



## ANDHRA PRADESH POLLUTION CONTROL BOARD

D. No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,  
Chalamalavari Street, Kasturibaipet, Vijayawada - 520 010

Website: www.pcb.ap.gov.in

### AMENDMENT TO THE CFE ORDER

**Order No.APPCB/ VSP/VZN/91/CFE/HO/2012**

**13/11/2022**

Sub:APPCB - CFE - **M/s. Mylan Laboratories Limited, Unit-8, G. Chodavaram (V), Pusapatirega (M) Vizianagaram District – Amendment of CFE - Amendment to the CFE order – Issued – Reg.**

- Ref:
1. CFO order Dt. 28.06.2022 valid upto 31.08.2027.
  2. CFE(CPM) order dt.12.10.2022.
  3. Industry's representation dt. 17.10.2022.
  4. R.O Ir. dt. 31.10.2022
  5. CFE Committee meeting held on 01.11.2022.

**M/s. Mylan Laboratories Limited, G. Chodavaram (V), Pusapatirega (M) Vizianagaram District** had obtained CFO from the Board vide reference 1<sup>st</sup> cited with a validity period 31.08.2027. Further, the industry obtained CFE(CPM) vide reference 2<sup>nd</sup> cited.

The industry submitted a representation vide reference 3<sup>rd</sup> cited requesting amendment to some of conditions stipulated in the reference 2<sup>nd</sup> cited. The RO: Vizianagaram submitted a report in this regard.

The item was placed before the CFE Committee meeting held on 01.11.2022. The representatives of the project proponent attended the meeting through video conference. They have informed that they would remove marine outfall pipe line and requested to consider remaining amendments. The committee opined that the industry shall remove marine outfall pipe line and also the amendment pertaining to the fire pumps may not be considered as it pertains to Fire Department. After detailed discussions, the Committee recommended to issue the necessary amendments to the CFE order incorporating above conditions.

The Board after careful scrutiny of the representation of the unit, report of the Regional Officer and recommendations of the CFE Committee, hereby issues amendments to the CFE (CPM) order issued vide reference 2<sup>nd</sup> cited as following:

#### **Products:**

| S. No. | Name of the Products | Consented capacity as per EC Order dt. 01/11/06 | Qty as per CFE Order dt 8/8/18 & amendment order dt 13/11/18 Kg/day | Qty as per CFO (CPM) order dt.28.06.2022 Kg/day | Qty after CFE (CPM) Kg/day | Qty after CFE (CPM) Kg/annum |
|--------|----------------------|---|---|---|----------------------------|------------------------------|
| 1      | Tia Profenic Acid    | 3.0 TPM   | ---   | ---   | ---                        | ---                          |

|    |   |          |         |         |         |           |
|----|---|----------|---------|---------|---------|-----------|
| 2  | Naproxen Sodium                           | 50 TPM   | 3.33    | 3.33    | ---     | ---       |
| 3  | Trazadone HCL                             | 3.0 TPM  | 333.33  | 333.33  | 500.0   | 180000    |
| 4  | Allopurinol                               | 8.0 TPM  | 166.67  | 166.67  | ---     | ---       |
| 5  | Nabumetone                                | 1.0 TPM  | 166.67  | 16.67   | ---     | ---       |
| 6  | Efavirenz (EFD 1 NBC (Grignard Reagent)   | 15.0 TPM | 1333.33 | 1033.33 | 70.0    | 25200     |
| 7  | Abacavir Sulfate                          | 3.0 TPM  | 333.33  | 400.00  | 666.0   | 239760    |
| 8  | Nelfinavir Mesylate                       | 5.0 TPM  | ---     | ---     | ---     | ---       |
| 9  | Indinavir sulfate                         | 3.0 TPM  | ---     | ---     | ---     | ---       |
| 10 | Ciprofloxacin HCL                         | 25.0 TPM | ---     | ---     | ---     | ---       |
| 11 | Cytosine Menthyl Ester (CME Intermediate) | 16.6 TPM | 400.0   | 400     | 160.0   | 57600     |
| 12 | Zidovidine                                | 25.0 TPM |         |         | ---     | ---       |
| 13 | Gabapentine                               | 40.0 TPM | 50.00   | 50      | ---     | ---       |
| 14 | Cyclohexyl Ester (CXE)                    | ---      | 333.33  | 333.33  | 333.33  | 119998.8  |
| 15 | Alendronate Sodium                        | ---      | 50      | 50.0    | 50.0    | 18000     |
| 16 | Propafenon HCL                            | ---      | 3.33    | 3.33    | 3.333   | 1199.88   |
| 17 | Fexofenadine HCL                          | ---      | 3.33    | 3.33    | 3.33    | 1198.8    |
| 18 | Menthyl Glyoxylate Hudrate (MGH)          | ---      | 3.33    | 3.33    | ---     | ---       |
| 19 | Emtricitabine                             | ---      | 16.67   | 16.67   | 422.333 | 152039.88 |
| 20 | Lanthanum carbonate                       | ---      | 73.33   | 233.33  | 233.33  | 83998.8   |
| 21 | Mirtazapine                               | ---      | 3.33    | 3.33    | ---     | ---       |
| 22 | Baclofen                                  | ---      | 10.00   | 10.0    | 3.33    | 1198.8    |
| 23 | Ritonavir                                 | ---      | 167.67  | 166.67  | 266.66  | 95997.6   |
| 24 | Atazanavir sulfate                        | ---      | 136.67  | 166.67  | 240.0   | 86400     |
| 25 | Clozapine                                 | ---      | 83.33   | 183.33  | 240.0   | 86400     |
| 26 | Memantine HCL                             | ---      | 40.0    | 40.0    | 50.0    | 18000     |
| 27 | Risedronate Sodium                        | ---      | 50.0    | 50.0    | 3.333   | 1199.88   |
| 28 | Valsartan                                 | ---      | 833.33  | 733.33  | 567.0   | 204120    |
| 29 | Tenofovir                                 | ---      | 800.0   | 1350    | 1360.0  | 489600    |
| 30 | Lopi Rito Premix                          | ---      | 283.33  | 283.33  | 433.0   | 155880    |
| 31 | Quetiapine                                | ---      | 3.33    | 3.33    | 3.333   | 1199.88   |
| 32 | Pentaprazole Sodium                       | ---      | 33.33   | 300.00  | 349.0   | 125640    |

