

F. No. IA-J-11011/382/2019-IA-II(I)

Government of India Ministry of Environment, Forest & Climate Change

Impact Assessment Division

Indira ParyavaranBhawan, Vayu Wing, 3rd Floor, Aliganj, JorBagh Road, New Delhi-110 003

Dated: 9th December, 2020

To

M/s CIPLA Limited, KIADB Industrial Area, Phase-IV, Taluk Anekal, Bangalore Email: Kapini.Gowda@cipla.com

Sub: Proposed Change in Product Mix for Bulk Drugs & Intermediates Manufacturing Unit by M/s CIPLA Limited, located at Plot No 285, 286 & 287, KIADB Industrial Area, Bommasandra-Jigani Link Road, Phase-IV, Taluk Anekal, Bangalore- Amendment in Environmental Clearance regarding.

Sir,

This refers to your online proposal No. IA/KA/IND2/163806/2020 dated 08th August, 2020 for amendment in the environmental clearance to the above mentioned project.

- 2. The Ministry of Environment, Forest and Climate Change has considered the above proposal for amendment in the environmental clearance granted by the Ministry vide letter dated 22/04/2020 in favour of M/s CIPLA Limited, to the Change in Product Mix for Bulk Drugs & Intermediates Manufacturing Unit of capacity 113460 Kg/A by M/s CIPLA Limited located at Plot No 285, 286 & 287, KIADB Industrial Area, Bommasandra-Jigani Link Road, Phase-IV, Taluk Anekal, Bangalore.
- 3. The project proponent has requested for amendment in the EC with the details are as under.

| S.n o | Para of EC Details as per issued by MoEF&CC | | To be revised as/ read as | Justification/ reasons by PP and deliberations by the EAC | |
|----------|---|----------------------------------|-------------------------------|---|--|
| 1. | Page No.2, Product category | Product 'GEMCITABIN E HCL' was | Product 'GEMCITABIN E HCL 800 | PP requested that the instant product was part | |

| 2. Page No. 2 | missed out but total production capacity was same 113.46 MTPA and Formulations Tablets: 1500 L/A & Capsules 1560 L/A | kg/A' may be included in Environmental Clearance | of EIA/EMP and it is missed out due to missing in summary report. After inclusion of the said product, there will be no change in the total Production quantity for existing and proposed as per the EC issued vide F.NoJ-11011/382/2019 -IA-II(I) dated: 22.04.2020. PP mentioned that they had not read the minutes and apologize for the same. The Committee deliberated and is of the view that minutes being uploaded on Parivesh Portal well before issuance of the EC and PP should read the minutes immediately and if any corrections found, can be rectified. The management of Company shall instruct the officials handling the subject accordingly. |
|---------------------|--|--|--|
| Section Specific | A. proponent shall obtain wildlife | proponent shall obtain wildlife | EIA report, Chapter 1, Page No. 5, Table 1-1 |

| , Point | standing | standing | (Salient features |
|-------------------|-----------------------------|--------------------------|-----------------------------------|
| No.1 | committee of NBWL, if | committee of NBWL, if | of the project |
| | applicable as | applicable as | and ito |
| | the project site | the project site | |
| | is located at a | is located at a | Bannerghatta |
| | distance of 2.5 | distance of 5.26 | National Park |
| | km from Dadra | km from | boundary is at a |
| | & Nagar Haveli wild life | Bannerghatta | distance of 5.26 |
| | sanctuary | National Park | Km towards |
| | zanotaar y | | West from the |
| | | | project site (as per Range forest |
| | | | office, |
| | | | Bannerghatta |
| | | | wild life Range, |
| | | | Kalkere, |
| | | | Bengaluru, |
| 1 8 Th | | | Letter No. |
| | | | 415/2018-19 dated: |
| | | | 18.01.2019). |
| | | | The Committee |
| | | | deliberated and |
| | | | is of the view |
| 11 - 11 - 11 | | | that minutes |
| (Cor. 18 (A Land) | | H | being uploaded |
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| | | 5.0 | found, can be rectified. The |
| | | | management of |
| | | | Company shall |
| | | | instruct the |
| | | | officials handling |
| | | | the subject |
| | | | accordingly. |

4. All 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) are listed in S.N. 5(f) of Schedule of Environment

Amendments in EC for M/s CIPLA Limited

Impact Assessment (EIA) Notification under category 'B' to be appraised at State level. However, being the project is located inside the critically polluted area, the project appraised at Central level in the Ministry.

