



State Level Environment Impact Assessment Authority-Karnataka

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

No. SEIAA 45 IND 2020

Date: 03-09-2020

To,

M/s Biocon Limited
Plot No 2, 3, 4 and , Biocon SEZ,
Bommasandra Industrial Area,
Phase 4, Bommasandra Jigani Link Road,
Anekal taluk, Bengaluru Urban District,

Sir,

Sub: Proposed Expansion of Manufacturing of Active Pharmaceutical Ingredients (APIs), Biosimilars, Drug Intermediates and contract Manufacturing Unit project at Plot No s 2, 3, 4 & 5 of Bommasandra, Jigani link road, Bommasandra Industrial Area Phase-IV, Bangalore Urban, Karnataka By M/s. Biocon Limited - SEZ - issue of Environmental Clearance Reg.

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This has reference to your online application dated 9th July 2020 bearing proposal No.SIA/KA/IND2/162789/2020 addressed to SEIAA, Karnataka and subsequent letters addressed to SEIAA/SEAC Karnataka furnishing further information/seeking prior Environmental Clearance for the above project under the EIA Notification, 2006. 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, EMP for the Proposed Expansion of Manufacturing of APIs, Drug Intermediates and contract Manufacturing Unit and the additional clarifications furnished in response to the observations of the SEIAA/SEAC, Karnataka.

2. It is inter alia noted that Environmental Clearance has been issued to this project By SEIAA, Karnataka vide letter No. SEIAA 30 IND 2016 dated 21.04.2017 for Expansion of manufacturing Biologicals, Antibodies and Derivatives unit.

3. It is inter-alia noted that M/s. Biocon Limited have Proposed Expansion of Manufacturing of Active Pharmaceutical Ingredients (APIs), Biosimilars, Drug Intermediates and contract Manufacturing Unit project. The total plot area is 3,55,314 Sqm (87.8 Acres). Industry will develop greenbelt in an area of 1,42,992 Sqm i.e 35.3 % out of total area of the project site. The estimated project cost is Rs. 1000 Crores. Details of existing and proposed products with capacities are given in Annexure-I:-

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4. The total water requirement for the proposed project is 6556 KLD, and It will be met from the KIADB water supply, The waste water generation will be 3098 KLD, out of which 434 KLD will be the domestic sewage shall be treated in two Sewage Treatment systems with total capacity of 550 KLD. The industrial effluent of 2664 KLD shall be treated in ETP with stripper MEE and ATFD.

Power requirement is 12,000 KVA and will be met from Bangalore Electricity Supply Company (BESCOM), a Branch of Karnataka State Power Distribution Corporation Limited (KPTCL). Existing unit has DG set of 1 No X 3000 KVA, 13 No's X 2000 KVA capacity and propose to install 18 No's X 2000KVA in additional to the existing DG Sets and it shall be used as standby during the power failure. Existing unit has 2 No's X 12 TPH of HRSG Boilers, 3 No's X 16 TPH CNG boilers and proposed to install Biomass Boiler of 1 No X 35 TPH capacity with 60 No's of Scrubbers and 12 No's Dust collectors for mitigation of air pollution.

5. The project proposal was considered by SEAC during the video conference meeting held on 20th August 2020 as B2 category activity in accordance with the Notification S. O. 1223 (E) dated 27th March 2020. Based on the information submitted by you, presentation made by you and your consultant, the State Level Expert Appraisal Committee (SEAC) appraised the proposal and has recommended for issue of Environmental Clearance.

6. The SEIAA Karnataka has considered the project in its meeting held on 31st August 2020 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. (Incasse of the presence of schedule-1 species in the study area)
- iv. The project proponent shall obtain Consent to Establish / Operate under the



