               | 5                             | To ETP                           |
| 6     | Gardening | 0               | 0                             |                                  |
| 7     | Total     | 66              | 59                            |                                  |

### Sources of Hazardous / Solid Wastes

| Sources | Type of pollutants | Preventive measures | Control Measures | Treatment Disposal |
|---------|--------------------|---------------------|------------------|--------------------|
|---------|--------------------|---------------------|------------------|--------------------|



|                                       |                            |  |  |                             |
|---------------------------------------|----------------------------|--|--|-----------------------------|
| DG Sets                               | Used / Spent Oil           | Spill prevention plans and training.<br>Changing oil as per operation and service manual | Proper collection and storage in close lid MS drum | Sell to authorized recycler |
| Process/Utility equipment maintenance | Oil Soaked Waste           | Control on Issue of material, Behavioral Trainings, Proper SOPs                          | Monitoring and Measurement of wastes               | To MPWM TSDF, Pithampur.    |
| Treatment of wastewater in ETP        | Chemical Sludge            | Reduction measures for waste water   | Proper storage in HDPE bags                        | To MPWM TSDF, Pithampur.    |
| Discarded empty containers            | Solid waste                | Optimum Usage of Chemicals   | Proper storage in covered Concrete Shed            | Sell to authorized recycler |
| DM Plant, Softener                    | Spent Ion Resin            | Spill prevention plans and training.   | Proper collection and storage in close lid MS drum | To MPWM TSDF, Pithampur.    |
| Mfg Process                           | Process Residue and wastes | Strict process control, Proper SOPs, QMS implementation.                                 | Monitoring and Measurement of wastes               | To MPWM TSDF, Pithampur.    |
| Mfg Process                           | Spent Catalyst/Carbon      | Reduction measures   | Proper storage in HDPE bags                        | Recovery                    |

The case was presented by the PP and their consultant for TOR to carryout EIA studies wherein it was observed by committee that MPAKVN has not issued the NOC for all the proposed products. However, committee after

deliberations decided that PP can go ahead with the standard TOR as prescribed by the MoEF&CC and should submit NOC of MPAKVN for all the proposed products within 03 weeks. Any additional TOR (if any) may be issued after receipt of NOC from MPAKVN.