- The proposal was appraised by the Expert Appraisal Committee 5. (Industry-2) in the Ministry in its meeting held on 15 -17 September, 2020. The EAC, after detailed deliberations, recommended the amendment in EC as proposed by the project proponent. Based on recommendations of the EAC, the Ministry of Environment, Forest and Climate Change hereby accords approval to the proposed amendments in the environmental clearance dated 22.04.2020 as stated in para3 above, for the project Change in Product Mix for Bulk Drugs & Intermediates Manufacturing Unit by M/s CIPLA Limited, located at Plot No 285, 286 & 287, KIADB Industrial Area, Bommasandra-Jigani Link Road, Phase-IV, Taluk Anekal, Bangalore.
- All other terms and conditions stipulated in the environmental clearance dated 22.04.2020 shall remain unchanged.
- This issues with approval of the competent authority. 7.

(Dr. R. B. Lal)

Scientist 'E'/Additional Director Tele-fax: 24695362

Email-rb.lal@nic.in

(डा. आर. बी. लाल) (Dr. R. B. LAL) वैज्ञानिक 'ई'/Scientist 'E' पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय Min. of Environment,Forest and Climate Chang-भारत संस्कार, नई दिल्ली Govt, of India

Copy to: -

- 1. Principal Secretary to Government (Forest), Forest, Environment and Ecology Department, Karnataka Government Secretariat, Room No. 442, Gate No. 2, M. S. Building, Bangalore-560001
- 2. Addl. Principal Chief Conservator of Forest (C), Ministry of Env. Forest and Climate Change, Regional Office (SZ), KendriyaSadan, 4th Floor, E&FWings, 17th Main Road, Koramangala II Block, Bangalore - 560034
- 3. The Chairman, Central Pollution Control Board PariveshBhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi -32
- The Member Secretary, Karnataka State Pollution Control Board "ParisaraBhavan", #49, 4th & 5th Floor, Church Street, Bangalore-560001
- 5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira ParyavaranBhawan, JorBagh road, New Delhi
- 6. District Magistrate, Bangalore, Karnataka
- 7. Guard File/Monitoring File/Parivesh portal/Record File

(Dr. R. B. Lal) Scientist 'E'/Additional Director



F. No.-J-11011/382/2019-IA-II(I)]

Government of India Ministry of Environment, Forest & Climate Change Impact Assessment Division

Indira Paryavaran Bhavan, Vayu Wing, 3rd Floor, Aliganj, Jor Bagh Road, New Delhi-110 003

Dated: 22nd April, 2020

To,

M/s Cipla Limited, Plot No.285, 286 & 287, KIABD Industrial Area, Bommasandra-Jigani Link Road, Taluk Anekal,

District **Bengaluru** (Karnataka)

Sub: Change in product mix for bulk drugs and intermediates manufacturing unit by M/s Cipla Limited at Plot No.285, 286 & 287, KIABD Industrial Area, Taluk Anekal, District Bengaluru (Karnataka) - Environmental Clearance-reg.

Sir,

This has reference to your online proposal No.IA/KA/IND2/106235/2016 dated 9th November, 2019 for environmental clearance to the above project.

