

Biocon Limited

20th KM Hosur Road

Electronics City

Bangalore 560 100, India

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CIN : L24234KA1978PLC003417

www.biocon.com

Ref: BC/EHS/COM/23/12/10

Date: 29/12/2023

To

The Director
Regional Office (Southern Zone),
Ministry of Environment and Forests,
Kendriya Sadan, IV the Floor,
E&F Wings, 17th Main Road,
2nd Block, Koramangala,
Bengaluru-560034,

Respected Sir/Madam,

**Sub: Half yearly compliance report for Environmental Clearance
From April-2023 to September-2023 & request to provide
certified compliance report**

Ref: 1. File No: SEIAA 70 IND 2020 dt: 19.06.2021 issued by State
Level Environment Impact Assessment Authority- Karnataka

2. File No: SEIAA 63 IND 2021 dt: 23.08.2022 issued by State
Level Environment Impact Assessment Authority- Karnataka

With reference to the above-mentioned subject, M/s. Biocon Limited, 20th KM, Hosur Road, Electronic City, Bengaluru, Karnataka- 560100, here with submitting Half Yearly Compliance report from April-2023 to September-2023 requirement of Environmental clearance issued on dated on 19th June-2021 & 23rd August-2022.

Thanking You,

Yours Sincerely,
For Biocon Limited


30/12/2023
Authorized Signatory

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CC: KSPCB-Regional Office, Sarjapura

**SIX MONTHLY ENVIRONMENTAL CLEARANCE COMPLIANCE REPORT
(December-2023)**

For

BIOPHARMACEUTICAL MANUFACTURING UNIT

AT



M/s. BIOCON LIMITED

**20th KM, Hosur Road, Electronic City, Bengaluru,
Karnataka 560100.**

**[Environmental Clearance issued by SEIAA, Karnataka
No SEIAA 70 IND 2020 dated 19-06-2021 & SEIAA 63 IND 2021 dated
23-08-2022]**

Submitted By

**M/s. Biocon Limited,
20th KM, Hosur Road,
Electronic City, Bengaluru,
Karnataka 560100**

| COMPLIANCE STATUS FOR ENVIRONMENTAL CLEARANCE <i>for</i> Biopharmaceutical Manufacturing Unit <i>of</i> M/s. Biocon Limited., 20th KM, Hosur Road, Electronic City, Bengaluru 560100, for Environmental Clearance issued by SEIAA, Karnataka, No SEIAA 70 IND 2020 dated 19-06-2021 & SEIAA 63 IND 2021 dated 23-08-2022. EC Copies are attached as Annexure-I | | |
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| I. Statutory Compliance | | |
| Sl. No. | Condition | Compliance Status |
| 1 | The project proponent shall obtain forest clearance under the provisions of Forest (Conservation) Act, 1986, in case of the diversion of forest land for non-forest purpose involved in the project. | Not applicable, there is no forest diversion is in vicinity of the site, the land is a converted to industrial utilizations from the relevant government agencies. |
| 2 | The project proponent shall obtain clearance from the National Board for Wildlife, if applicable. | The site is an industrial converted land hence this is not applicable. |
| 3 | The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and be approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan /Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (In case of the presence of schedule-1 species in the study area) | Not applicable, there is no forest diversion is in vicinity of the site, as such no clearance is required. |
| 4 | The project proponent shall obtain Consent to Establish / Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State Pollution Control Board/ Committee. | Applied for the CTEp under Water and Air Acts on 09.03.2023 to KSPCB authority for obtaining CTEp order and please find the attached acknowledgement copy as Annexure-II. |
| 5 | The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time | Noted and same will be applied to KSPCB regulatory authority after receiving CTEp and CTO orders. |
| 6 | The Company shall strictly comply with the rules and guidelines under the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended from time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989 | Not applicable, since the storage of hazardous chemicals does not exceed the prescribed limit mentioned in the MSIHC (Manufacture, Storage and Import of Hazardous Chemicals) guidelines under Rule 10. |
| II. Air quality monitoring and preservation | | |
| 1 | The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB and CPCB | CNG (Compressed Natural Gas) is used for boiler & high-speed diesel is used for DG-Sets as fuel. So according to KSPCB Memo no; KSPCB/DGS/OFB/MON/CC/2001/5269 dt 24.02.2001 |

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| | online servers and calibrate this system from time to time according to equipment supplier specification through labs recognized under Environment (Protection) Act, 1986 or NABL accredited laboratories | Online Continuous Stack Emission Monitoring Systems is not applicable. However, the air polluting sources stacks are monitoring monthly and quarterly respectively. |
| 2 | The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognized under Environment (Protection) Act, 1986. | The monitoring of ambient VOC is conducted monthly & find the attached analysis report as Annexure-III. |
| 3 | The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10 and PM2.5 in reference to PM emission, and SO2 and NOx in reference to SO2 and NOx emissions) within and outside the plant area at least at four locations (one within and three outside the plant area at an angle of 120 each), covering upwind and downwind directions. | Noted & the trend analysis of Ambient Air Quality monitoring parameters is attached as Annexure – IV. |
| 4 | To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines. | Noted, the DG set shall be of the enclosed type and conform to rules made under the Environment (Protection) Act, 1986. We will use only low Sulphur diesel to DG set & will maintain the stack height as needed for the combined capacity of all proposed DG sets. |
| 5 | Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions. | Storage of raw materials will be as per PESO rules and regulations. The materials will be stored in restricted areas. |
| 6 | National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July 2010 and amended from time to time shall be followed. | The emission parameters meet the National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July 2010 and same will be followed. |
| 7 | The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November 2009 shall be complied with. | Noted & the trend analysis of Ambient Air Quality monitoring parameters is attached as Annexure – IV. |
| III. Water quality monitoring and preservation | | |
| 1 | The project proponent shall provide 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 (applicable in case of the projects achieving ZLD) | As per the regulatory norms our facility has provided the web camera with night vision capability and flow meters for continuous monitoring of effluent and same is maintained. |

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| 2 | As already committed by the project proponent, Zero Liquid Discharge shall be ensured, and no waste/treated water shall be discharged outside the premises (applicable in case of the projects achieving the ZLD). | Our facility is already provided with ZLD system and there is no discharge of waste/treated water outside the premises. |
| 3 | The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the State Pollution Control Board while granting Consent under the Air/Water Act, whichever is more stringent. | No effluent will be discharged as the industry is ZLD based. The effluent will be treated and reused within the industry. Hence, there is no applicability of prescribed standards. |
| 4 | Total freshwater requirement shall not exceed the proposed quantity or as specified by the Committee. Prior permission shall be obtained from the concerned regulatory authority/CGWA in this regard. | Noted, the freshwater consumption will not exceed the proposed quantity and prior permission will be obtained from concerned regulatory authority/CGWA if any changes in the water requirement quantity. |
| 5 | 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. | The industry has provided separate conveyance system for both storm water managements. No Process effluent/any wastewater will be allowed to mix with storm water. |
| 6 | The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant. | The facility provided a rainwater collection tank for runoff water and utilized within the premises for gardening purposes. |
| 7 | The DG sets shall be equipped with suitable pollution control devices and the adequate stack height so that the emissions are in conformity with the extant regulations and the guidelines in this regard. | The DG sets will be provided with acoustic enclosures and adequate stack height as per CPCB norms. |
| IV. Noise monitoring and prevention | | |
| 1 | Acoustic enclosure shall be provided to DG set for controlling the noise pollution. | Noted and provide acoustic enclosure to all DG sets for controlling noise pollution. |
| 2 | 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. | Noted and noise levels shall be kept within the prescribed limits at all sources of noise generation by providing control measures. |
| 3 | The ambient noise levels should conform to the standards prescribed under E (P) A Rules, 1986 viz. 75 dB (A) during daytime and 70 dB (A) during nighttime. | Noted and adhered. The trend analysis for the noise monitoring is attached as Annexure – V. |
| V. Energy Conservation measures | | |
| 1 | The energy sources for lighting purposes shall preferably be LED based. | LED based energy sources are provided for lighting purposes and the same will be implemented for expansion projects. |

| VI. | Waste Management | |
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| 1 | Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps. | Noted, all hazardous chemicals will be stored in a designated area with limited personnel access and hazardous chemicals stored in tanks, tank farms, drums, carboys etc. will be provided with flame arresters on tank farm to the solvent transfer through pumps. |
| 2 | 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. | Currently the process residue and spent carbon wastes are disposing at in-house incinerator facility as per the existing H&OW authorization and same shall be disposed to cement plants once all necessary approvals & consents are received. ETP sludge sent to co-processing at cement industries and evaporation salts are disposed to the TSDF. |
| 3 | <p>The company shall undertake waste minimization measures as below:</p> <ol style="list-style-type: none"> Metering and control of quantities of active ingredients to minimize waste. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes. Use of automated filling to minimize spillage. Use of Close Feed system in batch reactors. | <ol style="list-style-type: none"> We are monitoring raw material input and output (yield) batch by batch & continuously working on improving yield to minimize the waste generation. The industry has an active R&D section and is actively trying to reuse by-products/wastes. Solvent batching system is installed for all manufacturing blocks, to pump the required solvent to the required equipment in closed loop. Chemicals which are corrosive in nature are charged to reactors in closed loop using Liquid Charging Station. <ul style="list-style-type: none"> <input type="checkbox"/> Solid Material is charged to reactor in presence of solvent using closed loop Powder Transfer System. <input type="checkbox"/> Reaction mass is transferred to other reactor for further processing is done through closed loop system by providing dedicated pump and transfer lines. <input type="checkbox"/> Layer separation is done in closed loop by providing layer separation tank with adequate capacity. |

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| | <p>e. Venting equipment through vapor recovery system.</p> <p>f. Use of high-pressure hoses for equipment clearing to reduce wastewater generation</p> | <p>e. The reactors are provided with primary and secondary condensers designed as per the maximum vapor load.</p> <p><input type="checkbox"/> All the vent condensers are provided with Chilled brine as utility to condense any vapor escaping from primary condenser.</p> <p><input type="checkbox"/> All the Vacuum Driers relate to pre and post-condenser with Chilled Brine as utility in both the condensers.</p> <p>f. Spray Nozzles are installed in the reactors for cleaning.</p> <p><input type="checkbox"/> For other equipment, High pressure hose with jet nozzles is used to minimize the water quantity.</p> |
| VII. Green Belt | | |
| 1 | The green belt of 5-10 m width shall be developed in more than 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along roadsides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department. | The green belt is developed at the plant periphery and same will be continued for the expansion project area. Apart from the existing green belt area we are exploring additional development with Karnataka State Forest department and land available at educational institute such as IIMB etc. |
| VIII. Safety, Public hearing, and Human health issues | | |
| 1 | Emergency preparedness plan based on the Hazard identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented | Noted and implemented. Emergency preparedness plan is performed based on the HIRA and attached the acknowledgment of approval copy as Annexure – VI. |
| 2 | The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Firefighting system shall be as per the norms. | The fire protection systems like fire alarms, fire detection system, fire extinguishers and fire hydrants are provided as per the norms and same will be implemented for the expansion project. |
| 3 | The PP shall provide Personal Protection Equipment (PPE) as per the norms of Factory Act | PPE's such as safety helmet, shoes, masks, ear plugs etc are provided for all workers, employees, vendors and same will be continued for expansion projects. |
| 4 | 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. | Training for all employees is implemented on safety and health aspects as per the annual planner on different topics of EHS. Pre-employment and routine periodical medical examinations for all employees is implemented and shall be continued. |
| 5 | Provision shall be made for the housing of construction labour within the site with all | Noted and there is no provision for housing of construction labour within the site. |

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| | necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project. | |
| 6 | Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act. | The occupational health surveillance for the workers is conducted on regular basis as per the Factories Act. |
| 7 | There shall be adequate space inside the plant premises earmarked for parking vehicles for raw materials and finished products, and no parking to be allowed outside in public places. | The industry has provided adequate space for parking of vehicles for raw materials and finished products within the boundary. |
| IX. Corporate Environment Responsibility | | |
| 1 | The project authorities have undertaken activities under Corporate Environment Responsibility (CER) with a total cost of not less than Rs. 65 Crores towards development of Hebbagodi Metro Station which is on the R.V. Road to Bommasandra line, and Rejuvenation of Hebbagodi Lake in accordance with the O.M. F. No.22-65/2017-IA.III dated 01st May 2018 and report be submitted to the Authority. | MoU (Memorandum of Understand) with BMRCL is attached as Annexure – VII. |
| 2 | The project proponent shall comply with provision contained in OM vide F.No22-65/2017-IA.III dated 20th October 2020, of the Ministry of Environment, Forest and Climate Change as applicable, regarding Corporate Environment Responsibility (CER) and shall execute the action plan of Plantation in Bommasandra Industrial Area, Provision of solar streetlights nearby villages, Development facilities for nearby Govt Schools in Karnataka. Project proponent shall implement the CER activities as part of EMP and submit report accordingly. | The rejuvenation of Hebbagodi Lake project has taken up in April-2023 and is under progress by Biocon Foundation. As a part of World Environment Day celebration plantation drive has been conducted at Yarendahalli Lake by Biocon group of companies, Hennagara and Tirupalya government school students. |
| 3 | The company shall have a well-laid environmental policy duly approved by the Board of Directors. The environmental policy should prescribe standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental / forest /wildlife norms/ conditions. The company shall have a defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife norms / conditions and / or shareholder's / stake holders. The copy of the board resolution in this regard | Copy of the EHS policy board resolution is attached as Annexure – VIII. |

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| | shall be submitted to the MoEF&CC as a part of six-monthly report. | |
| 4 | A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly to the head of the organization. | The dedicated and separate environment cell is provided both at the project and company head quarter level with qualified personnel under the control of Head EHS, who will directly report to the head of the organization. |
| 5 | Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Year wise progress of implementation of action plan shall be reported to the Ministry/Regional Office along with the Six-Monthly Compliance Report. | We received EC on 23.08.2022 and subsequently applied for CTEp on 09.03.2023 and this document is awaited from KSPCB authority. The EMP funds earmarked for environment protection shall be reported once we receive CTEp order. |
| 6 | Self-environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out. | The internal and external audits on EHS management system is carried out regularly based on the schedule. The internal audit is conducted every six months once and external audit is conducted once in a year by third-party vendor (TUV Nord), find attached ISO certificate as Annexure –IX. |
| X. Miscellaneous | | |
| 1 | The project proponent shall make public the environmental clearance granted for their project along with the environmental conditions and safeguards at their cost by prominently advertising it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days and in addition this shall also be displayed in the project proponent's website permanently. | The copy of newspaper advertising is attached as Annexure –X. |
| 2 | The copies of the environmental clearance shall be submitted by the project proponents to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt. | Noted and communication letter is sent to relevant local bodies, panchayats and municipal bodies attached as Annexure –XI. |
| 3 | The project proponent shall upload the status of compliance of the stipulated environment clearance conditions, including results of monitored data on their website and update the same on half-yearly basis. | Environment Clearance document & compliance report is uploaded on the website & same will be continued. Please find the link to view document in website at: |

