**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

## CONSENT ORDER FOR ESTABLISHMENT

**Order No. 297 /APPCB/CFE/RO-VSP/HO/2014** **17/07/2020**

Sub: APPCB – CFE - **M/s. Granules Omni Chem Pvt. Ltd., Plot No. 121 (P) & 122, JNPC, Parawada, Visakhapatnam District –** Consent for Establishment of the Board for **Change of Product Mix** under Sec. 25/26 of Water (P & C of P) Act, 1974 and under Sec. 21 of Air (P&C of P) Act, 1981 - Issued - Reg.

Ref:
1. EC Order dt: 10.03.2005 for the entire JNPC Parawada.
2. CFE Order dt. 30.11.2019.
3. Industry's application received through APOCMMS on 25.06.2020.
4. R.O's inspection report dt. 06.07.2020.
5. CFE Committee meeting held on 07.07.2020.

1. In the reference 3rd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **Change of Product Mix** within the existing premises to produce the products with installed capacities as mentioned below, with additional project cost of Rs.5 Lakhs.

**As per CFE order dt.30.11.2019:**

| S. No | Name of the Products and By-products | Quantity (Kg/Day) |
|---|---|---|
| 1. | Valsartan | 1.67 |
| 2. | Metformin HCL | 333.33 |
| 3. | N-Boc – L – Pyroglutamic Acid ethyl ester (PAC-2) | 33.33 |
| 4. | 8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4- yl)-8-azabicyclo[3.2.1]octane (BTC7) | 50.00 |
| 5. | Formyltosylamide (FTA-1) | 166.67 |
| 6. | 4-methoxy-1-(phenylsulfonyl)-2,3-dihydro-1Hpyrrolo[2,3-c]pyridine (BES 6) | 36.67 |
| 7. | 7-Bromo-4-methoxy-1H-pyrrolo[2,3-c]pyridine. Hydrochloride (BES-10) | 30.00 |
| 8. | 2,3,4,6-Tetra-Opivaloyl-D-glucopyranosyl-bromide (FBJ-2)** | 233.33 |
| | 2,3,4,6 - Tetra -O- pivaloyl-Dglucopyranosylbromide (GLU-2)** | |
| | | |

| | | |
|---|---|---|
| 9. | Tert-butyl (2S, 3R)-3-hydroxy-4-(isobutylamino)-1-phenylbutan-2-yl carbamate (BIN-1) | 166.67 |
| 10. | 2-Piperidinecarboxylic acid, 5- [(phenylmethoxy)amino]-, phenylmethyl ester, (2S,5R)- (ethanedioate)(SAM-0) | 200.00 |
| 11. | Tetrabutylammonium [(2S,5R)-2-Carbamoyl-7-oxo-1,6-diazabicyclo[3.2.1]octan-6-yl] Sulfate(SAM-3) | 200.00 |
| 12. | (2R,5S)-((1R,2S,5R)-2-isopropyl-5-methyl cyclohexyl) 5-(4-amino-2-oxopyrimidin-1(2H)-yl)-1,3-oxathiolane-2-carboxylate (LAM-5) | 33.33 |
| 13. | (R)-2-((4-aminopiperidin-1-yl)methyl)-1,2-dihydro3H,8H-2a,5,8a-triazaacenaphthylene-3,8-dione hemihydrochloride (GPO-3) | 80.00 |
| 14. | Sodium(3,4-dihydro-2H-pyrano[2,3-c] pyridin-6- yl) (hydroxyl) methane sulfonate (GPO-4) | 50.00 |
| 15. | (7-bromo-4-methoxy-1H-pyrrolo[2,3-c] pyridin-3- yl) (oxo)acetic acid (BES-12) | 18.33 |
| 16. | (2S)-2-(hydroxymethyl)-1,2-dihydro-3H,8H-2a,5, 8a-triazaacenaphthylene-3,8-dione (GPA-807A) | 37.27 |
| 17. | Methyl 3,4-Dihydro-2H-Pyrano[2,3-C]Pyridine-6-Carboxylate (GPE) | 15.33 |
| 18. | Quetiapine Lactam (SER-2) | 11.67 |
| | Total | 1300.00* |

* The industry shall manufacture any 6 products including API & Drug Intermediates at any point of time so that the maximum production shall not exceed 1300 Kg/day.
** Either FBJ-2 or GLU-2 will be manufactured at any given point of time.