- 2. The Ministry of Environment, Forest and Climate Change has examined the proposal for environmental clearance to the project for change in product mix for bulk drugs and intermediates manufacturing unit by M/s Cipla Limited in an area of 115335.23 sqm at Plot No.285, 286 & 287, KIABD Industrial Area, Taluk Anekal, District Bengaluru (Karnataka).
- 3. The details of existing and proposed are as under:

| S. No | Category | Products | Existing Quantity (Kg/A) | I Proposed | Category Wise Qty | Variation in quantity |
|-------|--------------------------|------------------------|--------------------------------|------------|----------------------|-----------------------|
| | | AMLODIPINE BESYLATE | 1000 | 1000 | | 0 |
| 1 1 | CARDIOVASCU LAR DRUGS | AMLODIPINE MESYLATE | 2000 | 1000 | 2600 | -1000 |
| | | CIOLASTRAZOLE | 1000 | 100 | | -900 |
| | | FELODIPINE | 1000 | 500 | | -500 |
| | | ANAGRELIDE | 25 | 25 | | 0 |
| | | BICALUTAMIDE | 1000 | 2500 | | 1500 |
| | ANTICANCER DRUGS | CARBOPLATIN | 50 | 50 | 174430 1 | 0 |
| 1 / 1 | | CISPLATIN | 50 | 50 | | 0 |
| | | ETOPOSIDE | 250 | 500 | | 250 |
| | | FLUTAMIDE | 2500 | 2000 | | -500 |
| | | MITIXANTRONE HCL | 20 | 10 | | -10 |