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| | | https://www.biocon.com/responsibility/sustainability/environmental_clearance/ |
| 4 | The project proponent shall monitor the criteria pollutants level namely, PM10, SO2, NOx (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects and display the same at a convenient location for disclosure to the public and put on the website of the company. | Noted and will be adhered. |
| 5 | The project proponent shall submit six-monthly reports on the status of the compliance of the stipulated environmental conditions on the website of the ministry of Environment, Forest and Climate Change at environment clearance portal. | The six-monthly reports on the status of the compliance of the stipulated environmental conditions is submitting to MoEF department through e-mail. |
| 6 | The Half Yearly Compliance Reports (HYCRs) with its contents of a covering letter, compliance reports, and environmental monitoring data has to be in PDF format merged into a single document. The email should clearly mention the name of project, EC No & date, period of submission and to be sent to the Regional Office of MOEF&CC by email only at email ID rosz.bng-mefcc@gov.in Hard copy of HYCRs shall not be acceptable. | The Half Yearly Compliance Reports (HYCRs) with its contents of a covering letter, compliance reports, and environmental monitoring data in PDF format merged into a single document and e-mailed to Regional Office of MOEF&CC for email ID rosz.bng-mefcc@gov.in every six months. |
| 7 | The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company | Noted and Form V is submitted to KSPCB authority every year within the stipulated period, please find the attached acknowledgement copy as Annexure-XII. |
| 8 | The project proponent 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, commencing the land development work and start of production operation by the project. | Noted and same will be communicated once the date of financial closure and final approval of the project by the concerned authorities for commencing the land development work and start of production operation by the project. |
| 9 | The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government. | Noted. |
| 10 | The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, commitment made during Public Hearing and also that during their presentation to the Expert Appraisal Committee. | Noted. |
| 11 | No further expansion or modifications in the plant shall be carried out without prior approval of this Authority or the Ministry of Environment, Forests and Climate Change (MoEF&CC). | Any expansion or modifications will be intimated and proper approvals will be obtained from relevant regulatory authorities before such activity is taken up. |

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| 12 | Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provisions of Environment (Protection) Act, 1986. | Noted. |
| 13 | The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory. | Noted. |
| 14 | The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions. | Noted. |
| 15 | The Regional Office of MoEF&CC shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports. | Noted, we shall extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/ monitoring reports. |
| 16 | The above conditions shall 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, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of Law relating to the subject matter. | Noted. |
| 17 | Any appeal against this EC 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. | Noted. |

ANNEXURE-I - COPY OF ENVIRONMENTAL CLEARANCES OF SEIAA 70 IND 2020 & SEIAA 63 IND 2021



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 70 IND 2020

Date: 19.06.2021

To,

M/s Biocon Limited
20th KM, Hosur Rd,
Electronic City, Bengaluru,
Karnataka 560100

Sir,

Sub: Proposed New Products of Biopharmaceutical Manufacturing Unit at Biocon Campus, 20th KM, Hosur Rd, Electronic City, Bengaluru, Karnataka 560100 by M/s Biocon Limited- issue of Environmental Clearance Reg.

This has reference to your online application dated 11th December 2020 bearing proposal No.SIA/KA/IND2/187366/2020 addressed to SEIAA, Karnataka on the subject mentioned above. The proposal has been appraised as per procedure prescribed in the provisions under the EIA notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the application in Form-1, Pre-feasibility report, and the additional clarification furnished in response to the observations of the SEAC, Karnataka.

2. It is a proposal seeking Environmental clearance for Proposed New Products of Biopharmaceutical Manufacturing Unit at Biocon Campus, 20th KM, Hosur Rd, Electronic City, Bengaluru, Karnataka 560100. This is a project covered under Sl.No.5(f) of the Schedule Under of EIA Notification 2006 and amendments made there on.

3. The total plot area is 1,03,634 Sqm (23.6 Acres). Industry has developed greenbelt in an area of 532165qm i.e 51.3 % out of total area of the project site. The estimated project cost is Rs. 650 Crores including expansion cost of 10 Crores. Details of Existing and Proposed product category to be manufactured with their capacity are given in Annexure-1:-

4. The total water requirement for the proposed project is 1152KLD, and It will be met from the BWSSB water supply, The waste water generation will be 636 KLD, out of which 95 KLD will be the domestic sewage shall be treated in existing Treatment system with capacity of 115 KLD. The industrial effluent of 543 KLD shall be treated in ETP of 550 KLD capacity and MEE of 300 KLD. Power requirement is 14 MW and will be met from Bangalore Electricity Supply Company (BESCOM), a Branch of Karnataka State Power Distribution Corporation Limited (KPTCL).

Room No. 706, 7th Floor, 4th Gate, M.S. Building, Bangalore - 560 001 Phone : 080-22832482, Fax : 080-22254377
Website : <http://environmentclearance.ric.in> <http://seiaa.karnataka.gov.in> e-mail : seiaakarnataka@gmail.com

State Level Environment Impact Assessment Authority-Karnataka
(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 70 IND 2020

Proposed New Products of Biopharmaceutical
Manufacturing Unit Project by M/s. Biocon Limited

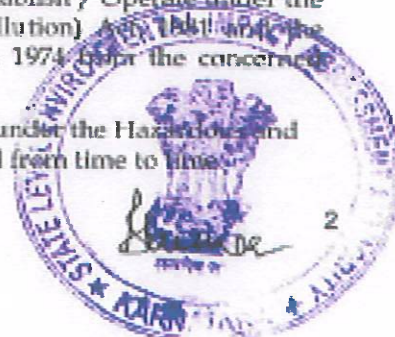
Existing unit has DG sets of 6 Nos of 2000 KVA and 4 Nos of 1250 KVA capacity and proposed to install 3 Nos of 2000 KVA in addition to existing DG sets and it shall be used as standby during the power failure. Existing unit has 2 Nos of 10 TPH, and 1 Nos 6 TPH, CNG fired boilers, and 1 Nos Incinerator, 19 Nos existing Scrubbers and 6 Nos Scrubbers are proposed for mitigation of air pollution.

5. The project proposal was considered by SEAC during the video conference meeting held on 7th January 2021 as B2 category activity in accordance with the Notification S.O. 1223 (E) dated 27th March 2020 and Notification S. O. 3636 (E) dated 15th October 2020. Based on the information submitted by you, presentation made by you and your consultant Dr. Mohammed Habibulla, the State Level Expert Appraisal Committee (SEAC) apprised the proposal and has recommended for issue of Environmental Clearance.

6. The SEIAA Karnataka has considered the project in its meeting held on 30th January 2021 and after due consideration of the relevant documents submitted by you and additional clarifications furnished in response to its observations and the appraisal and recommendation of the SEAC, decided to accord Environmental Clearance in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the following terms and conditions:

I. Statutory compliance

- i. The project proponent shall obtain forest clearance under the provisions of Forest (Conservation) Act, 1986, in case of the diversion of forest land for non-forest purpose involved in the project.
- ii. The project proponent shall obtain clearance from the National Board for Wildlife, if applicable.
- iii. The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan / Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (In case of the presence of schedule-I species in the study area)
- iv. The project proponent shall obtain Consent to Establish / Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1986 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State pollution Control Board/ Committee.
- v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.



State Level Environment Impact Assessment Authority-Karnataka
(Constituted by MoEF, Government of India under section 3(3) of EIA Act, 1986)

SEIAA 70 IND 2020

Proposed New Products of Biopharmaceutical
Manufacturing Unit Project by M/s. Biocon Limited

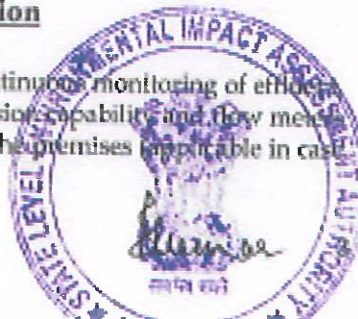
- vi. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989

II Air quality monitoring and preservation

- i. The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB and CPCB online servers and calibrate these system from time to time according to equipment supplier specification through labs recognised under Environment (Protection) Act, 1986 or NABL accredited laboratories.
- ii. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognised under Environment (Protection) Act, 1986.
- iii. The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10 and PM2.5 in reference to PM emission, and SO2 and NOx in reference to SO2 and NOx emissions) within and outside the plant area at least at four locations (one within and three outside the plant area at an angle of 120 each), covering upwind and downwind directions.
- iv. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
- v. Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.
- vi. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended from time to time shall be followed.
- vii. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with

III. Water quality monitoring and preservation

- i. The project proponent shall provide online continuous monitoring of effluent. The unit shall install web camera with night vision capability and flow meter in the channel/drain carrying effluent within the premises (applicable in case of the projects achieving ZLD)



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- ii. As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises (applicable in case of the projects achieving the ZLD).
- iii. The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the State Pollution Control Board while granting Consent under the Air/Water Act, whichever is more stringent.
- iv. Total fresh water requirement shall not exceed the proposed quantity or as specified by the Committee. Prior permission shall be obtained from the concerned regulatory authority/CGWA in this regard.
- v. 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.
- vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.
- vii. The DG sets shall be equipped with suitable pollution control devices and the adequate stack height so that the emissions are in conformity with the extant regulations and the guidelines in this regard.

IV. Noise monitoring and prevention

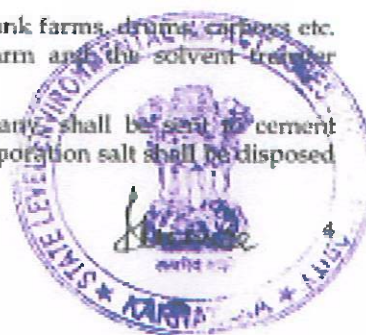
- i. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- ii. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation.
- iii. The ambient noise levels should conform to the standards prescribed under E(P)A Rules, 1986 viz. 75 dB(A) during day time and 70 dB(A) during night time

V. Energy Conservation measures

- i. The energy sources for lighting purposes shall preferably be LED based.

VI. Waste management

- i. Hazardous chemicals shall be stored in tanks, tank farms, drums, canisters etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps.
- ii. 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.



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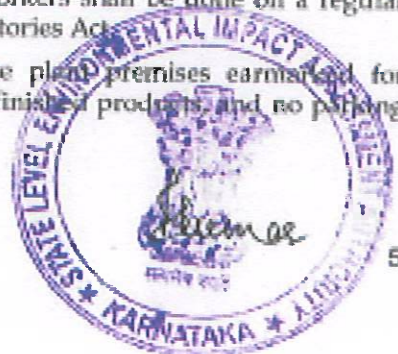
- iii. The company shall undertake waste minimization measures as below:-
 - a. Metering and control of quantities of active ingredients to minimize waste.
 - b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - c. Use of automated filling to 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

VII. Green Belt

- i. The green belt of 5-10 m width shall be developed in more than 33% 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.

VIII. Safety, Public hearing and Human health issues

- i. Emergency preparedness plan based on the Hazard identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented
- ii. 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.
- iii. The PP shall provide Personal Protection Equipment (PPE) as per the norms of Factory Act.
- iv. 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.
- v. Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile SIP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.
- vi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- vii. There shall be adequate space inside the plant premises earmarked for parking of vehicles for raw materials and finished products, and no parking to be allowed outside on public places



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Proposed New Products of Biopharmaceutical
Manufacturing Unit Project by M/s. Biocon Limited**IX. Corporate Environment Responsibility**

- i. The project authorities have undertaken activities under Corporate Environment Responsibility (CER) with a total cost of not less than Rs. 65 Crores towards development of Hebbagodi Metro Station which is on the R.V. Road to Bommasandra line, and Rejuvenation of Hebbagodi Lake in accordance with the O.M. F. No.22-65/2017-IA.III dated 01st May 2018 and report be submitted to the Authority.
- ii. The company shall have a well laid down environmental policy duly approve by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental / forest / wildlife norms/ conditions. The company shall have defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife norms / conditions and / or shareholders / stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF&CC as a part of six-monthly report.
- iii. A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly to the head of the organization.
- iv. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Year wise progress of implementation of action plan shall be reported to the Ministry/Regional Office along with the Six Monthly Compliance Report.
- v. Self environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out.

X. Miscellaneous

- i. The project proponent shall make public the environmental clearance granted for their project along with the environmental conditions and safeguards at their cost by prominently advertising it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days and in addition this shall also be displayed in the project proponent's website permanently.
- ii. The copies of the environmental clearance shall be submitted by the project proponents to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.



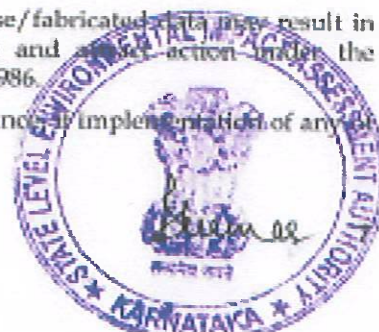
State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

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Proposed New Products of Biopharmaceutical
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- iii. The project proponent shall upload the status of compliance of the stipulated environment clearance conditions, including results of monitored data on their website and update the same on half-yearly basis.
- iv. The project proponent shall monitor the criteria pollutants level namely; PM10, SO2, NOx (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects and display the same at a convenient location for disclosure to the public and put on the website of the company.
- v. The project proponent shall submit six-monthly reports on the status of the compliance of the stipulated environmental conditions on the website of the ministry of Environment, Forest and Climate Change at environment clearance portal.
- vi. "The HYCRs with its contents of a covering letter, compliance reports, and environmental monitoring data has to be in PDF format merged into a single document. The email should clearly mention the name of project, EC No & date, period of submission and to be sent to the Regional Office of MOEF&CC by email only at email IDR@sz.bng-mefcc@gov.in Hard copy of HYCRs shall not be acceptable".
- vii. The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.
- viii. The project proponent 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, commencing the land development work and start of production operation by the project.
- ix. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.
- x. The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, commitment made during Public Hearing and also that during their presentation to the Expert Appraisal Committee.
- xi. No further expansion or modifications in the plant shall be carried out without prior approval of this Authority or the Ministry of Environment, Forests and Climate Change (MoEF&CC).
- xii. Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and strict action under the provisions of Environment (Protection) Act, 1986.
- xiii. The SEIAA may revoke or suspend the clearance if implementation of any of the above conditions is not satisfactory.