|    |  |                   |               |               |                                |                           |
|----|--|-------------------|---------------|---------------|--------------------------------|---------------------------|
| 33 | Lansoprazole                             | ---               | 3.33          | 33.33         | 3.33                           | 1198.8                    |
| 34 | Valacyclovir                             | ---               |               |               | ---                            | ---                       |
| 35 | Acyclovir                                | ---               | 400.00        | 166.67        | 186.0                          | 66960                     |
| 36 | Defrasirox                               | ---               | 3.33          | 16.67         | 65.0                           | 23400                     |
| 37 | Varapamil                                | ---               | 3.33          | 3.33          | ---                            | ---                       |
| 38 | Lamivudine                               | ---               | 866.67        | 66.67         | 66.67                          | 24001.2                   |
| 39 | Try Cyclic Ketone                        | ---               |               |               | ---                            | ---                       |
| 40 | FCE                                      | ---               | 333.33        | 400.00        | 166.0                          | 59760                     |
| 41 | Sildenafil Citrate                       | ---               | 166.67        | 333.33        | 260.0                          | 93600                     |
| 42 | Ambrisentan                              | ---               | 3.3           | 3.33          | 33.0                           | 11880                     |
| 43 | Atorvastatin Calcium                     | ---               | 306.67        | 400.00        | 400.0                          | 144000                    |
| 44 | Verenicline Tartrate                     | ---               | 1.67          | 1.67          | 1.67                           | 601.2                     |
| 45 | Sofosbuvir                               | ---               | 186.67        | 186.67        | 100.0                          | 36000                     |
| 46 | Cobicistat                               | ---               | 13.33         | 13.33         | 3.33                           | 1198.8                    |
| 47 | Pentaprazole Megnesium                   | ---               | 100.0         | 140.0         | 170.0                          | 61200                     |
| 48 | Ledipasvir                               | ---               | 33.33         | 33.33         | 3.33                           | 1198.8                    |
| 49 | Daclatasvir                              | ---               | 33.33         | 33.33         | 33.33                          | 11998.8                   |
| 50 | Velpatasvir                              | ---               | 33.33         | 33.33         | 33.33                          | 11998.8                   |
| 51 | Reltagravir                              | ---               | 33.33         | 33.33         | 3.333                          | 1199.88                   |
| 52 | Dolutegravir(DO T)                       | ---               | 33.33         | 33.33         | 33.33                          | 11998.8                   |
| 53 | Linagliptin                              | ---               | 3.33          | 3.33          | 3.33                           | 1198.8                    |
| 54 | Validation products                      | ---               | 33.33         | 33.33         | 33.33                          | 11998.8                   |
| 55 | Citalopram Hydrobromide                  | 2.50 TPM          | ---           | ---           | ---                            | ---                       |
| 56 | Naproxen Intermediate (Acetyl Yara Yara) | 50.0 TPM          | ---           | ---           | ---                            | ---                       |
| 57 | Irbesartan                               | ---               | ---           | ---           | 200.0                          | 72000                     |
| 58 | Tenofovir Alafenaminde                   | ---               | ---           | ---           | 33.333                         | 11999.88                  |
| 59 | Sitagliptin HCl                          | ---               | ---           | ---           | 200.0                          | 72000                     |
| 60 | Dolutegravir Sodium (DGS)                | ---               | ---           | ---           | 166.67                         | 60001.2                   |
| 61 | Tofacitinib                              | ---               | ---           | ---           | 3.333                          | 1199.88                   |
| 62 | Bictegravir Sodium                       | ---               | ---           | ---           | 3.33                           | 1198.8                    |
| 63 | Delamanid                                | ---               | ---           | ---           | 76.65                          | 27594                     |
| 64 | Apixaban                                 | ---               | ---           | ---           | 66.06                          | 23781.6                   |
|    |  | <b>250.10 TPM</b> | <b>8305.0</b> | <b>8305.0</b> | <b>8305.0 (or) 249.150 TPM</b> | <b>298980.36 kg/annum</b> |