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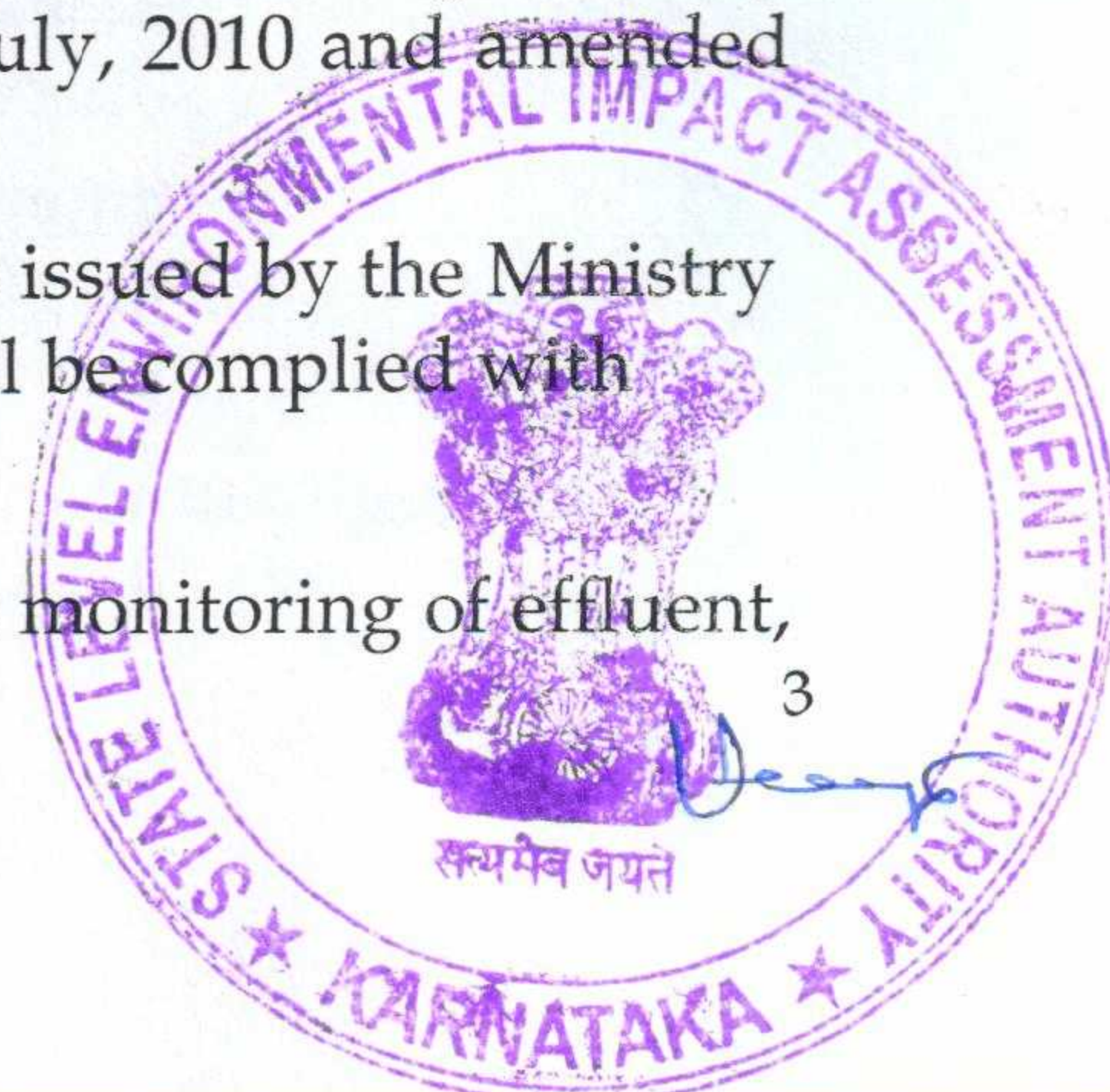
- provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State pollution Control Board/ Committee.
- v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.
 - vi. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (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,



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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). The sewage shall be treated to meet the urban standard and shall be used to cater to M/s Arvind Limited and Karnataka Forest Department as Committed.
- 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, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps.



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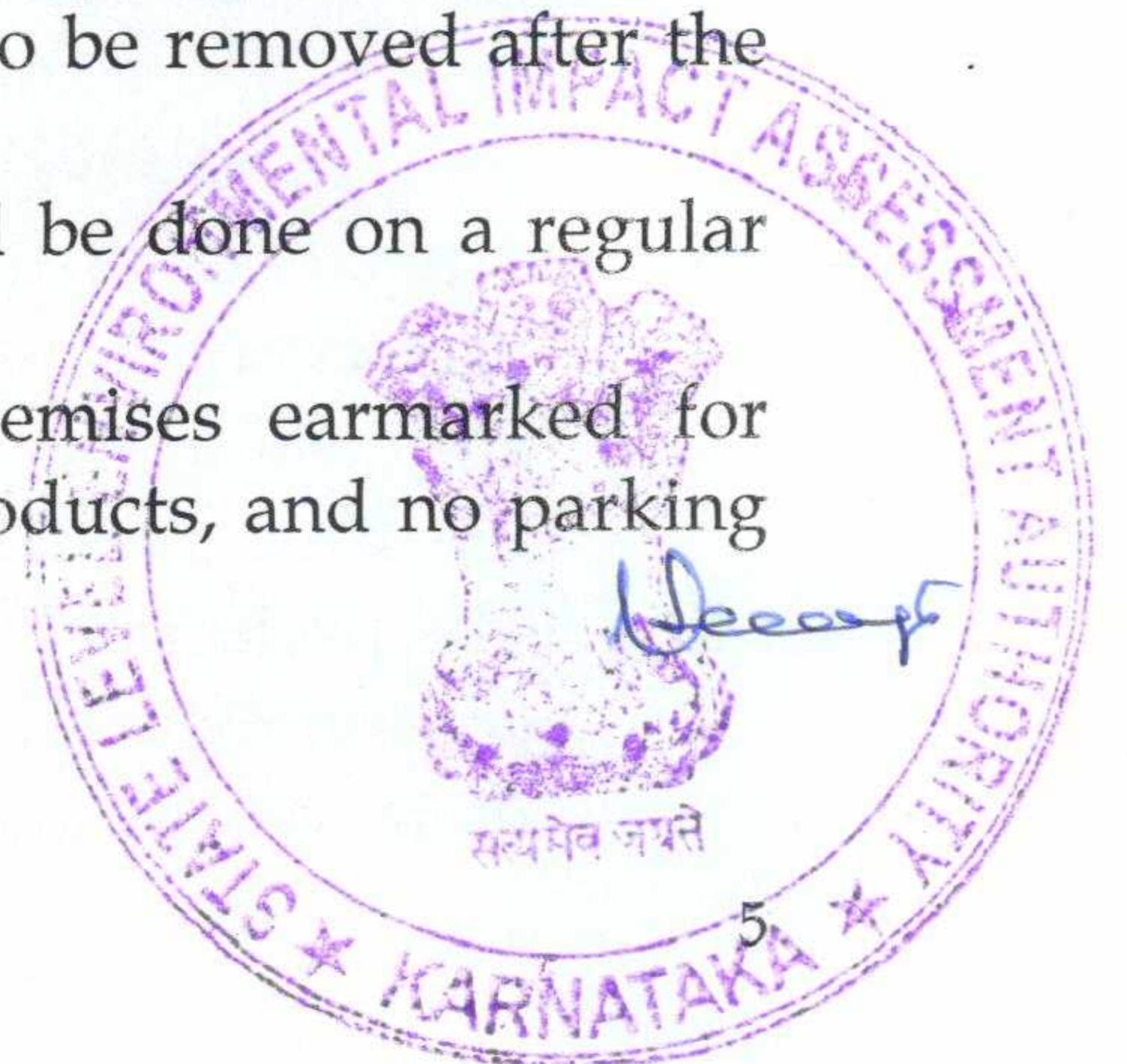
- ii. Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- iii. The company shall undertake waste minimization measures as below:-
 - a. Metering and control of quantities of active 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 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