State Level Environment Impact Assessment Authority-Karnataka
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SEIAA 70 IND 2020

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- xiv. The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- xv. The Regional Office of MoEF&CC shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
- xvi. The above conditions shall 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, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of Law relating to the subject matter.
- xvii. Any appeal against this EC 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.



Yours faithfully,

Brijesh Kumar 19/6/2024
(Brijesh Kumar)
Member Secretary,
SEIAA, Karnataka.

Copy to:

- 1) The Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, Aliganj, New Delhi- 110 003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The APCCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore - 560 034.
- 4) Guard File.

State Level Environment Impact Assessment Authority-Karnataka
(Constituted by MoEF, Government of India under section 3(3) of EIA Act, 1986)

SEIAA 70 IND 2020

Proposed New Products of Biopharmaceutical
Manufacturing Unit Project by M/s. Biocon Limited

ANNEXURE-I

Details of Existing and Proposed product category to be manufactured with their capacity

| List of products - Biocon Limited and Biocon Biologics Limited | | |
|--|-------------------------------------|---------------------|
| Sl. | Products | Quantity (MTA) |
| 1 | Biosimilar and rDNA Products | 3.24 |
| 2 | Biopharmaceuticals | 1116.00 |
| 3 | Synthetic API's & Intermediates | 336.60 |
| | Total Quantity of Production | 1,455.84 MTA |



Signature 19/6/2024



State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 63 IND 2021

To,

M/s. Biocon Limited
20th KM, Hosur Road,
Electronic city, Bengaluru
Karnataka-560100

Sir,

Sub: Expansion & Modification of Existing Products Capacity and Proposed New Additional Products of Biopharmaceutical Manufacturing Unit at Sy. Nos. 46/1, 46/2, 47/3, 48/6, 44/1, 44/2, 44/3B, 44/3A, 47/1, 47/2, 49/1, 49/2, 47/4, 31, 32, & 47/3B, Hebbagodi CMC, Anekal, Bengaluru Urban By M/s Biocon Limited - Issue of Environmental Clearance - Reg.

This has reference to your online application dated 24th December 2021 bearing proposal No. SIA/KA/IND3/246744/2021 addressed to SEIAA, Karnataka on the subject mentioned above. The proposal has been appraised as per the procedure prescribed in the provisions under the EIA notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the application in Form-1, Pre-feasibility report, EMP, and the additional clarification furnished in response to the observations of the SEAC, Karnataka.

2. It is a proposal seeking Environmental Clearance for Expansion & Modification of Existing Products Capacity and Proposed New Additional Products of Biopharmaceutical Manufacturing Unit at Sy. Nos. 46/1, 46/2, 47/3, 48/6, 44/1, 44/2, 44/3B, 44/3A, 47/1, 47/2, 49/1, 49/2, 47/4, 31, 32, & 47/3B, Hebbagodi CMC, Anekal, Bengaluru Urban by M/s Biocon Limited. This is a project covered under SI.No. 5(f) of the Schedule Under of EIA Notification 2006 and amendments made thereon.

3. It is inter-alia, noted that M/s Biocon Limited have been issued with the Environmental Clearance vide letter No. SEIAA 70 IND 2020 dated 19.06.2021 for Proposed new products of Biopharmaceutical Manufacturing Unit. The total land area was 1,03,722.03 Sqm (25.62 Acres). The total water requirement was 1152 KLD. The total production capacity was 1,455.84 MTA.

4. The total plot area is 1,03,722.03 Sqm (25.62 Acres), industry will develop a greenbelt in an area of 36316.43 Sqm (8.97 Acres) i.e., 35 % out of the total area of the project site. The

EC Identification No. - EC22B058KA154508 File No. - SEIAA 63 IND 2021 Date of Issue EC - 23/08/2022 Page 2 of 14

Room No. 706, 7th Floor, 4th Gate, M.S. Building, Bangalore - 560 001 Phone : 080-22032497 Fax : 080-22254377
Website : <http://environmentclearance.nic.in> <http://seiaa.karnataka.gov.in> e-mail : msseiaakarnataka@gmail.com

estimated project cost is Rs. 250 Crores. The details of Existing & proposed products with capacities are given **Annexure-I & IA**.

5. The total water requirement is estimated to be 1900 KLD (1530 KLD for Biocon Limited + 350 KLD for Biocon Biologics + 20 KLD for Drinking water for villagers) and it will be met from the BWSSB water supply. The unit total wastewater generation will be 1073 KLD. The total domestic sewage will be 200 KLD, which will be treated by STP capacity of 250 KLD. The total industrial effluent will be 873 KLD, which shall be treated by ETP capacity of 1000 KLD and MEE capacity of 300 KLD. Treated wastewater 700 KLD will be recycled to utilities. ZLD system will be adopted. Details of untreated water quantity & characteristics are given in **Annexure-II**. Power requirement is 14 MW and will be met from BESCOM.

6. The Existing unit has DG sets of 6 Nos of 2000 KVA and 4 Nos of 1250 KVA capacity and additionally proposed to install DG sets of 5 Nos of 2000 KVA Respectively and it shall be used as standby during the power failure. The existing unit has a Boiler capacity of 1 No of 6.0 TPH and 2 Nos of 10 TPH of CNG fired boiler and additionally proposed to install Boiler Capacity of 2 Nos of 5 TPH of Agro-based briquettes fired boiler. The existing unit has a 1 No of Incinerator capacity of 250 kg/hr dual fired by Methane gas and HSD and the existing unit has already provided 18 Nos of alkali scrubbers to process reactors, R & D fume hoods, ETP plant respectively. Additionally, proposed to install 15 Nos of alkali scrubbers to Process reactors, R & D fume hoods, ETP plant, Pilot plant etc.. The details of hazardous waste and air pollution control measures & process emission details are given in **Annexure -III** and **Annexure-IV** respectively.

7. The project proposal was considered by SEAC during the meeting held on 1st February 2022 and 13th April 2022 as B2 category activity in accordance with the Notification S.O. 2859 (E) dated 16th July 2021. Based on the information submitted by you, the presentation made by Project Proponent and your consultant Dr. Mohammed Habibulla, the State Level Expert Appraisal Committee (SEAC) apprised the proposal and has recommended the for issue of Environmental Clearance.

8. The SEIAA Karnataka has considered the project in its meeting held on 07th May 2022 and after due consideration of the relevant documents submitted by you and additional clarifications furnished in response to its observations and the appraisal and recommendation of the SEAC, decided to accord Environmental Clearance in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the following terms and conditions:

I. Statutory compliance

- i. The project proponent shall obtain forest clearance under the provisions of Forest (Conservation) Act, 1986, in case of the diversion of forest land for non-forest purpose involved in the project.
- ii. The project proponent shall obtain clearance from the National Board for Wildlife, if

applicable.

- iii. The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan / Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (In case of the presence of schedule-I species in the study area)
- iv. The project proponent shall obtain Consent to Establish / Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State pollution Control Board/ Committee.
- v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.
- vi. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSHIC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989

II Air quality monitoring and preservation

- i. The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB and CPCB online servers and calibrate these systems from time to time according to equipment supplier specification through labs recognised under Environment (Protection) Act, 1986 or NABL accredited laboratories.
- ii. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognised under Environment (Protection) Act, 1986.
- iii. The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10 and PM2.5 in reference to PM emission, and SO₂ and NO_x in reference to SO₂ and NO_x emissions) within and outside the plant area at least at two locations (one within and another one outside the plant area at an angle of 120 each), covering upwind and downwind directions.
- iv. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.

- v. Storage of raw materials, coal etc., shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.
- vi. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with

III. Water quality monitoring and preservation

- i. The project proponent shall provide 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 (applicable in case of the projects achieving ZLD)
- ii. As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises (applicable in case of the projects achieving the ZLD).
- iii. The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the State Pollution Control Board while granting Consent under the Air/Water Act, whichever is more stringent.
- iv. Total fresh water requirement shall not exceed the proposed quantity or as specified by the Committee. Prior permission shall be obtained from the concerned regulatory authority/CGWA in this regard.
- v. 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.
- vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.
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- i. The energy sources for lighting purposes shall preferably be LED based.

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- i. Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps.
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 - 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

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- iii. The PP shall provide Personal Protection Equipment (PPE) as per the norms of Factory Act.
- iv. 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.

- v. Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.
- vi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- vii. There shall be adequate space inside the plant premises earmarked for parking of vehicles for raw materials and finished products, and no parking to be allowed outside on public places

IX. Corporate Environment Responsibility

- i. The project proponent shall comply with provision contained in OM vide F.No. 22-65/2017-IA.III dated 20th October 2020, of the Ministry of Environment, Forest and Climate Change as applicable, regarding Corporate Environment Responsibility and shall execute the action plan of Plantation in Bommasandra Industrial Area, Provision of solar street lights nearby villages, Development facilities for nearby Govt Schools in Karnataka. Project proponent shall implement the CER activities as part of EMP and submit report accordingly.
- ii. The company shall have a well laid down environmental policy duly approved by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental / forest /wildlife norms/ conditions. The company shall have defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife norms / conditions and / or shareholders / stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF&CC as a part of six-monthly report.
- iii. A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly to the head of the organization.
- iv. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Year wise progress of implementation of action plan shall be reported to the Ministry/Regional Office along with the Six Monthly Compliance Report.
- v. Self environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out.



X. Miscellaneous

- i. The project proponent shall make public the environmental clearance granted for their project along with the environmental conditions and safeguards at their cost by prominently advertising it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days and in addition this shall also be displayed in the project proponent's website permanently.
- ii. The copies of the environmental clearance shall be submitted by the project proponents to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.
- iii. The project proponent shall upload the status of compliance of the stipulated environment clearance conditions, including results of monitored data on their website and update the same on half-yearly basis.
- iv. The project proponent shall monitor the criteria pollutants level namely; PM10, SO2, NOx (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects and display the same at a convenient location for disclosure to the public and put on the website of the company.
- v. The project proponent shall submit six-monthly reports on the status of the compliance of the stipulated environmental conditions on the website of the ministry of Environment, Forest and Climate Change at environment clearance portal.
- vi. "The HYCRs with its contents of a covering letter, compliance reports, and environmental monitoring data has to be in PDF format merged into a single document. The email should clearly mention the name of project, EC No & date, period of submission and to be sent to the Regional Office of MOEF&CC by email only at email ID rosz.bng-mefcc@gov.in Hard copy of HYCRs shall not be acceptable".
- vii. The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.
- viii. The project proponent 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, commencing the land development work and start of production operation by the project.
- ix. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.
- x. The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, commitment made during Public Hearing and also that during their presentation to the Expert Appraisal Committee.

- xi. No further expansion or modifications in the plant shall be carried out without prior approval of this Authority or the Ministry of Environment, Forests and Climate Change (MoEF&CC).
- xii. Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provisions of Environment (Protection) Act, 1986.
- xiii. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- xiv. The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- xv. The Regional Office of MoEF&CC shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
- xvi. The above conditions shall 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, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of Law relating to the subject matter.
- xvii. Any appeal against this EC 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.

Yours faithfully,

(Vijay Mohan Raj V)
Member Secretary,
SEIAA, Karnataka.

Copy to:

- 1) The Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, Aliganj, New Delhi- 110 003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The APCCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore – 560 034.
- 4) Guard File.

ANNEXURE - I**LIST OF EXISTING & PROPOSED PRODUCTS TO BE MANUFACTURED WITH THEIR BELOW GIVEN QUANTITIES**

| List of final products (existing + proposed)-Biocon Limited & Biocon Biologics Limited | | | | | |
|---|---------------------------|--------------------------|--------------------------|--|---------------|
| Sl. | Products | Existing Quantity in MTA | Proposed quantity in MTA | Total after expansion of Quantity in MTA | Remarks |
| 1 | Specialty Enzymes | 996 | - | 996 | No change |
| 2 | Anti-cholesterol agents | 60 | +60 | 120 | Qty Increased |
| 3 | Monoclonal Antibodies | 0.6 | -0.564 | 0.036 | Qty Decreased |
| 4 | Immunosuppressants | 240 | +240 | 480 | Qty Increased |
| 5 | Human insulin | 2.82 | - | 2.82 | No change |
| 6 | Nintedanib | - | +10 | 10 | New product |
| 7 | Eltromabopag | - | +10 | 10 | New product |
| 8 | Omadaacycline | - | +8 | 8 | New product |
| 9 | Palbociclib | - | +8 | 8 | New product |
| 10 | HSA | 0.12 | +0.12 | 0.24 | Qty Increased |
| 11 | Insulin Glargine | 0.2004 | +0.0396 | 0.24 | Qty Increased |
| 12 | IN 105 (Insulin Tregopil) | 0.0504 | +0.1896 | 0.24 | Qty Increased |
| 13 | Monoclonal Antibodies | 0.048 | -0.036 | 0.012 | Qty Decreased |
| 14 | Streptokinase | 0.000498 | -0.000098 | 0.0004 | Qty Decreased |
| 15 | Retepase | 0.000498 | -0.000098 | 0.0004 | Qty Decreased |
| 16 | Human Growth Hormone | 0.000498 | +0.000302 | 0.0008 | Qty Increased |
| 17 | GCSF (Filgrastim) | 0.0000996 | +0.0003004 | 0.0004 | Qty Increased |
| 18 | Specialty Enzymes | 120 | - | 120 | No change |
| 19 | Remdesivir (Covid-19) | 36 | +36 | 72 | Qty Increased |
| | Total Quantity | 1455.84 | +371.75 | 1827.590 | |

(Note: SL.No. 1 to 9 Products belongs to Biocon Limited and SL.N. 10 to 19 Products belongs to Biocon Biologics limited.)