**After Change of Product Mix:**

| S. No. | Name of the Products | Quantity (TPM) | No of Stages | Starting Raw Material | Quantity of Starting Raw Material (TPM) |
|---|---|---|---|---|---|
| 1. | Valsartan | 16.67 | 1 | (S)-Methyl N-[(2 cyanobiphenyl-4-yl)methyl]-L-Valinate Hydrochloride (vsv) | 27.80 |
| 2. | Metformin HCL | 533.33 | 1 | Dimethylamino Hydrochloride | 307.60 |
| 3. | 8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4- yl)-8-azabicyclo[3.2.1]octane (BTC7) | 33.33 | 2 | 2,5-dimethoxy THF (DMTHF) | 45.00 |

| | | | | | |
|---|---|---|---|---|---|
| 4. | Formyltosylamide ( FTA-1) | 83.33 | 1 | 4-methyl benze ne sulfonamide | 73.30 |
| 5. | 4-methoxy-1-(phen ylsulfonyl)-2,3-dihy dro-1Hpyrrolo[2,3-c ]pyridine (BES 6) | 36.67 | 4 | Formyltosylami de (FTA-1) | 56.70 |
| 6. | 7-Bromo-4-methox y-1H-pyrrolo[2,3-c] pyridine. Hydrochlo ride (BES-10) | 30.00 | 1 | 4-methoxy-1-(p henylsulfonyl)-2 -3-dihydro-1H-p yrrolo[2,3-c]pyri dine (BES-6) | 46.20 |
| 7. | 2,3,4,6-Tetra-Opival oyl-D-glucopyranos yl-bromide (FBJ-2)** or | 166.67 | 1 | D-Glucose | 67.00 |
| | 2,3,4,6 - Tetra -O- pi valoyl-Dglucopyran osylbromide (GLU-2 )** | | | D-Glucose | 69.00 |
| 8. | Tert-butyl (2S, 3R)- 3-hydroxy-4-(isobut ylamino)-1- phenylb utan-2-yl carbamat e (BIN-1) | 166.67 | 1 | S,S-BEP-3 | 185.60 |
| 9. | (2R,5S)-((1R,2S,5R)- 2-isopropyl-5-methy l cyclohexyl) 5- (4-a mino-2-oxopyrimidi n-1(2H)-yl)-1,3-oxat hiolane-2- carboxyl ate (LAM-5) | 66.67 | 1 | Methylglyoxylat e (MGH) | 66.67 |
| 10. | (R)-2-((4-aminopipe ridin-1-yl)methyl)-1, 2-dihydro3H,8H- 2a, 5,8a-triazaacenapht hylene-3,8-dione he mihydrochloride (G PO-3) | 50.00 | 2 | (2S)-2-(hydroxy methyl)-1,2-dihy dro-3H,8H-2a,5, 8a-triazaacenap hthylene-3,8-dio ne (GPA-807A) | 71.5 |
| 11. | Sodium(3,4-dihydro -2H-pyrano[2,3-c] p yridin-6- yl)(hydrox yl) methane sulfona te (GPO-4) | 50.00 | 1 | Methyl 3,4-Dihy dro-2H-Pyrano[2 ,3-C]Pyridine-6- Carboxylate (GP E) | 43.00 |
| 12. | (7-bromo-4-methox y-1H-pyrrolo[2,3-c] pyridin-3- yl)(oxo)ac etic acid (BES-12) | 26.67 | 1 | 7-Bromo-4-methox y-1H-pyrrolo[2,3-c] pyridine. Hydrochlo ride (BES-10) | 27.00 |

| | | | | | |
|---|---|---|---|---|---|
| 13. | (2S)-2-(hydroxymethyl)-1,2-dihydro-3H, 8H-2a,5, 8a-triazaacenaphthylene-3,8-dione (GPA-807A) | 50.00 | 4 | 2-Chloro-6-methoxy-3-nitropyridine | 148.00 |
| 14. | Methyl 3,4-Dihydro-2H-Pyrano[2,3-C]Pyridine-6- Carboxylate (GPE) | 50.00 | 2 | Glycine | 96.00 |
| 15. | Quetiapine Lactam (SER-2) | 133.33 | 2 | 2-Amino-diphenylsulfide | 135.00 |
| | **Total** | **1300 kg/ day** | | | |

The industry shall manufacture any 9 products including API & Drug Intermediates at point of time so that the maximum production shall not exceed 1300 Kg/day.