|               |  |        |        |        |        |
|---------------|--|--------|--------|--------|--------|
| Captive Power |  | 2.5 MW | 2.5 MW | 2.5 MW | 2.5 MW |
|---------------|--|--------|--------|--------|--------|

| By –products |  |   |                            |                              |   |
|--------------|--|---|----------------------------|------------------------------|---|
| S. No.       | Name of the Products                         | Qty as per CFO (CPM) order dt.28.06.2022 Kg/day | Qty after CFE (CPM) Kg/day | Qty after CFE (CPM) Kg/annum | Disposal option   |
| 1.           | Phosphate Salts(a)                           | 201.40  | 201.39                     | 72500.40                     | To be sold to Authorized users/ TSDf through M/s. APEMC |
| 2.           | Phosphorous Oxy Chloride                     | 15.23   | 15.23                      | 5482.80                      |   |
| 3.           | Phosphate Salts(a)                           | 159.75  | 10.64                      | 3830.40                      |   |
| 4.           | Sodium bromide water                         | 14 KLD  | 15.572                     | 5605.20 KL                   |   |
| 5.           | Spent Chloromethyl – 2 – Isopropyl Carbonate | ---   | 292.4                      | 105264.00                    |   |
| 6.           | Tributyl tin chloride                        | ---   | 1299.56                    | 467841.60                    |   |
| 7.           | Pentafluorophenol                            | ---   | 38.10                      | 13716.00                     |   |

| S. No. | As per CFE (CPM) order dt.12.10.2022   | Amendment to CFE (CPM) order dt.12.10.2022  |
|--------|--|---|
| 1.     | In the Water section Condition No.11 it has been given that:<br>The industry shall provide tank in tank system for effluent collection at production blocks. Free board shall be maintained in the tanks to prevent spillages.   | It shall be read as following:<br>“The industry shall maintain HDPE tanks/ impervious tanks/ line tanks in the effluent collection tank(both locations at block and common collection point). Free space shall be maintained HDPE tanks to prevent overflow”.                                     |
| 2.     | In the application, Air: section with stack details, we have proposed the following but not were not received in the granted CFE(CPM):<br>1. 16 TPH boiler in addition to existing boilers.<br>2. We had requested for inclusion of the existing 2x92 kw& 1x114 kw fire pump house diesel engines. | It shall be read as following:<br>The industry is permitted to install Coal fired boiler of capacity 16 TPH with Stack height 40 m and cyclone separator followed by ESP as control equipment.<br>The amendment pertaining to the fire pumps is not considered as it pertains to Fire Department. |
| 3.     | In the Air: Section Condition no:22(iv) it has been given that,<br>“All the solvent storage tanks shall be connected with vent condensers to prevent solvent vapours”.   | It shall be read as following:<br>“All the bulk solvent storage tanks are connected with vent condensers/ nitrogen blanketing to prevent solvent vapors’.   |