Annexure-1AConsented product list as per CFO

| List of BBL Products | | |
|----------------------|---|--------------|
| Sl No. | Product Name | Qty MT/Annum |
| 1 | Specialty Enzymes | 120 |
| 2 | Human insulin | 2.82 |
| 3 | Human Serum Albumin (HSA) | 0.12 |
| 4 | Insulin Glargine | 0.2004 |
| 5 | IN 105 (Insulin Tregopil) | 0.0504 |
| 6 | Monoclonal Antibodies | 0.048 |
| 7 | Streptokinase | 0.000498 |
| 8 | Reteplase | 0.000498 |
| 9 | Human Growth Hormone | 0.000498 |
| 10 | Granulocyte Colony Stimulating Factor (GCSF) (Filgrastim) | 0.0000996 |
| List of BL Products | | |
| Sl No. | Product Name | Qty MT/Annum |
| 1 | Specialty Enzymes | 240 |
| 2 | Anti-cholesterol agents | 36 |
| 3 | Mycophenolic acid (MPA) | 12 |
| 4 | Sirolimus | 0.6 |
| 5 | Tacrolimus | 1.2 |
| 6 | Temsirolimus | 0.0096 |
| 7 | Mycophenolate Mofetil (MMF) | 50.0004 |
| 8 | Pimecrolimus | 0.0996 |
| 9 | Somatropin | 0.0036 |
| 10 | OPT-80/PAR 101 | 1.2 |
| 11 | Eptibatide | 0.0204 |
| 12 | Daptomycin | 0.0204 |
| 13 | Voglibose | 0.0048 |
| 14 | Ivabradine | 0.0096 |
| 15 | Eplerenone | 0.0996 |
| 16 | Ibandronate | 0.0096 |
| 17 | Geldanamycin | 0.0996 |
| 18 | Dorzolomide | 0.0096 |
| 19 | Immunomycin | 0.0504 |
| 20 | Caspofuigin | 0.0504 |
| 21 | Everolimus | 0.0096 |
| 22 | Monoclonal Antibodies | 0.012 |
| 23 | Latanoprost | 0.0004008 |
| 24 | Bimatoprost | 0.0004008 |
| 25 | Lubiprostone | 0.00040128 |
| 26 | Carboprost | 0.0004008 |
| 27 | Travoprost | 0.0004008 |

ANNEXURE - II

As per the Office Memorandum dated 28.01.2021 which inter-alia stated SEAC has clearly recommended the permissible pollution load for this proposed project.

| S.No | Utility | Water Requirement (KLD) | Effluent Water (KLD) | | Total Effluent Generation (KLD) | Pollution Load in kgs | |
|------|------------------------------------|-------------------------|----------------------|-------------|---------------------------------|-----------------------|--------------|
| | | | HTDS | LTDS | | TDS | COD |
| 1 | Domestic use | 240 | - | 200 | 200 | 210 | 120 |
| 2 | Process & scrubbing | 940 | 30 | 787 | 817 | 25410 | 42350 |
| 3 | Utilities (boiler & cooling tower) | 700 | - | 56 | 56 | 196 | 1.68 |
| 4 | Drinking water For villagers | 20 | - | - | - | - | - |
| | TOTAL | 1900 | 30 | 1043 | 1073 | 25816 | 42472 |

ANNEXURE - III**Details of Hazardous Waste Management**

| S.No. | Waste Code | Waste Name | Quantity (MTA) | Disposal Mode |
|-------|------------|---|----------------|--|
| 1 | 5.1 | Used or Spent Oil | 19 | Disposed to authorized reprocessors /re-cyclers |
| 2 | 5.2 | Waste or residues containing oil | 1 | Disposed at in-house incinerator located at Biocon Ltd, 20th KM site |
| 3 | 20.3/28.1 | Distillation residue/ Process residue waste | 200 | Disposed at in-house incinerator located at Biocon Ltd, 20th KM site |
| 4 | 28.2 | Spent catalyst | 1 | Disposed to authorized re-cyclers/reprocessors |
| 5 | 28.3 | Spent carbon | 8 | Disposed at in-house incinerator located at Biocon Ltd, 20th KM site |
| 6 | 28.4 | Off specification products | 35 | Disposed at in-house incinerator located at Biocon Ltd, 20th KM site |
| 7 | 28.5 | Date expired products | 45 | Disposed at in-house incinerator located at Biocon Ltd, 20th KM site |
| 8 | 20.2/28.6 | Spent Solvent | 20000 | Partly reutilized in the process after inhouse Distillation and rest disposed to authorized Reprocessors /re-cyclers |
| 9 | 33.1 | Empty containers/barrels | 310 | Disposed to authorized re-cyclers |
| 10 | 33.1 | Liners contaminated with hazardous chemical waste | 32 | Disposed to authorized re-cyclers |

| | | | | |
|----|------|--|------|--|
| 11 | 33.2 | Contaminated cotton rags or other cleaning materials | 2.0 | Disposed at in-house incinerator located at Biocon Ltd, 20th KM site |
| 12 | 35.3 | Chemical sludge from waste water treatment | 1100 | Disposed to authorized TSDF |
| 13 | 37.1 | Sludge from Wet Scrubber | 65 | Disposed to authorized TSDF |
| 14 | 37.2 | Ash from Incinerator | 30 | Disposed to authorized TSDF |

ANNEXURE - IV**Air pollution Sources & Control Measures.**

| Sl. No | Stack attached to | Type of Fuel Used & quantity per day | Stack Height | Air pollution control equipment |
|---------------------------|--------------------------------|--------------------------------------|--------------|--|
| Existing Utilities | | | | |
| 1. | Process Reactor-10 Nos | | 3 m -ARL | 10 Nos alkali scrubbers connected 10 Nos Process Reactors. |
| | R & D Fume hood | | 9 m -AGL | 6 Nos of alkali scrubbers connected R & D fume hoods. |
| | ETP plant | | | 2 Nos of alkali scrubbers connected ETP. |
| | | | | Total 18 Nos of alkali scrubbers. |
| 2 | Boiler-6.0 TPH, (1 No) | CNG-460 spm | 30 m | Stack |
| 3 | Boiler -10 TPH (2 Nos) | CNG-760 spm | 30 m | Stack |
| 4 | Incinerator-250 kg/hr capacity | Dual fired: Methane gas and HSD. | 30 m | Wet scrubber & Stack |
| 5 | DG sets 2000 kva x 9 No. | HSD:420 liter/hour | 30 m | Acoustic enclosure & stack. |
| 6 | DG sets 1250 kva x 4 No. | HSD:230 liter/hour | 30 m | Acoustic enclosure & stack. |

| Proposed utilities (additional) | | | | |
|---------------------------------|---|---------------------------------------|------------------------|---|
| 1. | 1. Process reactor-10 Nos 2. R & D fume hoods. 3. ETP plant 4. Pilot Plant | -- | 3 m -ARI. 9 m -AGL. | 6 Nos. of alkali scrubbers connected 10 Nos of Process reactors. 6 Nos of alkali scrubber connected to R & D fume hoods. 1 No of alkali scrubbers connected ETP. 2 Nos. of scrubbers for pilot plant. 15 Nos of alkali scrubber to be provided. |
| 2. | Boiler-5 TPH (2 Nos) | Agro based briquettes: 1.2 T/Hours | 30 m | Stack |
| 3. | DG sets 2000 KVA x 3 No. | HSD:420 liter/hour | 30 m | Acoustic enclosure & stack. |

Details of process emission generation and its management

| S.No | Name of the Gas | Quantity in Kg/day | Treatment Method |
|------|------------------------------------|--------------------|--|
| 1 | Carbon Dioxide | 350 | Dispersed into the atmosphere |
| 2 | Hydrogen | 2.5 | Diffused by using through flame arrestor |
| 3 | Ammonia | 48 | Scrubbed by using chilled water media |
| 4 | Hydrogen chloride | 110 | Scrubbed by using C. S. Lye Solution |
| 5 | Sulphur dioxide (SO ₂) | 42 | Scrubbed by using C. S. Lye Solution |

(Vijay Mohan Raj V)

Member Secretary.

SEIAA, Government of Karnataka

Digitally signed by S/i Vijay Mohan

Raj V., IFS

Member Secretary

Date: 8/23/2022 4:30:08 PM

Page 14 of 14

ANNEXURE-II – ACKNOWLEDEMENT COPY OF SUBMISSION OF CTExp APPLICATION

o/c



Biocon Limited
20th KM Hosur Road
Electronic City
Bangalore 560 100, India
T 91 80 2808 2808
F 91 80 2852 3423
CIN : L24234KA1978PLC063417

www.biocon.com

Ref: BIL/EHS/23/03/02

Date: 09.03.2023

To,

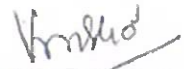
Office of the Environmental Officer,
Karnataka State Pollution Control Board,
Regional Office – Sarjapuar division,
Nisarga Bhavan, III floor,
Saneguruvanahalli, Thimmaiah Road,
Bengaluru – 560 001.

Sub: Filing of CTE expansion application for M/s Biocon Limited, 20th KM,
Hosur Road, Hebbagodi Village, Electronic city Post, Bengaluru – 560099.

With reference to the above subject, we are here with submitting the CTE expansion application in Form-I & Form-XIII for 5 years of M/s Biocon Limited, 20th KM, Hosur Road, Hebbagodi Village, Electronic city Post, Bengaluru – 560099 & payment towards consent fee is paid on 07.03.2023 (Bank ref no: YCH21771863824) as per the KSPCB fee structure. Kindly request you to accept the application and issue the consent to CTE expansion order for 5 years at the earliest.

Thanking you,

Yours sincerely
For Biocon Limited


Authorized Signatory



ANNEXURE-III – ANALYSIS REPORT OF AMBIENT VOC



ROBUST MATERIALS TECHNOLOGY PVT. LTD.
 (Recognised by MoEF&CC, DSIR-Government of India & Notified by FSSAI)
 (Approved by Drug Control Department-GoK ; Certified by OHSAS-ISO 45001:2018)
 No. 94, 2nd Floor Thirumala Complex, Nagarabhavi Main Road, NGEF Layout,
 Nagarabhavi, Bengaluru - 560 072. Tel : 080 23186230.
 Email : info@robustmaterials.com Website : www.robustmaterials.com

TEST REPORT

| | |
|--|-------------------------------|
| M/s. Blocon Limited 20 th KM, Hosur Road, Electronic City, Bengaluru-560 100. | Report No. : RCA/2023/10062 |
| | Report date : 23/11/2023 |
| | Ref. : Test Request Form |
| | Ref. Date : 15/11/2023 |
| | Job Order No : RCA/2023/10062 |
| | Date of Receipt : 16/11/2023 |
| Date of Analysis : 16/11/2023 | |
| Sample Particulars: Ambient VOC Monitoring on 15/11/2023. | |

| Discipline: Chemical | | | Group: Atmospheric Pollution | |
|----------------------|--|--|------------------------------|----------|
| Sl. No. | Test | Results Industry Premises (Incinerator Area) | Limits | Protocol |
| 1 | Benzene, µg/m ³ | BDL | 5.0 | E/WP/070 |
| 2 | Methanol, µg/m ³ | BDL | NS | E/WP/070 |
| 3 | Carbon Tetra Chloride, µg/m ³ | BDL | NS | E/WP/070 |
| 4 | Toluene, µg/m ³ | BDL | NS | E/WP/070 |
| 5 | Methyl Chloride, µg/m ³ | BDL | NS | E/WP/070 |
| 6 | Mercaptan, µg/m ³ | BDL | NS | E/WP/070 |
| 7 | Hydrogen Sulphate, µg/m ³ | BDL | NS | E/WP/070 |

Note: BDL- Below Detection Limit, NS: Not Specified.

| Details of Equipment used for monitoring | |
|--|------------|
| Name of the equipment: -Handy Sampler | |
| Model | IAS 019 |
| Sl. No. | 22-A-107 |
| Calibrated on date | 07-05-2023 |
| Calibration due date | 01-05-2024 |

-----END OF THE REPORT-----

P. Dey
Verified By

Authorized By
Rajesh S

Page 1 of 1

Note: 1. The results listed refer only to the tested samples and applicable parameters. 2. Test certificate should not be reproduced except in full, without written approval of the laboratory. 3. The submitted samples are drawn by the laboratory unless otherwise specified. 4. Endorsement of product is neither inferred nor implied. 5. Samples will be destroyed after 15 days from the date of issue of test report unless otherwise specified. 6. This report cannot be used as evidence in the court of law & should not be used in any advertising media without our permission in writing. 7. Total liability of our lab is limited to the invoice amount and any disputes arising out of this report are subject to Bangalore jurisdiction only. 8. Laboratory is not responsible for the authenticity of photocopied test reports.

RMT-QP16-TRF/R/10-03-2021

ANNEXURE-IV – TREND ANALYSIS OF SCRUBBER STACK & AMBIENT AIR QUANLITY**Trend Analysis of Process Stack Scrubber from April-2023 to September-2023**