Either FBJ-2 or GLU-2 will be manufactured at any given point of time.

**By-Products:**

| S. No. | Name of By-products | Quantity (TPD) |
|---|---|---|
| 1. | Palladium Carbon | 3.68 |

2. As per the application, the above activity is to be located within the existing industry premises located at Plot No.121/P & 122, JNPC, Parawada, Visakhapatnam in an area of 12.135 acres.

3. The industry was inspected by the Environmental Engineer, Regional Office, Visakhapatnam, A.P Pollution Control Board on 04.07.2020 and observed that the site is surrounded by

**North** : Plot No : 120 & Part of Plot No:121
**South** : 30 M wide SEZ internal road followed by hills.
**East** : Road followed by APEPDCL substation & Ramky Green belt.
**West** : M/s Eisai Pharma Ltd.

4. The Board, after careful scrutiny of the application, verification report of the Regional Officer and recommendation of the CFE committee hereby issues **CONSENT FOR ESTABLISHMENT FOR CHANGE OF PRODUCT MIX** to the project under Section 25/26 of Water (Prevention & Control of Pollution) Act 1974 and Section 21 of Air (Prevention & Control of Pollution) Act, 1981 and the rules made there under. **This order is issued to manufacture the products as mentioned at para (1) only.**

5. This Consent order now issued is subject to the conditions mentioned in the Annexure.

6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

7. **This order is valid for a period of 7 years.**

**Encl:**
Annexure.

**BATCHU SIVA PRASAD, JCEE(BSP), O/o JOINT CHIEF ENVIRONMENTAL ENGINEER1-APPCB**
**JOINT CHIEF ENVIRONMENTAL ENGINEER**

**To**

**M/s. Granules Omnichem Pvt., Ltd., (CPM)**
**Plot No.121/P & 122, JNPC,**
**Parawada, Visakhapatnam.**
santhoshkumar.k@granulesomnichem.com
tagore.ps@granulesomnichem.com

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

## ANNEXURE

1. The applicant shall provide separate energy meters for Effluent Treatme nt (ETP) and Air pollution Control equipments to record energy consumed lternative electric power source sufficient to operate all pollution control ms shall be provided.

2. The industry shall construct separate storm water drains and provide rair r harvesting structures. No effluents shall be discharged in to the storm v drains.

**Water:**

3. The source of water is JNPC, Parawada and the maximum permitted wate umption after Change of Product Mix is as following:

**After Change of Product Mix**:

| S. No. | Purpose | Quantity as per CFE order dated 30.11.2019 (KLD) | Quantity after CPM (KLD) |
|---|---|---|---|
| 1. | Process | 140.70 | 148.80 |
| 2. | Washings | | |
| 3. | RO rejects | | |
| 4. | Boiler | 100.00 | 100.00 |
| 5. | Cooling Towers | | |
| 6. | Domestic | 40.00 | 40.00 |
| 7. | Gardening | 120.00 | 120.00 |
| | **Total** | **400.70** | **408.80 KLD** |

Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned above.

4. The maximum waste water generation shall not exceed the following:

| S. No. | Source | Quantity as per CFE order dated 30.11.2019 (KLD) | | | Quantity after CPM (KLD) | | |
|---|---|---|---|---|---|---|---|
| | | HTDS | LTDS | TOTAL | HTDS | LTDS | TOTAL |
| 1. | Process | 29.74 | - | 29.74 | 36.24 | - | 36.24 |
| 2. | Washings | - | 10.00 | 10.00 | - | 10.00 | 10.00 |
| 3. | Boiler | - | 2.00 | 2.00 | - | 2.00 | 2.00 |
| 4. | Cooling Towers | - | 5.00 | 5.00 | - | 5.00 | 5.00 |
| 5. | DM Plant regeneration, | - | 15.00 | 15.00 | - | 15.00 | 15.00 |
| 6. | RO plant Rejects.& Back washes | - | 44.80 | 44.80 | - | 44.80 | 44.80 |
| 7. | Scrubber | 5.00 | - | 5.00 | 5.oo | - | 5.00 |
| 8. | Domestic | - | 32.00 | 32.00 | - | 32.00 | 32.00 |
| | **Total** | **34.74** | **108.80** | **143.54** | **41.24** | **108.80** | **150.04** |