₽Ć for M/s Cipla Limited

| OXALIPLATIN 100 100 | _ | 1 | ANASTRAZOLE | 100 | 100 | | 0 |
|--|----|-------|---------------------------------------|-------------|--------|----------|-------|
| CAPACITABINE 20000 38000 18000 18000 18000 18000 18000 18000 2500 10000 2500 | | | | | | - | |
| IMATINIB MESYLATE (Alpha 7500 10000 2500 300 | | | ···· | | | - | |
| MESYLATE (Alpha 7500 10000 2500 and Beta Forms) | | | ···· | 20000 | 20000 | | 10000 |
| And Beta Forms VINORELBINE 100 50 50 50 | | | | 7500 | 10000 | | 2500 |
| VINORELBINE 100 50 50 50 | | | | 7.500 | 1.0000 | | 2500 |
| TARTRATE 100 50 -50 -50 0 0 0 0 0 0 0 0 0 0 0 0 0 | | | | | | - | |
| RELOTINIB HCL 1000 1500 | | | | 100 | 50 | | -50 |
| CAPTINIB 1000 150 | | | TEMOZOLOMIDE | 500 | 500 | 7 | 0 |
| CAPTINIB 1000 150 | | | ERLOTINIB HCL | 1000 | 1500 | 1 | 500 |
| SORAFENIB 1500 1500 0 | | | GEFTINIB | 1000 | 1500 | 1 | |
| DOCETAXEL 100 | | | SORAFENIB | 1500 | 1500 | 1 | |
| TRIHYDRATE 100 | | | TOSYLATE | 1500 | 1500 | | 0 |
| IRINOTECAN 100 | | | DOCETAXEL | 100 | 100 | 1 | |
| TRIHYDRATE 100 | | | TRIHYDRATE | 100 | 100 | _ | 0 |
| PACLITAXEL 100 100 | | | | 100 | 100 | | |
| LAPATINIB DITOSYLATE LENALIDOMIDE 1000 500 500 0 0 0 0 0 0 | | | TRIMYDRATE | | | | 0 |
| DITOSYLATE 1000 500 -500 -500 | | | | 100 | 100 | _ | 0 |
| TOPOTECAN HCL 10 10 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | | | | 1000 | 500 | | -500 |
| PEMETREXED DISODIUM DISODIU | | | LENALIDOMIDE | 1000 | 1000 | 1 | 0 |
| DISODIUM 150 200 50 50 | | | TOPOTECAN HCL | <u>1</u> 0 | 10 | 7 | 0 |
| ANTICANCER DRUGS DISODIOM D | | | | 150 | 200 | | 50 |
| LETROZOLE 500 | | | DISODIUM | | | | 50 |
| SUNITINIB MALATE VINCRISTINE SULPHATE VINBLASTINE SULPHATE VINBLASTINE SULPHATE TEGAFUR PAZOPANIB HCL ABIRATERONE ACETATE CARFILZOMIB PHOSPHATE EVEROLIMUS EXEMBSTINE EVEROLIMUS EXEMBSTINE EVEROLIMUS ESTRAMUSTINE NILOTINIB PAGORAFENIB DASATINIB REGORAFENIB IO0 ESTRAMUSTINE NILOTINIB NINTEDANIB ESYLATE SOO SOO SOO SOO SOO SOO SOO S | | | | | | | 0 |
| MALATE 255 255 0 50 50 50 50 5 | | | | 500 | 500 | | 0 |
| VINCRISTINE SULPHATE VINBLASTINE SULPHATE VINBLASTINE SULPHATE TEGAFUR PAZOPANIB HCL ACETATE CARFILZOMIB PHOSPHATE EVEROLIMUS EXEMESTINE EVEROLIMUS DASATINIB DION REGORAFENIB DOO DINITEDANIB ESYLATE 500 500 500 500 500 500 500 500 500 5 | ļ | | | 255 | 255 | | 0 |
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| SULPHATE 50 50 1000 1000 2500 | | | | ····· | | | |
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| PAZOPANIB HCL 2500 ABIRATERONE 1000 ABIRATERONE 20 RUXOLITINIB 100 EVEROLIMUS 50 EXEMESTINE 500 ESTRAMUSTINE 500 NILOTINIB 4000 DASATINIB 500 REGORAFENIB 200 REGORAFENIB 200 REGORAFENIB 500 NINTEDANIB 500 NINTEDANIB 500 NINTEDANIB 500 NINTEDANIB 500 S00 S00 S00 S00 S00 S00 S00 S00 S00 | | | * | · · · . | 1000 | | 1000 |
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| DRUGS | 2 | | | | 1000 | 74430 | 1000 |
| RUXOLITINIB PHOSPHATE EVEROLIMUS EXEMESTINE 500 ESTRAMUSTINE 500 NILOTINIB DASATINIB REGORAFENIB 100 100 100 100 100 100 100 1 | _ | DRUGS | CARFILZOMIB | | 20 | 174450 | 20 |
| EVEROLIMUS 50 50 EXEMESTINE 500 500 ESTRAMUSTINE 500 500 NILOTINIB 4000 4000 DASATINIB 500 500 REGORAFENIB 200 200 IBRUTINIB 500 500 NINTEDANIB 500 500 | | | RUXOLITINIB | | | 1 | |
| EXEMESTINE 500 500 ESTRAMUSTINE 500 500 NILOTINIB 4000 4000 DASATINIB 500 500 REGORAFENIB 200 200 IBRUTINIB 500 500 NINTEDANIB 500 500 | | | PHOSPHATE | | 100 | | 100 |
| ESTRAMUSTINE 500 500 NILOTINIB 4000 4000 DASATINIB 500 500 REGORAFENIB 200 200 IBRUTINIB 500 500 NINTEDANIB 500 500 | | | EVEROLIMUS | | 50 | | 50 |
| NILOTINIB 4000 4000 DASATINIB 500 500 REGORAFENIB 200 200 IBRUTINIB 500 500 NINTEDANIB 500 500 ESYLATE 500 500 | | | EXEMESTINE | | 500 | | 500 |
| DASATINIB 500 500 REGORAFENIB 200 200 IBRUTINIB 500 500 NINTEDANIB 500 500 ESYLATE 500 500 | | | ESTRAMUSTINE | | 500 | ⊣ | 500 |
| DASATINIB 500 500 REGORAFENIB 200 200 IBRUTINIB 500 500 NINTEDANIB 500 500 ESYLATE 500 500 | | | NILOTINIB | | 4000 | | 4000 |
| IBRUTINIB 500 500 NINTEDANIB 500 500 | | | DASATINIB | | 500 | 1 | 500 |
| NINTEDANIB ESYLATE 500 | | | REGORAFENIB | | 200 | | 200 |
| ESYLATE 500 500 | | | IBRUTINIB | | 500 | | 500 |
| | | | 1 | | 500 | | 500 |
| | // | | POMALIDOMIDE | | 500 | 1 | 500 |