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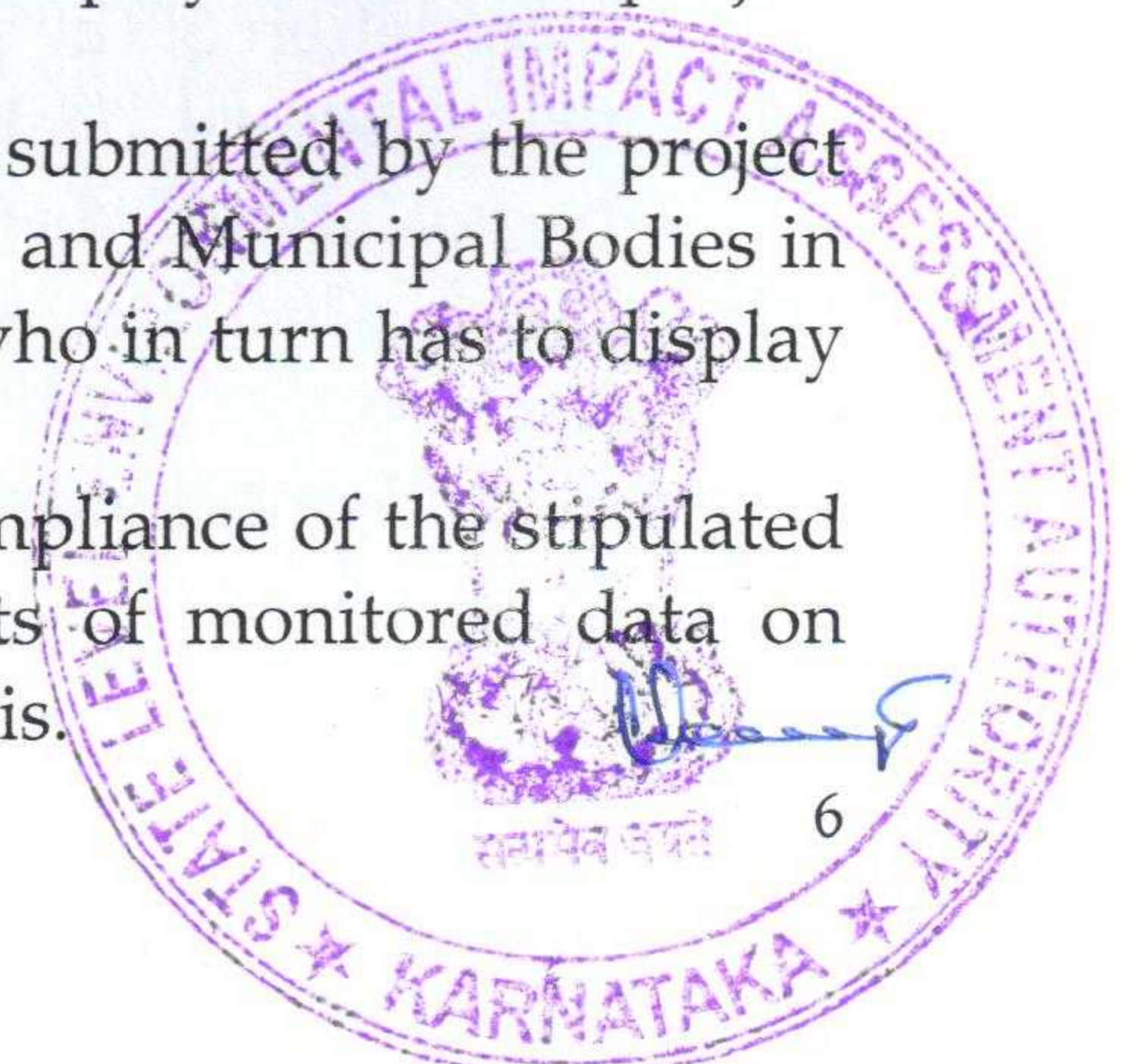
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IX. Corporate Environment Responsibility

- i. The project authorities shall undertake activities under Corporate Environment Responsibility (CER) with a total cost of not less than Rs. 150 Lakhs towards contribution of funds CM cares fund, 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.
- 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.