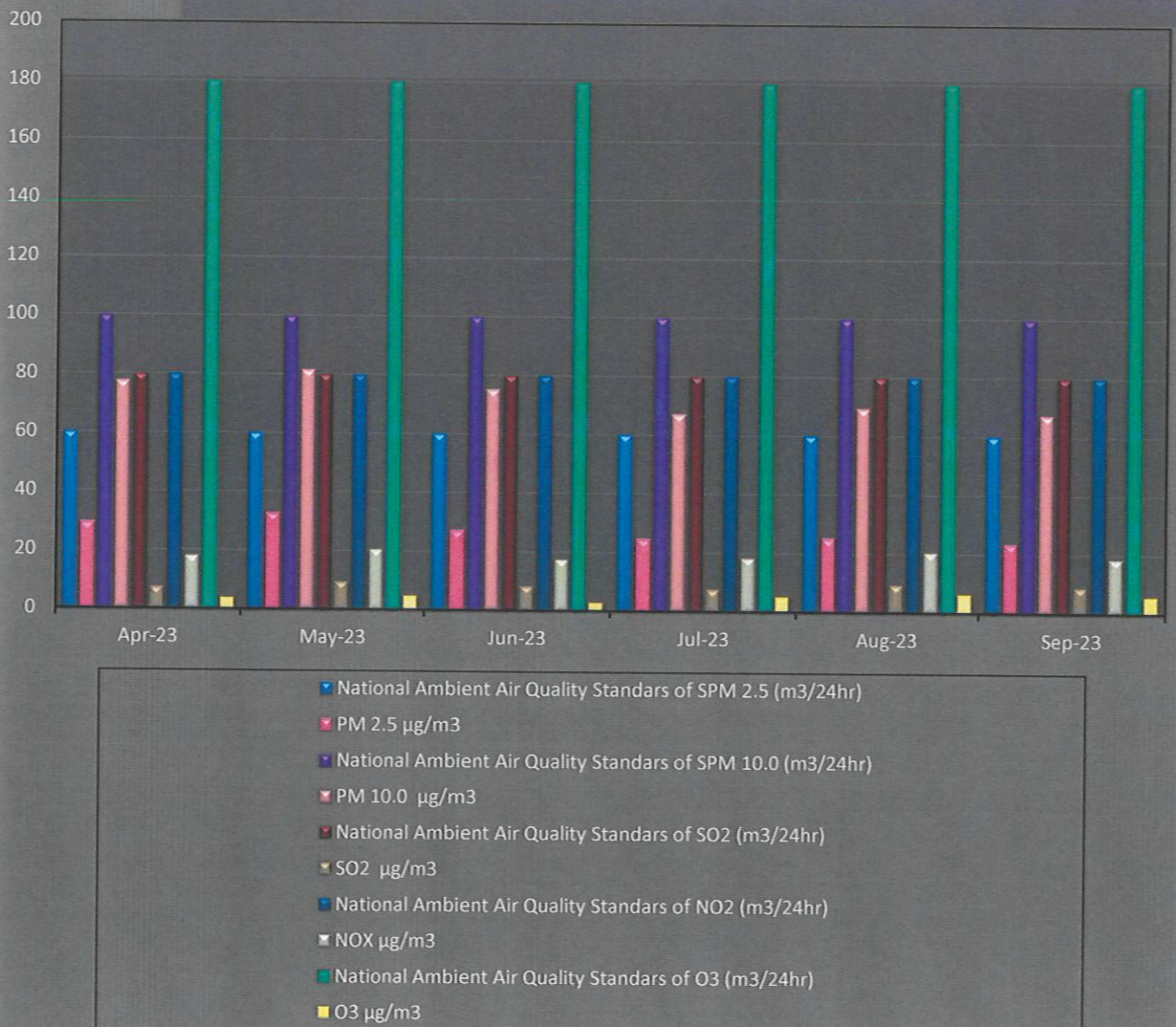
| Month | SCE-SRB-001 mg/Nm ³ | SCE-SRB-002 mg/Nm ³ | SCE-SRB-003 mg/Nm ³ | SCE-SRB-004 mg/Nm ³ | SCE-SRB-005 mg/Nm ³ | SCE-SRB-006 mg/Nm ³ | SEP-PE-047 mg/Nm ³ | SEP-PE-048 mg/Nm ³ | SAP-PE-162 mg/Nm ³ | SAP-PE-169 mg/Nm ³ | BL-ES-003/10 mg/Nm ³ | BL-ES-009/70 mg/Nm ³ | Oncology lab SRB-001 mg/Nm ³ | Oncology lab SRB-002 mg/Nm ³ | PFP-PE-269 mg/Nm ³ | PFPDS-PE-62 mg/Nm ³ | IFP-PE-24 mg/Nm ³ | Standard mg/Nm ³ |
|--------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|------------------------------------|------------------------------------|---|---|----------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Apr-23 | 1.27 | 1.52 | 1.65 | 1.18 | 1.05 | 1.22 | 1.36 | 1.55 | 1.12 | 1.07 | 1.44 | 1.28 | 1.27 | 1.5 | 0.95 | 1.1 | 0.81 | 35 |
| May-23 | 1.01 | 1.13 | 1.36 | 1.25 | 0.92 | 1.46 | 1.18 | 1.4 | 0.83 | 1.33 | 1.29 | 1.55 | 1.45 | 1.68 | 1.02 | 1.3 | 0.75 | 35 |
| Jun-23 | 1.27 | 1.06 | 1.13 | 1.21 | 0.85 | 1.15 | 1.02 | 0.97 | 1 | 1.25 | 1.32 | 1.4 | 1.33 | 1.37 | 0.81 | 1.2 | 1.09 | 35 |
| Jul-23 | 1.35 | 1.29 | 1.32 | 1.38 | 1.4 | 1.36 | 1.27 | 1.24 | 1.41 | 1.46 | 1.4 | 1.44 | 1.52 | 1.58 | 1.35 | 1.38 | 1.3 | 35 |
| Aug-23 | 1.32 | 1.25 | 1.28 | 1.36 | 1.34 | 1.31 | 1.23 | 1.2 | 1.35 | 1.38 | 1.33 | 1.37 | 1.42 | 1.46 | 1.37 | 1.4 | 1.32 | 35 |
| Sep-23 | 1.3 | 1.23 | 1.26 | 1.39 | 1.37 | 1.34 | 1.25 | 1.18 | 1.37 | 1.42 | 1.36 | 1.4 | 1.45 | 1.48 | 1.41 | 1.44 | 1.5 | 35 |

Trend Analysis of Process Stack Scrubber from April-2022 to September-2023

Ambient Air Quality Near Back Gate from April-2023 to September-2023

| Month | National Ambient Air Quality Standards of SPM 2.5 (m ³ /24hr) | PM 2.5 µg/m ³ | National Ambient Air Quality Standards of SPM 10.0 (m ³ /24hr) | PM 10.0 µg/m ³ | National Ambient Air Quality Standards of SO ₂ (m ³ /24hr) | SO ₂ µg/m ³ | National Ambient Air Quality Standards of NO ₂ (m ³ /24hr) | NO _x µg/m ³ | National Ambient Air Quality Standards of O ₃ (m ³ /24hr) | O ₃ µg/m ³ |
|--------|--|--------------------------|---|---------------------------|--|-----------------------------------|--|-----------------------------------|---|----------------------------------|
| Apr-23 | 60 | 29.5 | 100 | 77.7 | 80 | 7.4 | 80 | 18.1 | 180 | 3.8 |
| May-23 | 60 | 32.8 | 100 | 81.7 | 80 | 9.4 | 80 | 20.5 | 180 | 4.8 |
| Jun-23 | 60 | 27.3 | 100 | 75.4 | 80 | 8.3 | 80 | 17.4 | 180 | 2.7 |
| Jul-23 | 60 | 24.7 | 100 | 67.3 | 80 | 7.6 | 80 | 18.2 | 180 | 5.2 |
| Aug-23 | 60 | 25.3 | 100 | 69.5 | 80 | 9.4 | 80 | 20.5 | 180 | 6.3 |
| Sep-23 | 60 | 23.6 | 100 | 67.4 | 80 | 8.9 | 80 | 18.5 | 180 | 5.8 |

Ambient Air Quality Near Incinerator From April-2023 to September-2023



Ambient Air Quality Near Incinerator from April-2023 to September-2023

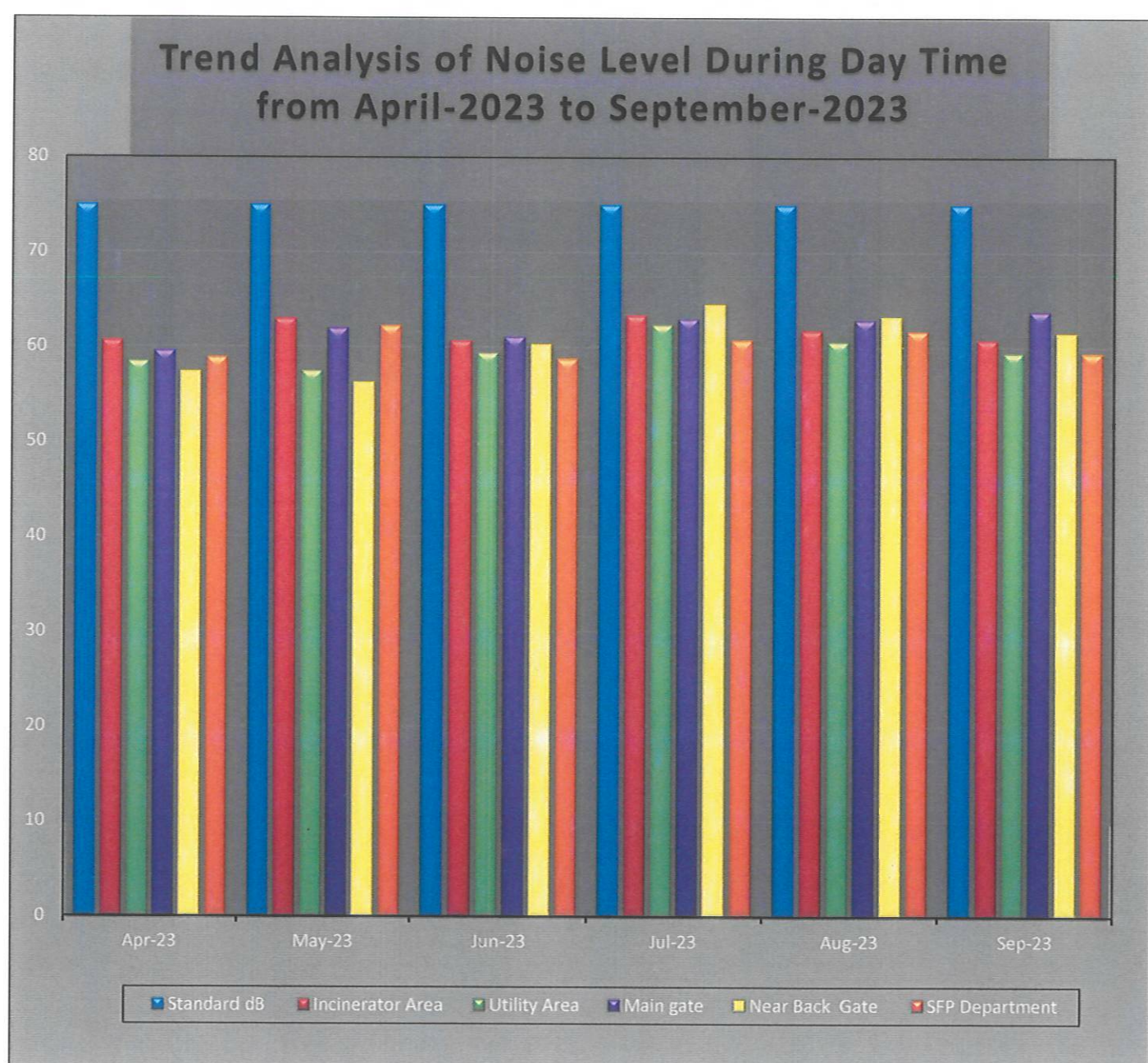
| Month | National Ambient Air Quality Standards of SPM 2.5 (m ³ /24hr) | PM 2.5 µg/m ³ | National Ambient Air Quality Standards of SPM 10.0 (m ³ /24hr) | PM 10.0 µg/m ³ | National Ambient Air Quality Standards of SO ₂ (m ³ /24hr) | SO ₂ µg/m ³ | National Ambient Air Quality Standards of NO ₂ (m ³ /24hr) | NO _x µg/m ³ | National Ambient Air Quality Standards of O ₃ (m ³ /24hr) | O ₃ µg/m ³ |
|--------|--|--------------------------|---|---------------------------|--|-----------------------------------|--|-----------------------------------|---|----------------------------------|
| Apr-23 | 60 | 26.7 | 100 | 73.3 | 80 | 9.1 | 80 | 20.5 | 180 | 4.8 |
| May-23 | 60 | 28.3 | 100 | 77.6 | 80 | 8.3 | 80 | 17.7 | 180 | 3.1 |
| Jun-23 | 60 | 24.5 | 100 | 73.1 | 80 | 7 | 80 | 14.6 | 180 | 4.8 |
| Jul-23 | 60 | 26.4 | 100 | 70.3 | 80 | 8.3 | 80 | 19.7 | 180 | 5.5 |
| Aug-23 | 60 | 27.2 | 100 | 72.5 | 80 | 10.3 | 80 | 22 | 180 | 6.8 |
| Sep-23 | 60 | 24.5 | 100 | 70.5 | 80 | 9.6 | 80 | 21.3 | 180 | 6.2 |

Ambient Air Quality Near Incinerator From April-2023 to September-2023



ANNEXURE-V – TREND ANALYSIS OF AMBIENT NOISE LEVELS

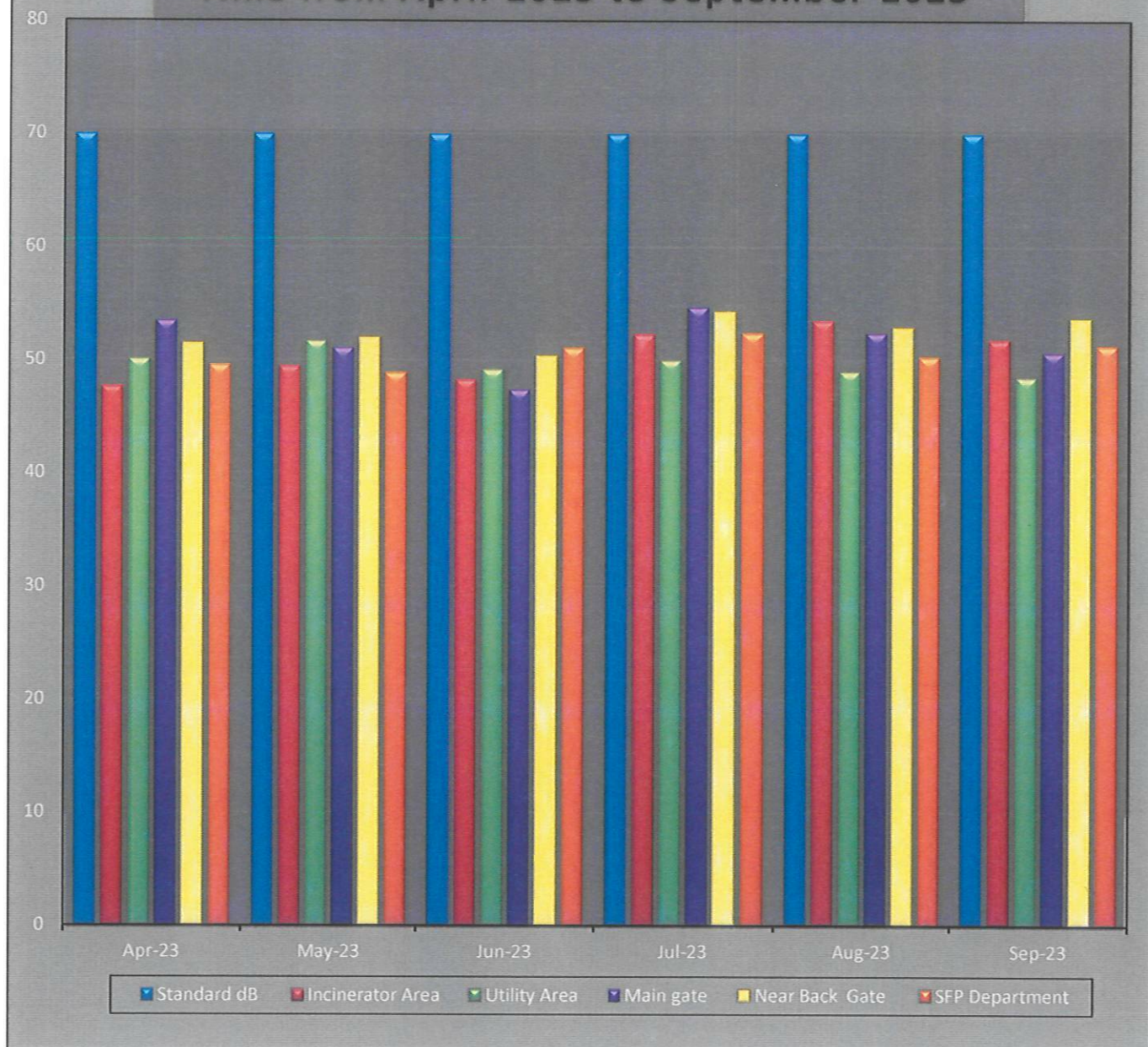
| Trend Analysis of Noise Level During Day Time from April-2023 to September-2023 | | | | | | |
|---|-------------|------------------|--------------|-----------|----------------|----------------|
| Month | Standard dB | Incinerator Area | Utility Area | Main gate | Near Back Gate | SFP Department |
| Apr-23 | 75 | 60.7 | 58.5 | 59.6 | 57.4 | 58.9 |
| May-23 | 75 | 63 | 57.5 | 62 | 56.3 | 62.3 |
| Jun-23 | 75 | 60.7 | 59.4 | 61.1 | 60.3 | 58.8 |
| Jul-23 | 75 | 63.4 | 62.4 | 63 | 64.5 | 60.8 |
| Aug-23 | 75 | 61.8 | 60.6 | 62.9 | 63.2 | 61.7 |
| Sep-23 | 75 | 60.8 | 59.4 | 63.8 | 61.5 | 59.4 |