| | } | AXITINIB | | 500 | | 500 |
|-----|-------------------------------------|------------------------|------|------|-------|-------|
| | | DULOXETINE | 1500 | 500 | | -1000 |
| 3 | | OXCARBAZEPINE | 200 | 50 | | -150 |
| | | RILUZOLE | 1000 | 580 | 7 | -420 |
| | CNC DDUC | RISPERIDONE | 1000 | 500 | 7,20 | -500 |
| | CNS DRUG | TOPIRAMATE | 2500 | 2500 | 7130 | 0 |
| | | LAMOTRIGINE POWDER | 5000 | 2500 | | -2500 |
| | | VENLAFAXINE | 1000 | 500 | 7 | -500 |
| | | ESOMEPRAZOLE | 2000 | 2000 | | 0 |
| | | LANSOPRAZOLE | 4500 | 1000 | | -3500 |
| | | OMEPRAZOLE | 8000 | 2000 | 7 | -6000 |
| İ | | PANTOPRAZOLE | 1000 | 500 | | -500 |
| 4 | GASTROINTES TINAL DRUGS | RABEPRAZOLE SODIUM | 1500 | 500 | 7000 | -1000 |
| | | RABEPRAZOLE POWDER | 2000 | 500 | | -1500 |
| | | ESOMEPRAZOLE POWDER | 2500 | 500 | | -2000 |
| 5 | OSTEOPOROSI S | RALOXIFENE | 5000 | 1500 | 1500 | -3500 |
| | | LEVOFLOXACIN | 8300 | 3000 | | -5300 |
| | ANTIBIOTICS / ANTIBACTERIA LS | OFLOXACIN USP | 1000 | 500 | | -500 |
| 6 | | | 190 | 190 | 4700 | 0 |
| | | GATIFLOXACIN POWDER | 10 | 10 | 7,00 | 0 |
| | | ENROFLOXACIN POWDER | 1500 | 1000 | | -500 |
| 7 | OTHERS - ANTOGONADO TROPHIN | DANAZOL | 500 | 500 | 500 | 0 |
| 8 | ARTHRITIC / RHEUMATIC AGENTS | LEFLUNOMIDE | 500 | 1000 | 1000 | 500 |
| | | RIBAVIRIN | 1500 | 1000 | | -500 |
| • | | STAVUDINE | 100 | 100 | | 0 |
| 9 | ANTIVIRALS | ZIDOVUDINE | 1500 | 1000 | 3100 | -500 |
| 3 | MINITATION | VALACICLOVIR HCL | 500 | 500 | 3100 | 0 |
| | | DIDANOSINE | 500 | 500 | | 0 |
| 10 | OPTHALMIC DRUGS | REPROTEROLE | 5000 | 1000 | 1000 | -4000 |
| | (| FEBANTEL POWDER | 2000 | 2000 | | 0 |
| 711 | HELMINTICS | MEBENDAZOLE POWDER | 2000 | 2000 | 10000 | 0 |
| | | ALBENDAZOLE POWDER | 4500 | 4500 | | 0 |

| | | FENBENDAZOLE POWDER | 1500 | 1500 | | 0 | |
|----|--------------|------------------------|---------------------|--------|--------|-----|--|
| 12 | R&D products | | | 500 | 500 | 500 | |
| | | | 114220 | 113460 | 113460 | | |
| 13 | FORMULATIONS | | TABLETS: 1500 L / A | | | | |
| | | | CAPSULES :1560 L/ A | | | | |

- 4. The total land area is 115335.23 sq.mts (28.49 acres). There is no additional land requirement for proposed change in product mix. Industry has already developed greenbelt in an area of 33 % i.e.38035.8 m² (9.39 Acres) out of total area of the project. There is no additional project cost as it is in existing unit. The cross value of the existing infrastructure is Rs.166 crore. Total capital cost earmarked towards environmental pollution control measures is Rs.67.5 Lakhs and the recurring cost (operation and maintenance) will be about Rs.6.75 Lakhs per annum. Total employment will be 300 persons as direct & indirect after expansion. As the project site is located inside the CPA, the EAC suggested to increase the greenbelt area. The project proponent was agreed for 40% green belt of the total area of the project.
- 5. Bannerghatta National Park boundary is at 5.26 km in West from the project site.
- 6. The water requirement is 300 cum/day of which fresh water requirement of 140 cum/day proposed to be met from ground water through bore well within the premises. Effluent of 160 cum/day will be treated through combined Effluent Treatment Plant. The plant will be based on Zero Liquid discharge system.