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- 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



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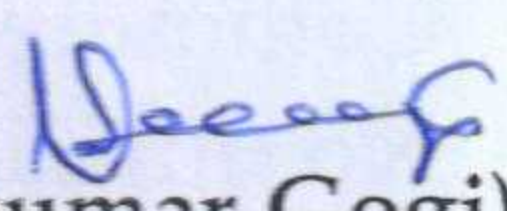
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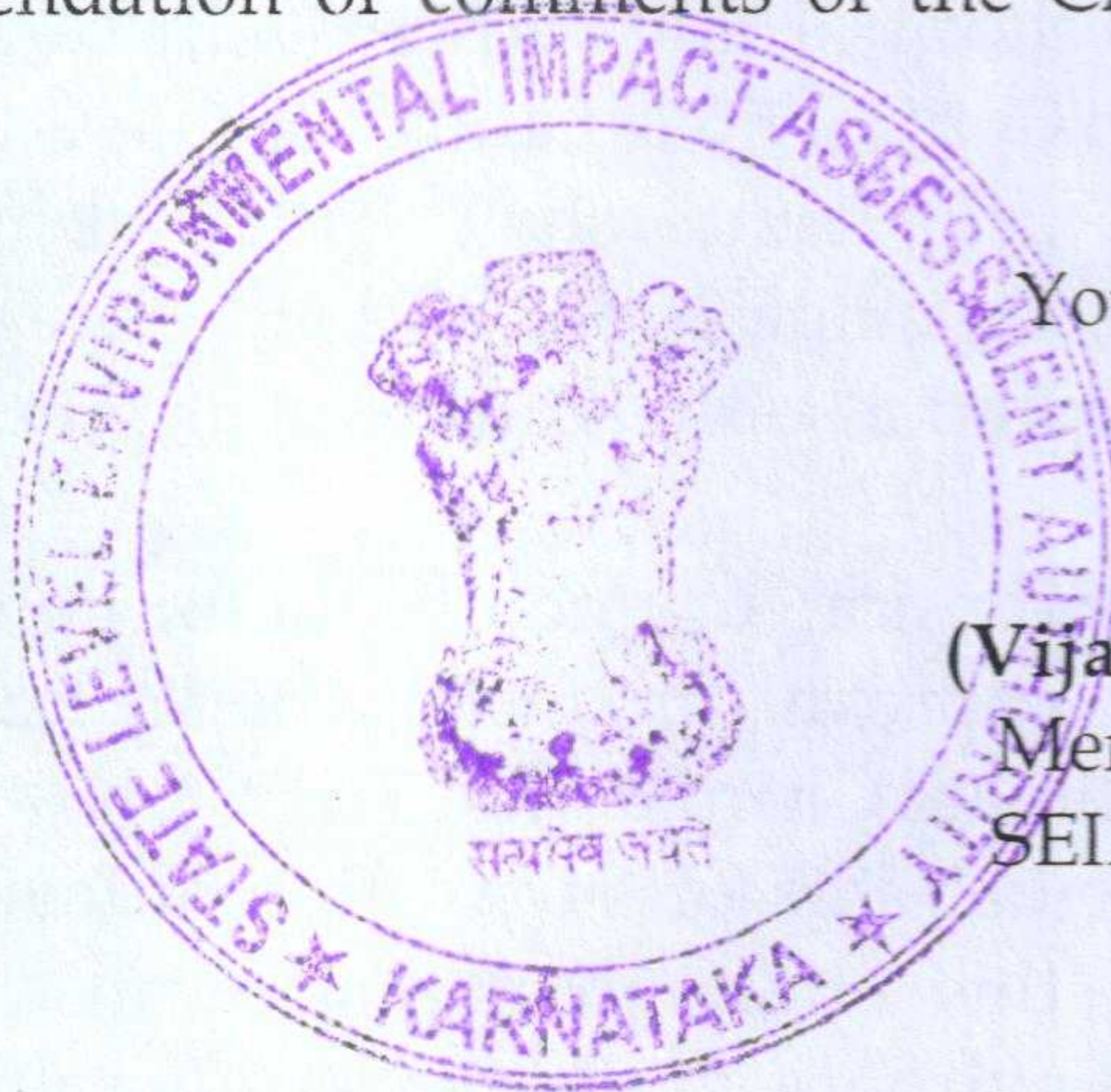
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- officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
- xvi. The above conditions shall be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (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.
- xviii. The project proponent shall adopt and comply all the mechanism included by the MoEF&CC which is given in the Annexure-II and shall be abide by the conditions there on. The project proponent shall undertake all necessary steps to bring down the CEPI score of the industrial area and the improve the environment condition in accordance with the mechanism evolved by MoEF & CC.
- xix. The project proponent shall submit the map duly authenticated by chief wild life warden showing the boundary of Bannerghatta National Park Vis a Vis the project location before undertaking construction activity and shall be adhered to the recommendation or comments of the Chief wildlife warden thereon as committed.

Yours faithfully,


(Vijayakumar Gogi)
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.

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ANNEXURE-I

List of Existing and Proposed products to be manufactured with their capacity

List of products – Biocon Limited				
S. No	Products	Existing Quantity in Kg/annum	Proposed Quantity in Kg/annum	Remarks
1	LOVASTATIN	25000	25000	No change
2	SIMVASTATIN	60000	80000	Qty Increased
3	PRAVASTATIN	20000	40000	Qty Increased
4	ATORVASTATIN	25000	100000	Qty Increased
5	ROSUVASTATIN	2500	2500	No change
6	FLUVASTATIN	2500	2500	No change
7	PIOGLITAZONE	10000	10000	No change
8	NATEGLINIDE	2000	2000	No change
9	REPAGLINIDE	2000	2000	No change
10	ROSIGLITAZONE MALEATE	1500	0	Product removed
11	MYCOPHENOLIC ACID (MPA)	5000	5000	No change
12	MYCOPHENOLATE MOFETIL (MMF)	5000	5000	No change
13	TACROLIMUS	200	200	No change
14	SIROLIMUS	250	250	No change
15	SPECIALITY ENZYMES	10000	10000	No change
16	HYDOROXY CANRENONE	220	220	No change
17	ALISKIREN	384	384	No change
18	BIMATOPROST	1.8	1.8	No change
19	BIVALIRUDIN	15	15	No change
20	BRINZOLAMIDE	21	21	No change
21	CARBOPROST	1.92	1.92	No change
22	CASPOFUNGIN DIACETATE	600	600	No change
23	DAPTOMYCIN	450	450	No change
24	DORZOLAMIDE HYDROCHLORIDE	10.5	10.5	No change
25	DULOXETIN	60000	60000	No change
26	EPLERENONE	6000	6000	No change
27	EPTIFIBATIDE	60	60	No change
28	EVEROLIMUS	36	100	Qty Increased
29	GLENDAMYCIN	300	300	No change
30	GLATIRAMER	10	10	No change
31	HYALURONIC ACID	6000	6000	No change
32	IBANDRONATESODIUM	552	552	No change
33	IMMUNOMYCIN	3000	3000	No change
34	IVABRADINEHYDROCHLORIDE	60	60	No change
35	LATANOPROST	0.5	0.5	No change
36	LUBIPROSTONE	0.5	0.5	No change
37	MICAFUNGIN	60	200	Qty Increased
38	OPT (80) / PAR101	500	500	No change
39	MONOCLONAL ANTIBODIES	1	1	No change
40	ORLISTAT	10000	40000	Qty Increased
41	PIMECROLIMUS	500	500	No change