Trend Analysis of Noise Level During Night-time from April-2023 to September-2023

| Month | Standard dB | Incinerator Area | Utility Area | Main gate | Near Back Gate | SFP Department |
|--------|-------------|------------------|--------------|-----------|----------------|----------------|
| Apr-23 | 70 | 47.7 | 50.1 | 53.5 | 51.5 | 49.6 |
| May-23 | 70 | 49.5 | 51.7 | 51.1 | 52 | 48.9 |
| Jun-23 | 70 | 48.3 | 49.2 | 47.4 | 50.4 | 51.1 |
| Jul-23 | 70 | 52.3 | 50 | 54.7 | 54.3 | 52.4 |
| Aug-23 | 70 | 53.5 | 49 | 52.4 | 52.9 | 50.3 |
| Sep-23 | 70 | 51.8 | 48.5 | 50.7 | 53.7 | 51.3 |

Trend Analysis of Noise Level During Night Time from April-2023 to September-2023



ANNEXURE-VI – ACKNOWLEDGMENT COPY APPROVAL OF EMERGENCY PLAN

OSEP BIOCON LIMITED CAMPUS



ONSITE EMERGENCY PLAN

BIOCON LIMITED

Licence Number: MYB 6083

**BIOCON LIMITED
20th KM HOSUR MAIN ROAD
ELECTRONIC CITY
BENGALURU-560100**

OSEP BIOCON LIMITED-CAMPUS

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OSEP BIOCON LIMITED-CAMPUS

| | | |
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OSEP BIOCON LIMITED-CAMPUS

39. ALL CLEAR SIGNAL:

Once the situation is brought under control, the emergency will be called off by the Site controller.
All clear decision will be given by site controller who had declared emergency to mitigate the same.

For Biocon Limited

Occupier/Factory Manager



ಕಾರ್ಖಾನೆ ಸಂರಕ್ಷಣೆ
ಕಾರ್ಖಾನೆಗಳು, ಬಾಂಧುರುಗಳು, ಕೈಗಾರಿಕಾ
ಸುರಕ್ಷತೆ ಮತ್ತು ಸ್ವಾಸ್ಥ್ಯ ಇಲಾಖೆ

ಕಾರ್ಖಾನೆ ಮತ್ತು ಬಾಂಧುರುಗಳ
ಸಿಬ್ಬಂದಿಗಳು (ಭೇರಿ, ಕಾರ್ಖಾನೆ ಭವನ,
2ನೇ ಗಾಂಧಿ, ಐ.ಟಿ.ಐ. ಕಾಲೇಜು ಆವರಣ,
ಬೆಂಗಳೂರು-29.

ಸಂಖ್ಯೆ:ಸಿಎಸ್ ಎಂ ಸಿ/ಎಂ ಎ ಹೆಚ್ ಸಿ/ಸಿಎಸ್ 52/44-23

ದಿನಾಂಕ : 17/10/2022

ಬಿಎಂಸಿ ಸಿ.ಆರ್. 84 ಕಾರ್ಖಾನೆಗಳ ಸುರಕ್ಷತೆ ಕಾರ್ಖಾನೆ
ಆನ್ ಸೈಟ್ ಎಮರ್ಜೆನ್ಸಿ ಪ್ರತಿಕ್ರಿಯೆ, ಈ ಕಛೇರಿ ಸಮಸಂಖ್ಯೆ.


ದಿನಾಂಕ : 17/10/2022 ರಂದು ಅನುಮೋದಿಸಿದೆ,

ನಿರ್ದೇಶಕರು,

ಕಾರ್ಖಾನೆಗಳು, ಬಾಂಧುರುಗಳು, ಕೈಗಾರಿಕಾ ಸುರಕ್ಷತೆ

ಮತ್ತು ಸ್ವಾಸ್ಥ್ಯ ಇಲಾಖೆ, ಬೆಂಗಳೂರು 2

ANNEXURE-VII - CER REPORT



INDIA NON JUDICIAL

Government of Karnataka


सत्यमेव जयते

Rs. 200

e-Stamp

| | |
|----------------------------------|---|
| Certificate No. | : IN-KA35408780113541S |
| Certificate Issued Date | : 01-Oct-2020 03:50 PM |
| Account Reference | : NONACC (FI)/ kacrs/08/ SHANTHINAGAR/KA-BA |
| Unique Doc. Reference | : SUBIN-KAKACHSFL0867213891211648S |
| Purchased by | : BANGALORE METRO RAIL CORPORATION LIMITED |
| Description of Document | : Article 37 Note or Memorandum |
| Description | : MEMORANDUM OF UNDERSTANDING |
| Consideration Price (Rs.) | : 0 (Zero) |
| First Party | : BANGALORE METRO RAIL CORPORATION LIMITED |
| Second Party | : BIOCON FOUNDATION |
| Stamp Duty Paid By | : BANGALORE METRO RAIL CORPORATION LIMITED |
| Stamp Duty Amount (Rs.) | : 200 (Two Hundred only) |

सत्यमेव जयते



RS. 200

01-OCT-2020 03:50 PM

Please write or type below this line

MEMORANDUM OF UNDERSTANDING


This Memorandum Of Understanding (MoU) is entered into on this the 08th day of October, 2020 at Bengaluru;

BETWEEN

BANGALORE METRO RAIL CORPORATION LIMITED (BMRL), a Company registered/incorporated under the provisions of the Companies Act, 1956 and having its registered

Statutory Alert:

1. The authenticity of the Stamp certificate should be verified at 'www.shoestamp.com' or using the Stamp Mobile App or Shook Holding.
2. Any discrepancy in details on the certificate and as available on the website / Mobile App renders it invalid.
3. The onus of checking the authenticity lies on the users of the certificate.
3. In case of any discrepancy, please inform the Competent Authority.



office at 3rd Floor, BMTC Complex, K.H.Road, Shantinagar, Bengaluru – 560027 represented herein by its Managing Director Mr. Ajay Seth, IAS (herein after referred to as the '**First Party**' which expression shall mean and include its Successors – in – Interest, Administrators, Executors, Legal Representatives and Assigns) of the one part;

AND

BIOCON FOUNDATION, a registered charitable trust, settled in terms of Trust Deed dated December 1, 2004, having its office at "Glenmore", Huskur Gate, off 20th KM, Hosur Road, Electronics City P.O., Bangalore (herein after referred to as the '**Second Party**' which expression shall mean and include its Successors – in Interest, Administrators, Executors, Legal Representatives and Assigns) of the other part represented herein by its authorised signatory Ms. Kiran Mazumdar Shaw.

Both the First Party and the Second Party are individually referred to herein as the "Party" and collectively referred to as the "Parties."

WHEREAS:

- A. The First Party is a 50:50 Joint Venture Company of Government of Karnataka and Government of India, formed for the purpose of implementing the Bangalore Metro Rail Project to provide efficient and sustainable mobility system in Bengaluru City is currently in the process of executing Phase – II of Bangalore Metro Rail Project thereby connecting Bengaluru city with the Urban and Rural areas situated in its vicinity (herein after referred to as the Project);
- B. As part of Phase – II of the Project, the First Party is undertaking construction of a new line i.e. Reach-5 from R.V. Road to Bommasandra totally measuring a length of 18.82 km from R.V. Road to Bommasandra, at a total cost of Rs.5,744 crores;
- C. The First Party being tasked with the mandate of providing "efficient and sustainable mobility system" and thereby "ensuring environmental sustainability" in Bengaluru City would like to partner with companies and organisations desiring to support "environmental sustainability".
- D. Biocon Foundation, the Corporate Social Responsibility arm of Biocon Group, is engaged in providing and promoting the welfare and well-being of the public at large in the fields of education, healthcare, environmental sustainability, women's empowerment, rural development, disaster relief and others.
- E. In response to the above proposal of the First Party, the Second Party has expressed its interest in funding certain activities in the construction of the proposed **Hebbagodi Metro Station** situated at Hosur Road, subject to the broad terms and conditions as set out in this MOU and subsequent definitive agreements.



2

NOW THEREFORE THIS MEMORANDUM OF UNDERSTANDING WITNESSETH AS UNDER:

1. The Second Party has expressed its interest to participate in funding the Metro Station constructed at Hebbagodi as part of the RV Road to Bommasandra line (Reach 5 of the Project) subject to the terms contained in this MoU and the subsequent definitive agreements to be executed by and between the Parties pursuant to these terms ("Definitive Agreements"). The Second Party agrees to provide a capital grant to an extent of INR 65,00,00,000/- (INR Sixty Five Crore only) (hereinafter "Capital Grant") for the naming rights of the Metro Station at Hebbagodi as part of the RV Road to Bommasandra line metro project as specified in this MoU.
2. The First Party gives warranty to the Second Party that it has obtained approval from Ministry of Corporate Affairs to receive CSR funds for construction of metro station vide Ministry of Corporate Affairs, Memo F. No. 10/06/2019 – CSR (Annexure-I).
3. Notwithstanding the Capital Grant by Second Party, First Party shall be owner of the assets. The provision of the Capital Grant shall not give any ownership or usage rights to Second Party in the Project Facilities.
4. The said amount of INR 65,00,00,000/- (Rupees Sixty Five Crores only) will be paid by the Second Party to the First Party, as per the timelines mentioned hereinafter:

| Year | Amount (INR Cr) |
|--------------|-----------------|
| October 2020 | 5.0 |
| April 2021 | 8.0 |
| April 2022 | 10.0 |
| April 2023 | 12.0 |
| April 2024 | 14.0 |
| April 2025 | 16.0 |
| Total | 65.0 |

5. Accordingly and in terms of the above understanding, the Second Party has paid a sum of INR 5,00,00,000/- (INR Five crore only) vide cheque dated 06th October, 2020 bearing No.001529, drawn on HDFC Bank to the First Party receipt whereof is acknowledged by First Party. The further sums to be paid shall be transferred by Second Party to the account of First Party either by cheque/ bank transfer, the details of which are mentioned below:

If made by wire transfer, payment will be wired to:

Name : Bangalore Metro Rail Corporation Limited
A/c No. : 31164006696
Bank : State Bank of India
Branch : Hudson Circle Branch
IFSC Code: SBIN0004196



If made through cheque:

Payee : Bangalore Metro Rail Corporation Limited

A/c No.: 31164006696

Acknowledgment of receipt will be sent to:

Biocon Foundation

"Glenmore", Huskur Gate, off 20th KM,

Hosur Road, Electronics City P.O.,

Bangalore 560100, Karnataka

6. The First Party will construct a foot overbridge ("FOB") connecting unpaid area of the Station concourse to other side of Hosur Road to provide access to metro commuters and general public. The First Party shall also undertake other station access infrastructure such as footpath improvement on either side of the station upto 500 meters distance.
7. The construction of the civil structure, Mechanical, Electrical and Plumbing ("MEP") and other technical works of the station, FOB and station access infrastructure shall be carried out by the First Party.
8. The First Party recognizing the contribution of the Second Party to the society will approach Government of Karnataka jointly with the Second Party for naming of Hebbagodi Metro Station as "*Biocon Hebbagodi Metro Station*" ("Station") or any other suitable name suggested by the Second Party for approval under Article 154 of the Constitution of India.
9. On issue of Government Order by the Government of Karnataka under Article 154 of the Constitution of India,
 - i. BMRCL shall name the Hebbagodi metro station as discussed herein above, with the prior approval of the requisite department of the State Government for a period of 30 years from the date of full commissioning of the metro line.
 - ii. BMRCL shall use the above- mentioned name at all station-name display boards at this Station, in announcements in the trains approaching the station, in metro network maps displayed at other stations and in trains, in its brochures meant for the commuters, in the relevant information on its website, and in this communication with external stakeholders.
 - iii. BMRCL shall display the logo of Second Party at such station-name display boards at this station, which carry the logo of BMRCL.
10. The Parties shall fulfil their respective obligations/conditions under this memorandum of Understanding within the timelines stipulated herein.
11. **AMENDMENT:**
All amendments/alterations to this Memorandum of Understanding shall be valid and operative only if recorded in writing and signed by both Parties, as an addendum to this MOU.



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12. CONFIDENTIALITY:

The Parties shall maintain as confidential the terms of this Memorandum of Understanding. Any information and / or contents of documents made available by a Party hereto to the other shall not be disclosed to any other person(s) without the prior written consent of such Party except to the extent required to be made to their consultants/Advocates or to the Public Authorities required to be provided as per the Applicable laws.

13. GOVERNING LAW AND DISPUTE RESOLUTION:

The laws of the Republic of India shall govern this MoU and the Definitive Agreements. In case of any dispute or differences between the Parties arising out of or in connection with this MoU or its performance, a sole arbitrator to be mutually appointed by both the Parties, including the interpretation thereof and any non-contractual obligations shall be referred to arbitration. The arbitration shall be conducted in English and the seat and venue of arbitration shall be Bengaluru, India

14. DUPLICATE SETS:

This Memorandum of Understanding is executed in duplicate and the First Party and the Second Party shall retain one set each, both of which shall be considered as one and the same.

IN WITNESS WHEREOF, the Parties through their duly authorised representatives have executed this Memorandum of Understanding on the day and date written above.

The First Party
For Bangalore Metro Rail Corporation Limited

The Second Party
For Biocon Foundation



Name: Ajay Seth, IAS

Title: Managing Director

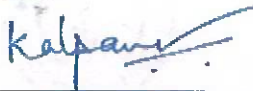
AJAY SETH, IAS

Managing Director

Bangalore Metro Rail Corporation Ltd,
3rd Floor, BMTG Complex, K.H. Road,
Shanthi Nagar, Bengaluru - 560 027

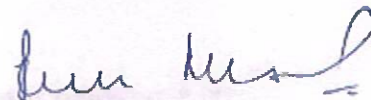
Witnesses:

1.



Name: KALPANA KATARIA

Address: Executive Director
BMRC L



Name: Kiran Mazumdar Shaw

Title: Managing Trustee



2.