Power requirement will be 1500 kVA including and will be met from BESCOM. The unit has 3 No of 1250 kVA DG set will be used as the standby during power failure. Stacks will be (height 20 m AGL) provided as per CPCB norms. The unit has 1 x 2000000 k cal TFH (fire wood heater). Stacks will be (height 20 m AGL) provided as per CPCB norms. Existing the unit has 1 x 2000000 k cal TFH (fire wood heater). Stacks will be (height 20 m AGL) provided as per CPCB norms.

- 7. The project/activity is covered under category B of item 5(f) 'Synthetic Organic Chemicals' of schedule to the Environment Impact Assessment (EIA) Notification, 2006, and requires appraisal at Sate level. However being the project is located inside the critically polluted area, the project appraised at Central level in the Ministry.
- 8. The ToR for the project was granted by the SEIAA, Karnataka on 24th September, 2016. Public hearing is exempted as per para 7(i), III. Stage (3), (i)(b) of the EIA Notification, 2006, and in accordance with the Ministry's OM dated 27th April 2018, as the project site is located in the notified industrial area.
- 9. The proposal for environmental clearance was considered by the EAC (Industry-2) in its meetings held on 30-31 December, 2019 and $1^{\rm st}$ January, 2020. The project proponent and their consultant M/s Hubert Enviro Care Systems (P) Ltd have presented the EIA/EMP report. The Committee found the EIA/EMP report to be satisfactory, complying with the ToR, and recommended the project for grant of environmental clearance.
- 10. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), Ministry of Environment, Forest and Climate Change hereby accords environmental clearance to the project for change in product mix for bulk drugs and intermediates manufacturing unit by M/s Cipla Limited at Plot No.285, 286 & 287, KIABD

EØ for M/s Cipla Limited

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Industrial Area, Taluk Anekal, District Bengaluru (Karnataka), under the provisions of the EIA Notification, 2006, and the amendments therein, subject to compliance of the terms and conditions as under:-

A. Specific Condition:

- (i) The project proponent shall obtain wildlife clearance from standing Committee of NBWL, if applicable as the project site is located at a distance of 2.5 km from Dadra & Nagar Haveli Wild life Sanctuary.
- (ii) Necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, shall be obtained from the State Pollution Control Board.
- (iii) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
- (iv) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.
- (v) National Emission Standards for Pharmaceuticals Industry (Bulk Drugs) issued by the Ministry vide G.S.R.149(E) dated 4th March, 2009 and amended from time to time shall be followed. Fugitive emissions shall be controlled at 99.98% with effective chillers.
- (Vi) No raw material/solvent prohibited by the concerned regulatory authorities from time to time, shall be used.
- (vii) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
- (viii) Solvent management shall be carried out as follows:
 - (a) Reactor shall be connected to chilled brine condenser system.
 - (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - (c) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - (d) Solvents shall be stored in a separate space specified with all safety measures.
 - (e) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - (f) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - (g) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.

EE for M/s Cipla Limited

- (ix) Total fresh water requirement shall not exceed 140 cum/day, proposed to be met from ground water. Prior permission in this regard shall be obtained from the concerned regulatory authority/ CGWA.
- (x) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- (Xi) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (Xii) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- (Xiii) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
- (xiv) Fly ash should be stored separately as per CPCB guidelines so that it may not adversely affect the air quality. Direct exposure of workers to fly ash and dust should be avoided.
- (XV) The company shall undertake waste minimization measures as below:-
 - (a) Metering and control of quantities of active ingredients to minimize waste.
 - (b) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - (c) Use of automated filling to minimize spillage.
 - (d) Use of Close Feed system into batch reactors.
 - (e) Venting equipment through vapour recovery system.
 - (f) Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- (xvi) The green belt of at least 5-10 m width shall be developed in nearly 40% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (xvii) At least 3 % of the total project cost shall be allocated for Corporate Environment Responsibility (CER) and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (xviii) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.