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42	PNEUMOCANDIN	70	70	No change
43	SOMATROPIN CONCENTRATED SOLUTION	1	1	No change
44	TEMSIROLIMUS	120	120	No change
45	TRAVOPROST	0.5	0.5	No change
46	VOGLIBOSE	10	10	No change
47	EXENATIDE	100	100	No change
48	IN-105 (Insulin Tregpoil)	6000	6000	No change
49	Sacubitril-Na	0	10000	New Product
50	Valsartan-2Na	0	10000	New Product
51	Fingolimod	0	13	New Product
52	Teriflunomide	0	100	New Product
53	Tacrolimus Premix	0	1500	New Product
54	Everolimus Premix	0	200	New Product
55	Mirabegron	0	6000	New Product
56	Tofacitinib	0	20	New Product
57	Erdafitinib	0	20	New Product
58	Binimetinib	0	20	New Product
59	Cabozantinib	0	20	New Product
60	Mupirocin	0	5300	New Product
61	Dalbavancin	0	20	New Product
62	Oritavancin	0	10	New Product
63	Pristinamycin	0	10000	New Product
64	Fidaxomicin	0	250	New Product
65	Orlistat Pellets	0	20000	New Product
66	Sitagliptin	0	23000	New Product
67	Vildagliptin	0	30000	New Product
68	Limuses	0	1000	New Product
69	Fungins	0	1000	New Product
70	Peptides	0	500	New Product
71	Hydroxychloroquine	0	20000	New Product
Total Quantity		266035	548712	

List of formulation products - Biocon Limited		
S. No	Activity	Quantity
1	Formulation of Syrup	5000 kgs/day
2	Formulation of Capsules	8 Lakh/day
3	Formulation of Dry Syrup	5000 kgs/day
4	Formulation of tablets	300 kgs/day
5	Semisolid Dosage Forms	80 kgs/day

List of Products - Syngene International Limited				
S. No	Products	Existing Quantity in Kg/annum	Proposed Quantity in Kg/annum	Remarks
1	Adalimumab	0	55	New Product
2	Bevacizumab	0	60	New Product
3	Talazoparib	0	58	New Product
4	Avelumab	0	67	New Product



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5	Luteinizing hormone	0	50	New Product
6	Follicle stimulating hormone	0	48	New Product
7	Etanercept	0	52	New Product
8	Rituximab	0	50	New Product
9	Infliximab	0	52	New Product
10	Trastuzumab	0	55	New Product
11	Ranibizumab	0	55	New Product
12	Darbepoetinalfa	0	45	New Product
13	Blood factors for coagulation (recombinant origin)	0	55	New Product
14	Cetuximab	0	61	New Product
15	Erythropoietin	0	51	New Product
16	Recombinant origin proteins	0	55	New Product
17	Palivizumab	0	55	New Product
18	Abatacept	0	55	New Product
19	Monoclonal antibodies	0	45	New Product
20	Therapeutic proteins	0	57	New Product
21	Imiglucerase	0	49	New Product
22	Omalizumab	0	48	New Product
23	Gonadotropin hormone	0	55	New Product
24	Somatropin	0	45	New Product
25	Tenecteplase	0	55	New Product
26	Tocilizumab	0	59	New Product
27	HPV vaccine (recombinant origin)	0	55	New Product
28	Hepatitis vaccine (recombinant origin)	0	53	New Product
29	SAPI 01 (Benzodiazepine Phenylacetamido Acetic Acid)	0	2000	New Product
30	SAPI 02 (Imidazole Dicarbamate)	0	2000	New Product
31	SAPI 03 (Phenoxy Alaninate)	0	2000	New Product
32	SAPI 04 (Biphenyl Derivative)	0	2000	New Product
33	SAPI 05 (Dibenzofuran)	0	2000	New Product
34	SAPI 06 ((Aminocyclopropyl Benzoate)	0	2000	New Product
35	SAPI 07 (BromoPyrazine)	0	2000	New Product
36	SAPI 08 (FlouroOxazine)	0	2000	New Product
37	SAPI 09 (Phenylquinazoline)	0	2000	New Product
38	SAPI 10 (Azaspiro carboxylic acid)	0	2000	New Product
39	SAPI 11 (AzabicycloOctanone)	0	2000	New Product
40	SAPI 12 (PyrrolidineCarboxamide)	0	2000	New Product