**Treatment & disposal:**

| Source | Treatment | Mode of final disposal |
|---|---|---|
| HTDS | Pretreatment (Neutralization) 60 KL – 4 Nos | To M/s. Ramky Pharmacity for forced evaporation. |
| LTDS | Pretreatment (Neutralization) 180 KL - 4 Nos. | To CETP of M/s. Ramky Pharmacity for further treatment and disposal |

| | | |
|---|---|---|
| Domestic waste water | --- | The overflow of the Septic tank shall be sent to the CETP for further treatment. |

5. Effluents shall not be discharged on land or into any water bodies or aqui nder any circumstances.

6. The industry shall properly operate and maintain online real time monito ystem along with web camera facilities and shall ensure that it is connect APPCB / CPCB websites as per CPCB directions.

7. Floor washing shall be admitted into the effluent collection system only a all not be allowed to find their way in storm drains or open areas. All pip es, sewers, drains shall be leak proof.

**Air:**

8. The Air pollution Control equipment shall be maintained properly to comp h the following for controlling air pollution after Change of Product Mix:

| **S. No** | **Details of Stack** | **Stack – I** | **Stack – II** | **Stack –III** |
|---|---|---|---|---|
| a) | Attached to: | Boiler | D.G Set | D.G Set |
| b) | Capacity | 1 x 6 TPH | 1 x 1500 KVA | 1 x 1450 KVA |
| c) | Fuel form : | Coal | Diesel | Diesel |
| d) | Stack height: | 40 m | 8 m above roof level | 8 m above roof level |
| e) | Details of Air Pollution Control Equipment: | Cyclone separator & Bag Filter | Acoustic Enclosures & silencer | Acoustic Enclosures & silencer |

9. A sampling port with removable dummy of not less than 15 cm diameter be provided in the stack at a distance of 8 times the diameter of the sta m the nearest constraint such as bends etc. A platform with suitable lad all be provided below 1 meter of sampling port to accommodate three pe with instruments. A 15 AMP 250 V plug point shall be provided on the pla

10. The industry shall properly operate and maintain the monitoring system t he stacks / vents in the plant. Regular monitoring shall be carried out and rt shall be submitted to the Regional officer.

11. The industry shall properly operate and maintain multi-stage scrubbers t process vents to control the process emissions. The industry shall ensure online pH measuring facility with auto recording system is connected to t rubbers.

    The emissions containing Bromine gases shall be routed through water s er, caustic scrubber provided in series. The vent of the caustic scrubber s e dipped into dilute caustic soda lye for effective removal of Bromine in tl issions. Two stage Caustic scrubbers shall be provided to control acid em s.

12. The industry shall properly operate and maintain VOC monitoring system auto recording facility.

13. The industry shall implement adequate measures to control all fugitive er ns from the plant.

14. The proponent shall ensure compliance of the National Ambient Air quali ndards notified by MoEF, GoI vide notification No. GSR. 826 (E), dated. 16 009 during construction and regular operational phase of the project at th iphery.

    The generator shall be installed in a closed area with a silencer and suital ise absorption systems. The ambient noise level shall not exceed 75 dB(A ing day time and 70 dB(A) during night time.

15. The proponent shall not use or generate odour causing substances or Me ans and cause odour nuisance in the surroundings.

16. The industry shall send the used / spent solvents to the recyclers (or) pro hem at their own solvent recovery facility within the premises.