Name: PRATIMA RAO

Address: MISSION DIRECTOR
BIOCON FOUNDATION
20TH KM HOSUR ROAD
BENGALURU 560 100

ANNEXURE - I

Ministry of Corporate Affairs, Memo F. No. 10/06/2019 – CSR; Funding of Metro Station permitted as CSR.

22/07/2020 (MRTS-COORD)



F.No.10/06/2019-CSR
Government of India
Ministry of Corporate Affairs
'A' Wing, 5th Floor, Shastri Bhawan
Dr. R.P. Road, New Delhi-110001
22nd January, 2020

OFFICE MEMORANDUM

Subject: Request to include 'Sustainable Urban Development and Urban Transport' in the list of CSR activities listed in Schedule VII of Companies Act.


The undersigned is directed to refer to D.O. No. K-14011/8/2018-MRTS-Coord dated 06.12.2019 on the subject and to state that Schedule VII of Companies Act, 2013 (Act) enlists the areas or subjects which a company may undertake as CSR activities. Item no. (iv) of Schedule VII inter alia provides for "ensuring environmental sustainability". The items enlisted in Schedule VII are broad based and intended to cover a wide range of activities. General Circular dated 18.06.2014 clarifies that Schedule VII entries be interpreted liberally to capture the essence of the subjects enumerated therein. Accordingly, companies may undertake CSR project related to urban transport. However, CSR funds cannot be used for plugging the viability gap for commercial projects.


2. It is further informed that the High Level Committee on CSR (HLC-2018) constituted by this Ministry has also recommended that Schedule VII of the Act be mapped and aligned with Sustainable Development Goals (SDGs) to develop a SDG+ framework.

3. This issues with approval of Competent Authority.

(Aparna Mudiam)
Deputy Director
011-23070216

To,
Shri. Durga Shanker Mishra,
Secretary,
Ministry of Housing and Urban Affairs,
Room No. 122, 'C' wing, Nirman Bhawan
New Delhi-110011.





**ANNEXURE-VIII – ENVIRONMENTAL POLICY DULY APPROVED BY THE BOARD OF
DIRECTORS BOARD RESOLUTION**



Syngene



The Biocon Group, an integrated Biopharmaceutical enterprise, is committed to high standards and continual improvement in the areas of Environment, Occupational Health, Safety and Sustainability (EHSS).

We shall strive to achieve this by :

- Complying with all applicable laws, regulations, legal requirements and other requirements in all countries in which the company operates.
- Ensuring protection of environment and prevention of pollution at all levels of operations.
- Providing safe and healthy working environment for our employees, contract workmen, visitors and other stakeholders by eliminating hazards and reducing occupational health and safety risks to prevent work-related injury and ill-health.
- Empowering employees and contract workmen through training programs that are focused on operational safety, occupational health and environmental protection.
- Ensuring a sustainable value chain by building a network of responsible business partners committed to environmental stewardship across the product life cycle starting from sourcing of raw materials to manufacturing and distribution of our products.
- Adopting energy conservation, reduction of waste through recovery, recycle and reuse, mitigation of climate change risks and threats to biodiversity in all process operations thereby integrating sustainability into our business operations.
- Providing the framework and resources for setting, reviewing and achieving Environment, Health, Safety and Sustainability objectives & targets. Continually evaluating and improving Environment, Health, Safety and Sustainability performance through compliance, periodic audits and effective documentation.
- Adopting best practices in Environment, Health, Safety and Sustainability through continual improvements in EHSS management system that pursues the latest developments in this area.
- Using effective communication, consultation and participation of employees and contract workmen to maintain highest standards of Environment, Health, Safety and Sustainability.

The Biocon Group management is committed towards implementation of the EHSS policy. This policy is applicable to all businesses, employees and contract workmen of all entities of the Biocon Group.

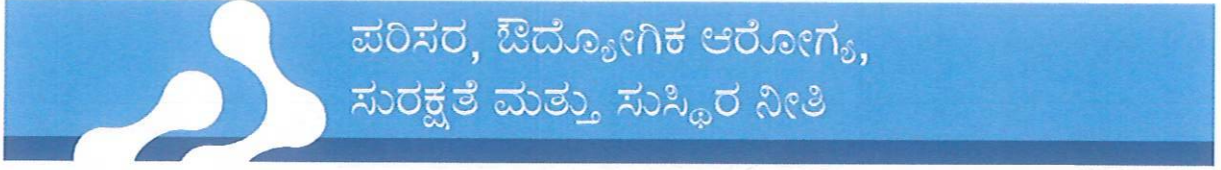
Kiran Mazumdar Shaw
Chairperson & Managing Director

Date: 21-08-2019
V: 007

Emergency Contact No. 2000



Syngene



ಬಯೋಕಾನ್ ಗ್ರೂಪ್ ಒಂದು ಕ್ರೋಢೀಕೃತ ಬಯೋಫಾರ್ಮಾಸುಟಿಕಲ್ ಸಂಸ್ಥೆಯಾಗಿದ್ದು, ಪರಿಸರ, ಔದ್ಯೋಗಿಕ ಆರೋಗ್ಯ, ಸುರಕ್ಷತೆ ಮತ್ತು ಸುಸ್ಥಿರ ನೀತಿ (ಇಎಚ್‌ಎಸ್‌ಎಸ್) ವಲಯದಲ್ಲಿ ಉನ್ನತ ಗುಣಮಟ್ಟದ ಮತ್ತು ನಿರಂತರ ಸುಧಾರಣೆಗೆ ಬದ್ಧವಾಗಿದೆ.

ಈ ಮೂಲಕ ನಾವು ಈ ಸಾಧನೆಗಳನ್ನು ಮಾಡಲು ಯತ್ನಿಸುತ್ತಿದ್ದೇವೆ,

- ಕಂಪನಿ ಕಾರ್ಯನಿರ್ವಹಣೆ ಮಾಡುವ ಎಲ್ಲ ದೇಶಗಳಲ್ಲಿ ಎಲ್ಲ ಆಸ್ತಿಯ ಕಾನೂನುಗಳು, ನಿಯಮಾವಳಿಗಳು, ಕಾನೂನು ಅಗತ್ಯಗಳು ಮತ್ತು ಇತರ ಅಗತ್ಯಗಳಿಗೆ ಬದ್ಧವಾಗುವುದು.
- ಕಾರ್ಯನಿರ್ವಹಣೆಯ ಎಲ್ಲ ಹಂತಗಳಲ್ಲಿ ಪರಿಸರ ರಕ್ಷಣೆ ಮತ್ತು ಮಾಲಿನ್ಯ ತಡೆಯನ್ನು ಖಚಿತಪಡಿಸುವುದು.
- ಆವಾಯಗಳನ್ನು ನಿರ್ಮೂಲಗೊಳಿಸಿ ಮತ್ತು ಔದ್ಯೋಗಿಕ ಆರೋಗ್ಯ ಮತ್ತು ಸುರಕ್ಷತಾ ರಿಸ್ಕ್ ಕಡಿಮೆ ಮಾಡಿ ಕೆಲಸ ಸಂಬಂಧಿ ಗಾಯ ಮತ್ತು ಆನಾರೋಗ್ಯವನ್ನು ತಡೆಯುವ ಮೂಲಕ ನಮ್ಮ ಉದ್ಯೋಗಿಗಳು, ಒಪ್ಪಂದದ ಕೆಲಸಗಾರರು, ಸಂದರ್ಶಕರು ಮತ್ತು ಇತರ ಪಾಲುದಾರರಿಗೆ ಸುರಕ್ಷಿತ ಮತ್ತು ಆರೋಗ್ಯಕರ ಕೆಲಸದ ಪರಿಸರವನ್ನು ಒದಗಿಸುವುದು.
- ಕಾರ್ಯನಿರ್ವಹಣೆ ಸುರಕ್ಷತೆ, ಔದ್ಯೋಗಿಕ ಆರೋಗ್ಯ ಮತ್ತು ಪರಿಸರ ರಕ್ಷಣೆಯ ಮೇಲೆ ಗಮನ ಕೇಂದ್ರೀಕರಿಸಿದ ತರಬೇತಿ ಕಾರ್ಯಕ್ರಮಗಳ ಮೂಲಕ ಉದ್ಯೋಗಿಗಳು ಮತ್ತು ಒಪ್ಪಂದದ ಕೆಲಸಗಾರರನ್ನು ಸಜ್ಜುಗೊಳಿಸುವುದು.
- ಕಚ್ಚಾ ಸಾಮಗ್ರಿಗಳ ಖರೀದಿಯಿಂದ ಆರಂಭಿಸಿ ನಮ್ಮ ಉತ್ಪನ್ನಗಳ ಉತ್ಪಾದನೆ ಮತ್ತು ವಿತರಣೆಯ ಎಲ್ಲ ಉತ್ಪನ್ನ ಜೀವಿತಾವಧಿಯಲ್ಲಿ ಪರಿಸರ ರಕ್ಷಣೆಗೆ ಬದ್ಧವಾದ ಜವಾಬ್ದಾರಿಯುತ ಪರಿವಾಟು ಪಾಲುದಾರರ ಜಾಲವನ್ನು ನಿರ್ಮಿಸುವ ಮೂಲಕ ಸುಸ್ಥಿರವಾಗಿ ವ್ಯಾಪ್ತಿ ಜೈನ್ ಅನ್ನು ನಿರ್ಮಿಸಲು ಬದ್ಧವಾಗಿರುವುದು.
- ಇಂಧನ ಸಂರಕ್ಷಣೆ, ರಿಕವರಿ, ರಿಸೈಕಲ್ ಮತ್ತು ಮರುಬಳಕೆ ಮೂಲಕ ತ್ಯಾಜ್ಯವನ್ನು ಕಡಿಮೆ ಮಾಡುವುದು, ಹವಾಮಾನ ವೈಪರೀತ್ಯದ ರಿಸ್ಕ್‌ಗಳನ್ನು ನಿವಾರಿಸುವುದು ಮತ್ತು ಎಲ್ಲ ಪ್ರಕ್ರಿಯೆ ಕಾರ್ಯನಿರ್ವಹಣೆಗಳಲ್ಲಿ ಜೈವಿಕ ವೈವಿಧ್ಯಕ್ಕೆ ಇರುವ ರಿಸ್ಕ್‌ಗಳನ್ನು ನಿವಾರಿಸಿ ನಮ್ಮ ಪರಿವಾಟು ಕಾರ್ಯನಿರ್ವಹಣೆಯಲ್ಲಿ ಸುಸ್ಥಿರತೆಯನ್ನು ಅಳವಡಿಸಿಕೊಳ್ಳುವುದು.
- ಪರಿಸರ, ಆರೋಗ್ಯ, ಸುರಕ್ಷತೆ ಮತ್ತು ಸುಸ್ಥಿರ ಉದ್ಯೋಶಗಳು ಮತ್ತು ಗುರಿಗಳನ್ನು ಸಾಧಿಸಲು, ನಿಗದಿಸಲು ಮತ್ತು ಮರುಪರಿಶೀಲಿಸಲು ರೂಪುರೇಷೆ ಮತ್ತು ಸಂಪನ್ಮೂಲಗಳನ್ನು ಒದಗಿಸುವುದು. ಬದ್ಧತೆ, ಸಕಾಲಿಕ ಆಡಿಟ್ ಮತ್ತು ಪರಿಣಾಮಕಾರಿ ದಾಖಲೆಗಳ ಮೂಲಕ ಪರಿಸರ, ಆರೋಗ್ಯ, ಸುರಕ್ಷತೆ ಮತ್ತು ಸುಸ್ಥಿರತೆಯನ್ನು ನಿರಂತರವಾಗಿ ಮೌಲೀಕರಿಸುವುದು ಮತ್ತು ಸುಧಾರಿಸುವುದು.
- ಪರಿಸರ, ಆರೋಗ್ಯ, ಸುರಕ್ಷತೆ ಮತ್ತು ಸುಸ್ಥಿರತೆ ವಲಯದಲ್ಲಿ ಇತ್ತೀಚಿನ ಬೆಳವಣಿಗೆಗಳನ್ನು ಅಧ್ಯಯನ ನಡೆಸುವ ಇಎಚ್‌ಎಸ್‌ಎಸ್ ಆಡಳಿತ ವ್ಯವಸ್ಥೆಯಲ್ಲಿ ನಿರಂತರ ಸುಧಾರಣೆಯ ಮೂಲಕ ಈ ಪ್ರದೇಶದಲ್ಲಿನ ಉತ್ತಮ ಅಭ್ಯಾಸಗಳನ್ನು ಅಳವಡಿಸಿಕೊಳ್ಳುವುದು.
- ಉನ್ನತ ಗುಣಮಟ್ಟದ ಪರಿಸರ, ಆರೋಗ್ಯ, ಸುರಕ್ಷತೆ ಮತ್ತು ಸುಸ್ಥಿರತೆಯನ್ನು ನಿರ್ವಹಿಸಲು ಉದ್ಯೋಗಿಗಳು ಮತ್ತು ಒಪ್ಪಂದದ ಕೆಲಸಗಾರರೊಂದಿಗೆ ಪರಿಣಾಮಕಾರಿ ಸಂವಹನ, ಸಲಹೆ ಮತ್ತು ತೊಡಗಿಸಿಕೊಳ್ಳುವಿಕೆಯನ್ನು ಬಳಸುವುದು.

ಇಎಚ್‌ಎಸ್‌ಎಸ್ ನೀತಿಯ ಅನುಷ್ಠಾನಕ್ಕೆ ಬಯೋಕಾನ್ ಗ್ರೂಪ್ ಆಡಳಿತವು ಬದ್ಧವಾಗಿದೆ. ಈ ನೀತಿಯು ಬಯೋಕಾನ್ ಗ್ರೂಪ್ ಎಲ್ಲ ಸಂಸ್ಥೆಗಳ ಎಲ್ಲ ಪರಿವಾಟುಗಳು, ಉದ್ಯೋಗಿಗಳು ಮತ್ತು ಒಪ್ಪಂದದ ಕೆಲಸಗಾರರಿಗೆ ಅನ್ವಯಿಸುತ್ತದೆ.