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41	SAPI 13 (Triflouromethoxy Imidazole)	0	2000	New Product
42	SAPI 14 (1H-Pyrazole-3-Carboxamide)	0	2000	New Product
43	SAPI 15 (Butanoic Acid)	0	2000	New Product
44	SAPI 16 (Oxathiepine Carboxylate Derivative)	0	2000	New Product
45	SAPI 17 (Methoxynaphthanlene Derivative)	0	2000	New Product
46	SAPI 18 (Quinoline Derivative)	0	2000	New Product
47	SAPI 19 (Cetyl Ester)	0	2000	New Product
48	SAPI 20 (Cyclene Ester)	0	2000	New Product
49	SAPI 21 (HydroxymethylTrihydrofuran)	0	2000	New Product
50	SAPI 22 (Indolpiperidone Carboxylate)	0	2000	New Product
51	SAPI 23 (Methylpyrrolidine Hydrochloride)	0	2000	New Product
52	SAPI 24 (MethoxyphenylOxetane)	0	2000	New Product
53	SINT 01 (Dichlorocarboxamide)	0	2000	New Product
54	SINT 02 (BenzamideMethanesulfonate)	0	2000	New Product
55	SINT 03 (Flouren Glutamine)	0	2000	New Product
56	SINT 04 (Benzonitrile Amide)	0	2000	New Product
57	SINT 05 (Pyrrole - Pyrimidine)	0	2000	New Product
58	SINT 06 (Bromo - Methoxy - PyrrolePyrimidine)	0	2000	New Product
59	SINT 07 (MethoxyOxobutanoic Acid)	0	2000	New Product
60	SINT 08 (Benzyl chloro pyrimidine derivative)	0	2000	New Product
61	SINT 09 (Bromo Aniline)	0	2000	New Product
62	SINT 10 (TriflouromethoxyOxazine)	0	2000	New Product
63	SINT11(AcetamideTetrahydrobe nzothiadizepene)	0	2000	New Product
64	SINT 12 (Nitro Imadazole)	0	2000	New Product
65	SINT 13 (TetramethylHydopyran)	0	2000	New Product
66	SINT 14 (Pyran-3-Carboxamide)	0	2000	New Product
67	SINT 15 (Proline Derivative)	0	2000	New Product
68	SINT 16 (Aniline Derivative)	0	2000	New Product
69	SINT 17 (DibromoPyrazine)	0	2000	New Product
70	SINT 18 (BocPyrolidine)	0	2000	New Product
71	SINT 19 (Nicotinic Acid Ester)	0	2000	New Product



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72	SINT 20 (Itaconic Acid Ester)	0	2000	New Product
73	SINT 21 (Allyl Derivative)	0	2000	New Product
74	SINT 22 (Benzyl Indanone)	0	2000	New Product
75	SINT 23 (Indanone derivative)	0	2000	New Product
76	SINT 24 (Isophthalate Derivative)	0	2000	New Product
77	Custom synthesis of Novel R&D products	0	20500	New Product
78	Orlistat	0	2000	New Product
79	Pyranone	0	2000	New Product
80	CBTA	0	2000	New Product
81	ACH-0145993	0	2000	New Product
82	LYP 010	0	2000	New Product
83	APR-246	0	2000	New Product
84	Hydroxychloroquine	0	2000	New Product
85	Remdesivir	0	2000	New Product
86	Bromothiadiazepine	0	2000	New Product
87	Methoxyacridin diamine	0	2000	New Product
88	Diketotriazolo pyridine der	0	2000	New Product
89	Vactosertib	0	1000	New Product
90	8-chloronaphthalen-piperizine derivative	0	1000	New Product
	TOTAL	0	142000	

List of products - Biocon Biologics India Limited				
S. No	Products	Existing Quantity in Kg/annum	Proposed Quantity in Kg/annum	Remarks
1	Abatacept	10	10	Qty Increase
2	Adalimumab	100	100	No change
3	Aflibercept	4	40	Qty Increase
4	Agalsidase beta	1	10	Qty Increase
5	Albiglutide	5	50	Qty Increase
6	Alemtuzumab	1	10	Qty Increase
7	Alglucosidasealfa	10	20	Qty Increase
8	Alirocumab	1	10	Qty Increase
9	Antihemophilic Factor (Recombinant)	10	100	Qty Increase
10	Atezolizumab	5	50	Qty Increase
11	Avelumab	1	10	Qty Increase
12	Belimumab	550	550	No change
13	Bevacizumab	1	100	Qty Increase
14	Blinatumomab	1	10	Qty Increase
15	BrentuximabVedotin	1	10	Qty Increase