CEC for M/s Cipla Limited

- (xix) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire-fighting system shall be as per the norms.
- (xx) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (xxi) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.
- (xxii) Process safety and risk assessment studies shall be further carried out using advanced models, and the mitigating measures shall be undertaken accordingly.

B. General Conditions

- (i) The Project Proponent shall obtain all other statutory/necessary permissions/recommendations/NOCs prior to start of construction/operation of the project, which inter alia include, permission/approvals under the Forest (Conservation) Act, 1980; the Wildlife (Protection) Act, 1972; the Coastal Regulation Zone Notification, 2019, as amended from time to time, and other Office Memoranda/Circular issued by the Ministry of Environment, Forest and Climate Change from time to time, as applicable to the project.
- (ii) The project proponent shall ensure compliance of 'National Emission Standards', as applicable to the project, issued by the Ministry from time to time. The project proponent shall also abide by the rules/regulations issued by the CPCB/SPCB for control/abatement of pollution.
- (iii) The project authorities shall adhere to the stipulations made by the State Pollution Control Board/Committee, Central Pollution Control Board, State Government and any other statutory authority.
- (iv) The project proponent shall prepare a site specific conservation plan and wildlife management plan in case of the presence of Schedule-1 species in the study area, as applicable to the project, and submit to Chief Wildlife Warden for approval. The recommendations shall be implemented in consultation with the State Forest/Wildlife Department in a time bound manner.
- (v) No further expansion or modifications in the plant, other than mentioned in the EIA Notification, 2006 and its amendments, shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

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- (vi) The energy source for lighting purpose shall be preferably LED based, or advance having preference in energy conservation and environment betterment.
- (vii) The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one station each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (viii) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be followed.
- (ix) The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- (x) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and to utilize the same for process requirements.
- (xi) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- (xii) The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, and risk mitigation measures relating to the project shall be implemented.
- (xiii) The company shall undertake all relevant measures for improving the socioeconomic conditions of the surrounding area. CER activities shall be undertaken by involving local villages and administration and shall be implemented.
- (xiv) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- (xv) A separate Environmental Management Cell (having qualified person with Environmental Science/Environmental Engineering/specialization in the project area) equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- (xvi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation

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schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.

(xvii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad/Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.

(xviii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

- (xix) The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF&CC by e-mail.
- (xx) The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry and at https://parivesh.nic.in/. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.
- (xxi) The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
- (xxii) This Environmental clearance is granted subject to final outcome of Hon'ble Supreme Court of India, Hon'ble High Court, Hon'ble NGT and any other Court of Law, if any, as may be applicable to this project.
- 11. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.
- 12. Concealing factual data or submission of false/fabricated data and failure to comply with of the conditions mentioned above may any the withdrawal of this clearance and attract action under provisions of Environment (Protection) Act, 1986.

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- 13. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
- 14. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 read with subsequent amendments therein.
- 15. This issues with the approval of the competent authority.

(डा. आर. बी. लाल)
(Dr. R. B. LAL)
वैज्ञानिक ई /Scientist E
पर्यावरण, वन एवं **Scientist** में कि / Additional Director
Min.of Environment, Forest and Climate Charg
भारत सरकार, नई दिल्ली
Govt. of India, New Della

Copy to: -

 The Deputy DGF (C), MoEF&CC Regional Office (SZ), KendriyaSadan, 4th Floor, E&F Wings, 17th Main Road, Koramangala II Block, **Bangalore** - 34

2. The Secretary, Department of Forest, Environment & Ecology, Government of Karnataka, Room No. 708, Gate 2, Multi Storey Building, Dr. AmbedkarVeedhi, **Bangalore** - 1

3. The Member Secretary, Central Pollution Control Board, PariveshBhawan, CBD-cum-Office Complex East Arjun Nagar, **Delhi** - 32

4. The Member Secretary, Karnataka State Pollution Control Board, ParisaraBhavan, #49, 4th& 5th Floor, Church Street, **Bangalore** -1

5. The District Collector, District **Bengaluru** (Karnataka)

6. Guard File/Monitoring File/Website/Record File

(Dr. R. B. Lal)
Scientist 'E'/Additional Director