ಕಿರಣ್ ಮಜುಂದಾರ್ ಪಾ
ಜೀವಕಾನ್ ಮತ್ತು ವ್ಯವಸ್ಥಾಪಕ ನಿರ್ದೇಶಕರು

ದಿನಾಂಕ: 21-08-2019

ಆವೃತ್ತಿ: 007

ತುರ್ತು ಸಂಪರ್ಕ ಸಂಖ್ಯೆ: 2000

ANNEXURE-IX – ISO CERTIFICATE ON ENVIRONMENT MANAGEMENT SYSTEM**CERTIFICATE**

Management system as per
ISO 14001 : 2015

The Certification Body TÜV NORD CERT GmbH hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

BIOCON LIMITED
20th KM, Hosur Road, Electronic City,
Bengaluru - 560 100, Karnataka,
India
with the locations according to the annex



operates a management system in accordance with the requirements of ISO 14001 : 2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope -

Development, Manufacture and Distribution of Biopharmaceuticals

Certificate Registration No. 04 104 047323
Audit Report No. 2,5-0324/93

Valid from 30.11.2022
Valid until 29.11.2025
Initial certification 22.12.2004

Certification Body
at TÜV NORD CERT GmbH

Mumbai, 28.11.2022

TÜV NORD CERT GmbH

Am TÜV 1

45307 Essen

www.tuv-nord-cert.com

TUV India Pvt. Ltd., 801, Raheja Plaza – 1, L.B.S. Marg,

Ghatkopar (W), Mumbai - 400 086, India www.tuv-nord.com/in



ANNEXURE-X – NEWSPAPER ADVERTISINGPublished in Kannada daily Vijayavani on 01.07.2021.

ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್
CIN: L24234KA1978PLC003417
ನೋಂದಾಯಿತ ಕಛೇರಿ: 20ನೇ ಕಿ.ಮೀ, ಹೊಸೂರು ರಸ್ತೆ, ಎಲೆಕ್ಟ್ರಾನಿಕ್ ಸಿಟಿ, ಬೆಂಗಳೂರು,
ಕರ್ನಾಟಕ - 560 100. ದೂರವಾಣಿ: 91 80 2808 2808; ಫ್ಯಾಕ್ಸ್: 91 80 2852 3423.
Email: co.secretary@blocon.com; Website: www.blocon.com

ಸಾರ್ವಜನಿಕ ಸೂಚನೆ

ಸಾರ್ವಜನಿಕರಿಗೆ ಈ ಮೂಲಕ ತಿಳಿಸುವುದೇನೆಂದರೆ ಎಸ್‌ಇಐಎಎ (ರಾಜ್ಯ ಮಟ್ಟದ ಪರಿಸರ ಅಂದಾಜೇಕರಣ ಪ್ರಾಧಿಕಾರ) ಇವರು ಮೆ: ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್, ಫೈಲ್ ನಂ: ಎಸ್‌ಇಐಎಎ 70 ಐಎನ್‌ಡಿ 2020 ದಿನಾಂಕ 19.06.2021 ರಲ್ಲಿ ಅವರ ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್ ಹೆಸರಿನ ವಿಸ್ತರಣೆ ಘಟಕವನ್ನು ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್, 20ನೇ ಕಿ.ಮೀ, ಹೊಸೂರು ರಸ್ತೆ, ಎಲೆಕ್ಟ್ರಾನಿಕ್ ಸಿಟಿ ಪೋಸ್ಟ್, ಬೆಂಗಳೂರು ನಗರ ಜಿಲ್ಲೆ, ಕರ್ನಾಟಕ ರಾಜ್ಯ-560100, ಇಲ್ಲಿ ಸ್ಥಾಪಿಸಲು ಪರಿಸರ ವಿಮೋಚನಾ ತಿದ್ದುಪಡಿ ಮಾಡಲಾದ ಪತ್ರವನ್ನು ನೀಡಿರುತ್ತಾರೆ. ಈ ಪರಿಸರದ ವಿಮೋಚನಾ ಪತ್ರವನ್ನು ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಟ್ಟದ ಪರಿಸರ ಅಂದಾಜೇಕರಣ ಪ್ರಾಧಿಕಾರದ ವೆಬ್‌ಸೈಟ್ (<http://seiaa.karnataka.gov.in>) & MoEF & CC (<http://environmentclearance.nic.in>) ಇಲ್ಲಿ ನೋಡಬಹುದಾಗಿದೆ ಹಾಗೂ ಈ ಪತ್ರದ ಪ್ರತಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿಯಲ್ಲೂ ಲಭ್ಯವಿರುತ್ತದೆ.

Published on English daily Financial Express on 01.07.2021.

Blocon Limited
CIN: L24234KA1978PLC003417
Registered Office: 20th KM, Hosur Road, Electronic City, Bengaluru,
Karnataka - 560100, T: 91 80 2808 2808; F: 91 80 2852 3423
Email: co.secretary@blocon.com; Website: www.blocon.com

PUBLIC NOTICE

This is to inform the public that the SEIAA (State Level Environment Impact Assessment Authority) has issued Amended Environmental Clearance to M/s. Biocon Limited. File no. SEIAA 70 IND 2020 dated 19.06.2021 for its expansion of manufacturing capacity at Biocon Limited, 20th km, Hosur Road, Electronic City Post, Bengaluru Urban District, Karnataka State - 560100.

The Environmental Clearance issued by SEIAA is available in the official website of SEIAA, Karnataka (<http://seiaa.karnataka.gov.in>) & MoEF & CC (<http://environmentclearance.nic.in>) and copies are available with the State Pollution Control Board.

Published in Kannada daily newspaper Vijayavani on 22.09.2022.

ವಿಜಯವಾಣಿ

ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್
CIN: L24234KA1978PLC003417
ನೋಂದಾಯಿತ ಕಛೇರಿ: 20ನೇ ಕಿ.ಮೀ. ಹೊಸೂರು ರಸ್ತೆ, ಎಲೆಕ್ಟ್ರಾನಿಕ್ ಸಿಟಿ, ಬೆಂಗಳೂರು,
ಕರ್ನಾಟಕ - 560 100. ದೂರವಾಣಿ: 91 80 2808 2808; ಫ್ಯಾಕ್ಸ್: 91 80 2852 3423.
Email: co.secretary@biocon.com; Website: www.biocon.com

ಸಾರ್ವಜನಿಕ ಸೂಚನೆ

ಸಾರ್ವಜನಿಕರಿಗೆ ಈ ಮೂಲಕ ತಿಳಿಸುವುದೇನೆಂದರೆ ಎಸ್‌ಇಐಎಎ (ರಾಜ್ಯ ಮಟ್ಟದ ಪರಿಸರ ಅಂದಾಜೀಕರಣ ಪ್ರಾಧಿಕಾರ) ಇವರು ಮೆ: ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್, ಫೈಲ್ ನಂ: ಎಸ್‌ಇಐಎಎ 63 ಐಎನ್‌ಡಿ 2021 ದಿನಾಂಕ 23.08.2022 ರಲ್ಲಿ ಅವರ ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್ ಹೆಸರಿನ ವಿಸ್ತರಣೆ ಘಟಕವನ್ನು ಬಯೋಕಾನ್ ಲಿಮಿಟೆಡ್, 20ನೇ ಕಿ.ಮೀ. ಹೊಸೂರು ರಸ್ತೆ, ಎಲೆಕ್ಟ್ರಾನಿಕ್ ಸಿಟಿ ಫೋರ್ಸ್, ಬೆಂಗಳೂರು ನಗರ ಜಿಲ್ಲೆ, ಕರ್ನಾಟಕ ರಾಜ್ಯ-560100, ಇಲ್ಲಿ ಸ್ಥಾಪಿಸಲು ಪರಿಸರ ವಿಮೋಚನ ತಿದ್ದುಪಡಿ ಮಾಡಲಾದ ಪತ್ರವನ್ನು ನೀಡಿರುತ್ತಾರೆ.

ಈ ಪರಿಸರದ ವಿಮೋಚನಾ ಪತ್ರವನ್ನು ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಟ್ಟದ ಪರಿಸರ ಅಂದಾಜೀಕರಣ ಪ್ರಾಧಿಕಾರದ ವೆಬ್‌ಸೈಟ್ (<http://seiaa.karnataka.gov.in>) & MoEF & CC (<http://environmentclearance.nic.in>) ಇಲ್ಲಿ ನೋಡಬಹುದಾಗಿದೆ ಹಾಗೂ ಈ ಪತ್ರದ ಪ್ರತಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿಯಲ್ಲೂ ಲಭ್ಯವಿರುತ್ತದೆ.

Bengaluru Edition
Sep 22, 2022 Page No. 2
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Published in English daily newspaper Financial Express on 22.09.2022.

Biocon Limited
CIN: L24234KA1978PLC003417
Registered Office: 20th KM, Hosur Road, Electronic City, Bengaluru,
Karnataka - 560100, T: 91 80 2808 2808; F: 91 80 2852 3423
Email: co.secretary@biocon.com; Website: www.biocon.com

PUBLIC NOTICE

This is to inform the public that the SEIAA (State Level Environment Impact Assessment Authority) has issued Environmental Clearance to M/s. Biocon Limited. File no. SEIAA 63 IND 2021 dated 23.08.2022 for its expansion of manufacturing capacity at Biocon Limited, 20th km, Hosur Road, Electronic City Post, Bengaluru Urban District, Karnataka State - 560100.

The Environmental Clearance issued by SEIAA is available on the official website of SEIAA, Karnataka (<http://seiaa.karnataka.gov.in>) & MoEF & CC (<http://environmentclearance.nic.in>) and copies are available with the State Pollution Control Board.

**ANNEXURE-XI – ACKNOWLEDEMENT COPY OF COMMUNICATION LETTER TO
OTHER GOVERNMENT LOCAL BODIES**

Ref: BIL/EHS/22/09/03
Date: 08/09/2022



To,

The Commissioner,
Hebbagodi City Municipal Corporation,
Anekal Taluk,
Bengaluru – 560099

Biocon Limited
20th KM Hosur Road
Electronics City
Bangalore 560 100, India
T 91 80 2808 2808
F 91 80 2852 3423
CIN : L24234KA1978PLC003417

www.biocon.com

Dear Sir,

Sub: Expansion & Modification of Existing products Capacity and proposed New Additional Products of Biopharmaceutical Manufacturing unit at Sy. Nos. 46/1, 16/2, 47/3, 48/ 6, 44/1, 44/2, 44/3B., 44/3A, 47/1, 47/2 49/1, 49/2,47/4,31,32, & 47/3B, Hebbagodi CMC, Anekal, Bengaluru Urban By M/s Biocon Limited - Issue of Environmental Clearance - Reg.

Ref: Letter no: SEIAA 63 IND 2021 dated:23.08.2022

With reference to the above subject, would like to bring to your kind notice that we have received Environmental Clearance from State Level Environment Impact Assessment Authority-Karnataka for Expansion & Modification of Existing products Capacity and proposed New Additional Products of Biopharmaceutical Manufacturing unit for M/s Biocon Limited-20th KM, Hosur Road, Electronic City, Bengaluru-560100. The copy of the EC report is enclosed.

This is for your information & kindly request you to acknowledge the same.

Thanking you,

Yours sincerely
For Biocon Limited


Authorized Signatory



D/C



Biocon Limited
20th KM Hosur Road
Electronics City
Bangalore 560 100, India
T 91 80 2808 2808
F 91 80 2852 3423
CN : L24234KA1978PLC003417

www.biocon.com

Ref: BIL/EHS/22/09/05
Date: 08/09/2022

To,

Office of the Environmental Officer,
Karnataka State Pollution Control Board,
Regional Office – Sarjapura division,
Nisarga Bhavan, III floor,
Saneguruvanahalli, Thimmaiah Road,
Bengaluru – 560 001

Dear Sir,

Sub: Expansion & Modification of Existing products Capacity and proposed New Additional Products of Biopharmaceutical Manufacturing unit at Sy. Nos. 46/1, 16/2, 47/3, 48/ 6, 44/1, 44/2, 44/3B., 44/3A, 47/1, 47/2 49/1, 49/2, 47/4, 31, 32, & 47/3B, Hebbagodi CMC, Anekal, Bengaluru Urban By M/s Biocon Limited - Issue of Environmental Clearance - Reg.

Ref: Letter no: SEIAA 63 IND 2021 dated:23.08.2022

With reference to the above subject, would like to bring to your kind notice that we have received Environmental Clearance from State Level Environment Impact Assessment Authority-Karnataka for Expansion & Modification of Existing products Capacity and proposed New Additional Products of Biopharmaceutical Manufacturing unit for M/s Biocon Limited-20th KM, Hosur Road, Electronic City, Bengaluru-560100. The copy of the EC report is enclosed.

This is for your information & kindly request you to acknowledge the same.

Thanking you,

Yours sincerely
For Biocon Limited

Authorized Signatory



ANNEXURE-XII – ACKNOWLEDEMENT COPY OF FORM-V

Biocon Limited
20th KM Hosur Road
Electronics City
Bangalore - 560 100, India
T 91 80 2808 2808
F 91 80 2852 3423
CIN: L24234KA1978PLC003417

www.biocon.com

Ref: BC/EHS/COM/23/09/11
Date: 20.09.2023

To,

Office of the Environmental officer,
Regional office - Sarjapura,
Karnataka State Pollution Control Board,
Nisarga Bhavan, III Floor (West wing),
Saneguruvanahalli, Thimmaiah Road,
Bengaluru - 560 0001.

Dear Sir,

Sub: Environmental Statement in Form-V for the year 2022-23 for
M/s. Biocon Limited, 20th KM, Hosur Road, Electronic city Post,
Hebbagodi Village, Bengaluru -560100.

With reference to the above-mentioned subject, please find the enclosed Environmental Statement in Form V for the financial year ending with 31st March-2023. Request you to kindly acknowledge the receipt on our 'office copy' enclosed and oblige.

Thanking you,

Yours sincerely,
For Biocon Limited

Authorized Signatory



LIST OF FINAL PRODUCTS OF BIOCON LIMITED

| SL No. | Products Name | Final Quantity in MTA |
|--------|-------------------------|-----------------------|
| 1. | Speciality Enzymes | 996 |
| 2. | Anti-Cholesterol Agents | 120 |
| 3. | Monoclonal Antibodies | 0.036 |
| 4. | Immunosuppressant | 480 |
| 5. | Nintedanib | 10 |
| 6. | Eltromabopag | 10 |
| 7. | Omadacycline | 8 |
| 8. | Palbociclib | 8 |
| 9. | Remdesivir (Covid-19) | 72 |

LIST OF FINAL PRODUCTS OF BIOCON BIOLOGICS LIMITED

| SL No. | Products Name | Final Quantity in MTA |
|--------|---------------------------|-----------------------|
| 1. | Human Insulin | 2.82 |
| 2. | HSA | 0.24 |
| 3. | Insulin Glargine | 0.24 |
| 4. | IN 105 (Insulin Tregopil) | 0.24 |
| 5. | Monoclonal Antibodies | 0.012 |
| 6. | Streptokinase | 0.0004 |
| 7. | Reteplase | 0.0004 |
| 8. | Human Growth Hormone | 0.0008 |
| 9. | GCSF (Filgrastim) | 0.0004 |
| 10. | Speciality Enzymes | 120 |