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16	Canakinumab	1	10	Qty Increase
17	CertolizumabPegol	1	10	Qty Increase
18	Cetuximab	1	10	Qty Increase
19	Daratumumab	1	10	Qty Increase
20	Darbepoetin Alfa	1	10	Qty Increase
21	Denosumab	10	100	Qty Increase
22	Dulaglutide	4	40	Qty Increase
23	Eculizumab	1	10	Qty Increase
24	Elotuzumab	1	10	Qty Increase
25	Epoetin Alfa	1	10	Qty Increase
26	Etanercept	300	300	No change
27	Evolocumab	10	100	Qty Increase
28	Filgrastim	1	10	Qty Increase
29	Golimumab	10	100	Qty Increase
30	Idarucizumab	1	10	Qty Increase
31	Imiglucerase	1	10	Qty Increase
32	Infliximab	4	40	Qty Increase
33	Interferon Beta 1A	1	10	Qty Increase
34	Ipilimumab	1	10	Qty Increase
35	Itolizumab	1	100	Qty Increase
36	Ixekizumab	1	10	Qty Increase
37	Liraglutide	4	40	Qty Increase
38	Mepolizumab	10	100	Qty Increase
39	Natalizumab	4	40	Qty Increase
40	Nimotuzumab	4	40	Qty Increase
41	Nivolumab	10	100	Qty Increase
42	Obiltoxaximab	1	10	Qty Increase
43	Obinutuzumab	1	10	Qty Increase
44	Omalizumab	1	10	Qty Increase
45	Palivizumab	1	10	Qty Increase
46	Panitumumab	1	10	Qty Increase
47	Pegfilgrastim	1	100	Qty Increase
48	Pembrolizumab	1	10	Qty Increase
49	Pertuzumab	10	100	Qty Increase
50	Ramucirumab	1	10	Qty Increase
51	Ranibizumab	1	10	Qty Increase
52	Raxibacumab	1	10	Qty Increase
53	Reslizumab	1	10	Qty Increase
54	Rituximab	4	10	Qty Increase
55	Romiplostim	1	10	Qty Increase
56	Sebelipasealfa	1	10	Qty Increase
57	Secukinumab	10	100	Qty Increase
58	Siltuximab	1	10	Qty Increase
59	Tbo-Filgrastim	1	10	Qty Increase
60	Tenecteplase	1	10	Qty Increase

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61	Tocilizumab	1	10	Qty Increase
62	Trastuzumab	500	1000	Qty Increase
63	TrastuzumabEmtansine	10	100	Qty Increase
64	Ustekinumab	10	100	Qty Increase
65	Vedolizumab	1	10	Qty Increase
66	Fusion mABS	1	100	Qty Increase
67	Anti-CD20 targettedmAB	1	100	Qty Increase
68	EPO	0.0132	0.0132	No change
69	GcSF	0.167	0.167	No change
70	hR3	60.16	60.16	No change
71	RETEPLASE	3.6	3.6	No change
72	STREPTOKINASE	5.04	5.04	No change
73	HUMAN GROWTH HORMONE	3	3	No change
74	HUMAN INSULIN	4000	4000	No change
75	ASTOSIBIN	60	60	No change
76	BMAB 100	60	60	No change
77	BMAB 200	60	60	No change
78	INSULIN GLARGINE	250	1000	Qty Increase
79	HUMAN SERUM ALBUMIN (HSA)	2400	2400	No change
80	INSULIN LISPRO / ASPART	1920	1920	No change
81	MONOCLONAL ANTIBODIES	4	500	Qty Increase
82	Speciality Enzymes	5000	5000	No change
	TOTAL	15476	19272	

List of formulation products - Biocon Biologics India Limited			
S. No	Activity	Quantity	
1	Formulations of Antibodies, Derivatives, Proteins, Peptides and Biologicals (Vials)	10 Million/ annum	
2	Formulations of Antibodies, Derivatives, Proteins, Peptides and Biologicals (Injectable Pens)	4 Million/ annum	
3	Formulations of Injections, vials, cartridges and Insulin Pens	100 million/ annum	
List of formulation products - Biocon Pharma Limited			
S. No	Activity	Quantity	UOM
1	Formulation of Syrup	5000	Kg/ day
2	Formulation of Capsules.	0.8	Million/ day
3	Formulation of dry Syrup.	5000	Kg/ day
4	Formulation of Injections	5000	Injections/ day
5	Formulation of Tablets	300	Kg/ day
6	Semisolid dosage forms	80	Kg/ day

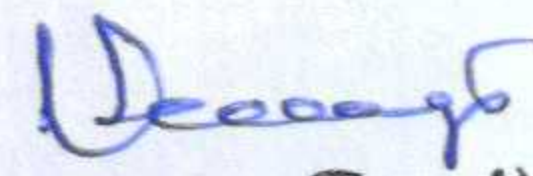
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List of formulation products - Biocon Biosphere Limited			
SL. No	Activity	Quantity	UOM
1	Formulation of Syrup	5000	Kg/Day
2	Formulation of Capsules.	0.8	million/day
3	Formulation of Dry Syrup.	5000	Kg/Day
4	Formulation of Tablets	300	Kg/Day
5	Semisolid dosage forms	80	Kg/Day
6	Formulation of Injections	1	million/Day
7	Formulation of pre-filled pens, vials and cartridges	0.5	million/Day




(Vijayakumar Gogi)
Member Secretary,
SEIAA, Karnataka.

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ANNEXURE-II

Additional conditions as per the Mechanism evolved by MoEF & CC as compliance to the orders of Hon'ble NGT dated 19-8-2019 in O A No. 1038 of 2018

Environment	Mitigation Measure
Air	<p><u>Stipulation of conditions such as:</u></p> <ol style="list-style-type: none"> Stack emission levels should be stringent than the existing standards in terms of the identified critical pollutants. CEMS may be installed in all large/medium red category industries (air polluting) and connected to SPCB and CPCB server. Effective fugitive emission control measures should be imposed in the process, transportation, packing etc. Transportation of materials by rail/ conveyor belt, wherever feasible. Encourage use of cleaner fuels (pet coke/ furnace oil/ I.SHS may be avoided). Best Available Technology may be used. For example; usage of EAF/SAF/ IF in place of Cupola furnace. Usage of Supercritical technology in place of sub-critical technology. Increase of green belt cover by 40% of the total land area beyond the permissible requirement of 33%, wherever feasible. Stipulation of greenbelt outside the project premises such as avenue plantation, plantation in vacant areas, social forestry, etc. Assessment of carrying capacity of transportation load on roads inside the industrial premises. If the roads required to be widened, shall be prescribed as a conditions
Water	<p><u>Stipulation of conditions such as:</u></p> <ol style="list-style-type: none"> Reuse/recycle of treated wastewater, wherever feasible. Continuous monitoring of effluent quality/quantity in large and medium Red Category Industries (water polluting). A detailed water harvesting plan may be submitted by the project proponent -Zero- liquid-discharge-whenever-technically-ecologically feasible.