17. The evaporation losses in solvents shall be controlled by taking the follo measures:

    i. Chilled brine circulation shall be carried out to effectively reduce the ent losses into the atmosphere.
    ii. Transfer of solvents shall be done by using pumps instead of manua dling.
    iii. Closed centrifuges shall be used to reduce solvent losses.
    iv. All the solvent storage tanks shall be connected with vent condense prevent solvent vapours.
    v. The reactor vents shall be connected with primary & secondary cond rs to prevent escaping of solvent vapour emissions into atmosphere

**Solid / Hazardous Waste:**

18. The industry shall comply with the following for disposal of Solid waste:

| S. No. | Name of the waste | Quantity as per CFE Order dt:30.11.2019 | Total after CPM | Mode of Disposal |
|---|---|---|---|---|
| 1. | Organic Solid Waste (kg/day) | 1077.49 | 1350.94 | To authorized cement industries for Co-processing or TSDF parawada Visakhapatnam for Incineration |
| 2. | Inorganic Solid Waste (from Process) (kg/day) | 419.74 | 3033.09 | To TSDF parawada for secured land filling or Authorized cement industries for Co-processing. |
| 3. | Spent Carbon (kg/day) | 8.33 | 83.33 | To TSDF parawada for secured land filling or Authorized cement industries for Co-processing. |
| 4. | ETP Sludge (kg/day) | 100.00 | 100.00 | To TSDF parawada for secured land filling or Authorized cement industries for Co-processing. |
| 5. | Time expired / reject Raw materials (kg/day) | 50.00 | 50.00 | To TSDF parawada for secured land filling or Authorized cement industries for Co-processing. |
| 6. | Off Specification & Discarded Products (kg/day) | 50.00 | 50.00 | |
| 7. | Insulation Waste (kg/day) | 10.00 | 10.00 | To TSDF Parawada for secured land filling / Incineration. |
| 8. | Used PPE | 10.00 | 10.00 | |
| 9. | Used filter Bags & Filters (kg/day) | 20.00 | 20.00 | |
| 10. | Containers & Container liners of Hazardous chemicals | 800 Nos./month | 800 Nos./ month | After detoxification, it shall be disposed to the outside agencies |
| 11. | Waste Oils & Grease | 800 LPA | 800 LPA | Authorized Reprocesses / Recyclers |
| 12. | Spent Solvents | 160 TPM | 220 TPM | Shall be recovered within the premises / disposed to PCB authorized recycling units. |
| 13. | Coal Ash | 2.3 TPD | 2.3 TPD | Brick Manufacturing units |

19. The proponent shall place the chemical drums and / or any drums in a shed provided with concrete platform only. The Platform shall be provided with sufficient dyke wall and effluent collection system. The industry shall provide containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.

20. The following rules and regulations notified by the MoEF&CC, GoI shall be implemented.

    a) Regulation of Persistent Organic Pollutants Rules, 2018.
    b) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
    c) Plastic Waste Management Rules, 2016.
    d) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
    e) Fly Ash Notification, 2016.
    f) Batteries (Management & Handling) Rules, 2010.
    g) E-Waste (Management) Rules, 2016.
    h) Construction and Demolition waste Management Rules, 2016.
    i) Solid Waste Management Rules, 2016.
    j) The Public Liability Insurance Act, 1991 and its amendments thereof.

**Other Conditions:**

21. The industry shall connect VOC absorption media to vent condenser within 2 months.
22. The industry shall install online analyzer for TOC at the vent out let within 3 months
23. The industry shall update the safety audit report and submit the same at the Regional office.
24. The industry shall validate PLI policy and submit the same at the Regional office.
25. Existing green belt shall not be disturbed due to the proposed expansion. Thick green belt shall be maintained all along the boundary & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.
26. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Regional Office and Zonal Office of the Board.

27. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order attracts action under the provisions of relevant pollution control Acts.

28. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec. 27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21(4) of Air (Prevention and Control of Pollution) Act, 1981 to revoke the order, to review any or all the conditions imposed herein and to make such modifications as deemed fit and stipulate any additional conditions.

29. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules,1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution)Act,1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

**BATCHU SIVA PRASAD, JCEE(BSP), O/o JOINT CHIEF ENVIRONMENTAL ENGINEER1-APPCB**
**JOINT CHIEF ENVIRONMENTAL ENGINEER**

**To**

**M/s. Granules Omnichem Pvt., Ltd., (CPM)**
**Plot No.121/P & 122, JNPC,**
**Parawada, Visakhapatnam.**
santhoshkumar.k@granulesomnichem.com
tagore.ps@granulesomnichem.com

Signature Not Verified

Digitally signed by BATCHU SIVA PRASAD
Date: 2020.07.17 15:57:41 IST
Reason: Approved