23. The industry shall comply with the following for disposal of Solid wastes:

| S. No. | Name of the Hazardous Waste                                       | Stream Number as per HWM Rules | Quantity as per CFE CPM Application TPM | Mode of Disposal Option   |
|--------|---|--------------------------------|---|---|
|        | <b>Hazardous Waste With Disposal Option</b>                       |                                |   |   |
| 1      | Process Organic Residue   | 28.1 of Sch-I                  | 105.17                                  | Shall be routed through M/s APEMC to TSDF, Parawada for incineration / authorized cement industries for co-processing / APPCB authorized pre-processing units.                |
| 2      | Spent Carbon  | 28.3 of Sch-I                  | 17.07                                   |   |
| 3      | Process Inorganic Salts & Distillation Bottom Residue             | 28.1 of Sch-I                  | 27.03                                   |   |
|        |   |                                | 31.31                                   |   |
| 4      | Off Specified & Discarded Raw Materials, Lab Chemicals & Products | 28.4 of Sch-I                  | 2.0                                     |   |
| 5      | Spent Solvents (Coloured)   | 28.6 of Sch-I                  | 300                                     |   |
| 6      | Stripper VOCs   | 35.1 of Sch-I                  | 300                                     |   |
| 7      | Discarded PPE   | 33.1 of Sch-1                  | 1 TPM                                   |   |
| 8      | ETP Sludge  | 35.3 of Sch-I                  | 250.0                                   | Shall be routed through M/s APEMC to APPCB authorized pre-processing units/ TSDF, Parawada for landfill.  |
| 9      | Evaporation Salts   | 35.3 of Sch-I                  | 449.55                                  | Shall be routed through M/s APEMC to TSDF, Parawada for landfill / APPCB authorized pre-processing units.   |
| 10     | Insulation waste (glass recyclers wool)                           | 33.2 of Sch-I                  | 2.0                                     |   |
| 11     | Contaminated cotton rags  | 33.2 of Sch-I                  | 0.5                                     |   |
|        | <b>Hazardous Waste With Recycling Option</b>                      |                                |   |   |
| 1      | Used Oil / Waste Lubricating Oil                                  | 5.1 of Sch-I                   | 3.0                                     | Shall be routed through M/s APEMC to authorized re-processors/ recyclers.   |
| 2      | Mixed Solvents / Recovered Solvents (Colourless)                  | 28.6 of Sch-I                  | 3000                                    | Shall be routed through M/s. APEMC disposed to Authorized re-processors / Recyclers / authorized cement industries for co-processing / APPCB authorized pre-processing units. |
| 3      | Detoxified Containers (Drums / Carboys / Containers)              | 33.1 of Sch.-I                 | 4000 Nos/ month or 48 TPM               | Shall be routed through M/s. APEMC to TSDF for detoxification and disposal / authorized pre-  |

|   |  |                |                 |   |
|---|--|----------------|-----------------|---|
|   |  |                |                 | processing units (or) after complete detoxification to authorized Recyclers   |
| 4 | Detoxified liners  | 33.1 of Sch.-I | 10,000 kg/Month | After complete detoxification, Shall be routed through M/s. APEMC authorized agencies , for reuse / recycle (or) to TSDF for detoxification and disposal / authorized cement industries for co-processing / APPCB authorized pre-processing units |
|   | <b>Non-Hazardous</b>   |                |                 |   |
| 1 | Coal Ash   | --             | 500.0 TPM       | CWMP, Parawada / Brick manufacturers  |
| 2 | Metal Scrap  | --             | 100.0 TPM       | To be sold out to recyclers   |
| 3 | Industrial Garbage   | --             | 30.0 TPM        | Shall be routed through M/s. APEMC to TSDF, Parawada / to authorized cement industries for co-processing / APPCB authorized pre-processing units.   |
| 4 | Non-Hazardous Domestic / Laboratory Solid Waste etc.)              | --             | 1.0 TPM         |   |
| 5 | Discarded Bulbs, Tube Lights etc.                                  | --             | 0.5 TPM         | CWMP, Parawada / authorized e-waste recyclers   |
| 6 | Paper, Cotton Waste, Packing Waste, Play wood wooden boxes, carton | --             | 5.0 TPM         | Sale to recyclers / CWMP, Parawada / cement industries for co-processing / APPCB authorized pre-processing units  |
| 7 | E-Waste  | --             | 2.0 TPM         | To authorized recycler  |
| 8 | Thermocol waste  | ---            | 2.0 TPM         | Shall be disposed TSDF for incineration / cement industries for co-processing / authorized recyclers / APPCB authorized preprocessing units   |

| S. No. | As per CFE (CPM) order dt.12.10.2022  | Amendment to CFE (CPM) order dt.12.10.2022  |
|--------|---|---|
| 4.     | Other condition no.26 has been given as follows:<br>"The industry shall comply with all the conditions stipulated in the EC orders dt.01.11.2006, dt.12.09.2007 for marine disposal and dt.18.12.2020 issued by MoEF & CC, Gol, New Delhi." | It shall be read as following:<br>The industry shall remove marine outfall pipe line as ZLD system is installed. The industry shall comply with other conditions stipulated in the EC orders. |

- All other conditions mentioned in the orders issued vide reference 2nd cited remain the same.

VIJAY KUMAR

GSRKR IAS, MEMBER SECY(GSRKRVK), O/o MEMBER SECRETARY-APPCB

To

M/s. Mylan Laboratories Limited, Unit-8,  
G. Chodavaram (V), Pusapatirega (M)  
Vizianagaram District

**Copy to:** 1. The JCEE, Z.O: Visakhapatnam for information and necessary action.  
2. The E.E., R.O: Vizianagaram for information and necessary action.