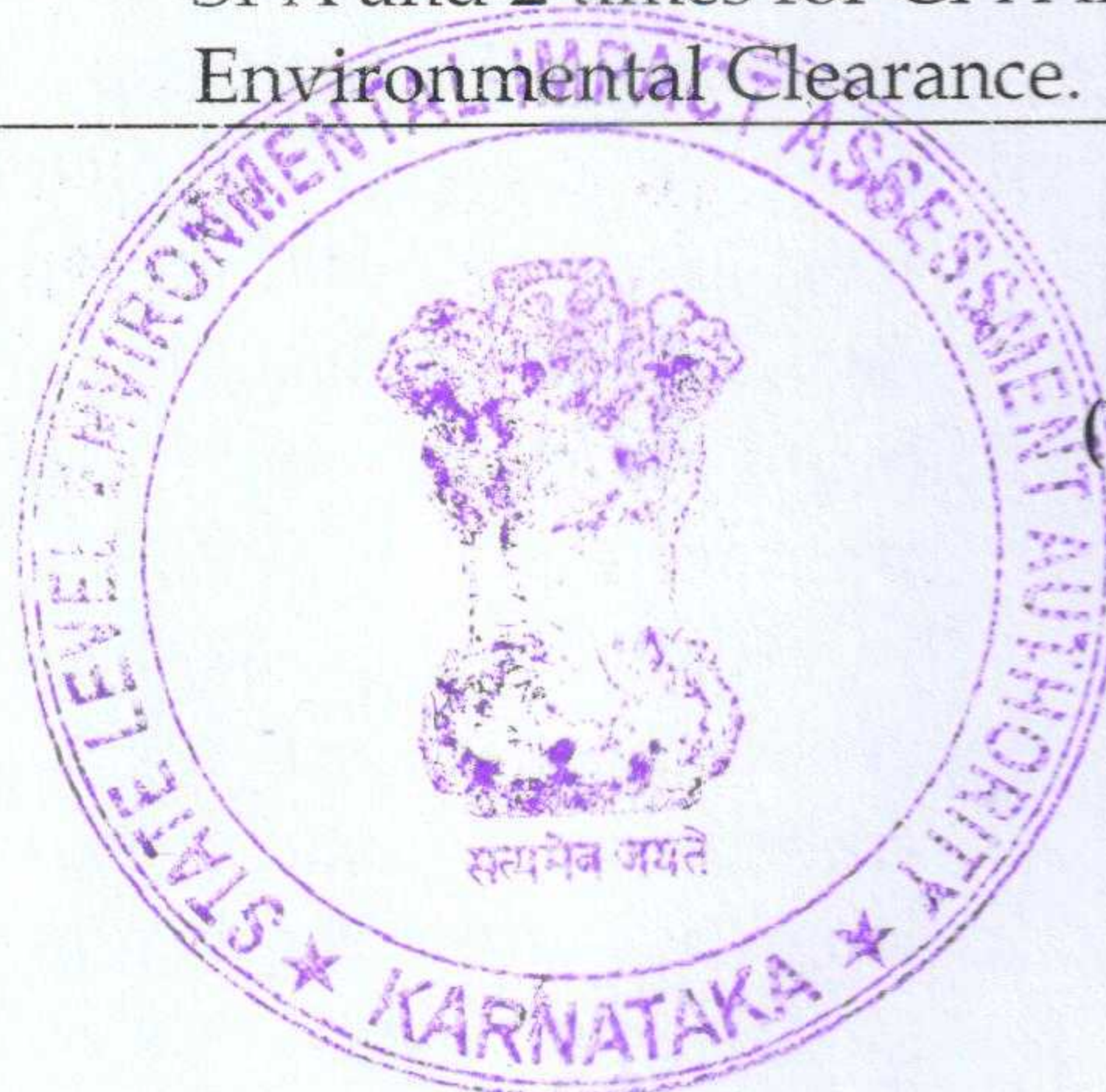
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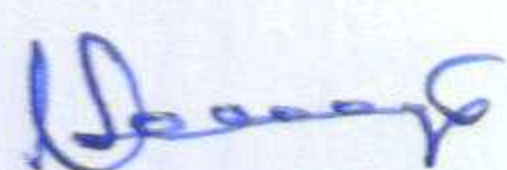
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	v. In case, domestic waste water generation is more than 10 KLD, the industry may install STP.
Land	<p><u>Stipulation of conditions such as:</u></p> <ol style="list-style-type: none"> Increase of green belt cover by 40% of the total land area beyond the permissible requirement of 33%, wherever, feasible for new projects. Stipulation of greenbelt outside the project premises such as avenue plantation, plantation in vacant areas, social forestry, etc. Dumping of waste (fly ash, slag, red mud, etc.) may be permitted only at designated locations approved by SPCBs/ PCCs. iv. More stringent norms for management of hazardous waste. The waste generated should be preferably utilized in co-processing
Other Condition(Additional).	<ol style="list-style-type: none"> Monitoring of compliance of EC conditions may be submitted with third party audit every year. ii. The % of the CER may be at least 1.5 times the slabs given in the OM dated 01.05.2018 for SPA and 2 times for CPA in case of Environmental Clearance.




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