



Ref: BP/EHS/COM/22/06/13
Date: 29/06/2022

Biocon Limited - SEZ Developer
Biocon Special Economic Zone
Plot Nos. 2,3,4 & 5, Phase IV - B.I.A.
Bommasandra-Jigani Link Road
Bangalore 560 099, India
T 91 80 2808 2808
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CIN : L24234KA1978PLC003417
www.biocon.com

To,
Regional Office (Southern Zone),
Ministry of Environment and Forests,
Kendriya Sadan, IVth Floor,
E&F Wings, 17th Main Road,
2nd Block, Kormangala,
Bengaluru- 560034.

Respected Sir,

Sub: Half Yearly compliance report for Environmental clearance from December 2021 to May 2022.

- Ref: 1. EC. No: J-11011/96/2005-IA-II. (I) issued by Ministry of Environment and Forests department dt: August 16, 2005.**
- 2. File No: SEIAA 30 IND 2016 issued by State Level Environment Impact Assessment Authority- Karnataka dt: 21.04.2017.**
- 3. Corrigendum issued on 02.11.2017 for the EC No: SEIAA 30 IND 2016 dt: 21.04.2017**
- 4. Corrigendum issued on 29.01.2019 for the EC No: SEIAA 30 IND 2016 dt: 21.04.2017.**
- 5. File No: SEIAA 45 IND 2020 issued by State Level Environment Impact Assessment Authority- Karnataka dt: 03.09.2020**

With reference to the above mentioned subject, herewith submitting Half Yearly Environmental Compliance report for the M/s. Biocon Limited, Plot No. 2, 3, 4 & 5 Bommasandra- Jigani Link Road, 4th Bommasandra Industrial Area, Anekal Taluk, Bangalore Urban District- 560099 for the period of June 2021 to November 2021.

Kindly accept and acknowledges at the earliest.

Thanking You,

Yours Sincerely,

For Biocon Limited-SEZ

**COMBINED ENVIRONMENTAL CLEARANCE COMPLIANCE REPORT
(December 2021- May 2022)**

For

BIOPHARMACEUTICAL MANUFACTURING UNIT

AT



M/s. BIOCON LIMITED

**Plot No. 2, 3, 4 and 5, Bommasandra Industrial Area, Phase-4,
Bommasandra-Jigani Link Road, Bengaluru-560099**

Submitted By

**M/s. Biocon Limited,
Plot No. 2, 3, 4 and 5, Bommasandra Industrial Area,
Phase-4, Bommasandra-Jigani Link Road,
Bengaluru-560099**

Specific Conditions:

1. The gaseous emissions (SO₂, NO_x and HCL) and particulate matters from various process units should confirm to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels should go beyond the stipulated standards. In the event of failure of pollution control systems(s) adopted by the unit, the respective unit should not be restarted until the control measures are rectified to achieve the desired efficiency. (EC- 2005)

- Air polluting sources are identified such as Gas turbine, Boiler, Process Reactors, DG sets and Dust Collectors. Control for Air pollution sources are in place such as Chimney, Scrubbers, Blowers and Bag filters respectively. The gaseous emissions (SO₂, NO_x and Acid mist) and particulate matters values are significantly lower than the prescribed standards. Suitable corrective action shall be considered if any deviation or failure of pollution control system(s) in consultation with KSPCB.
- All the gaseous emissions from the process units are monitored monthly and reports are being submitted to Regional office and Head Office, Karnataka State Pollution Control Board. Detailed statement of emissions of process (Scrubbers & Dust Collectors), DG sets, Boilers & Gas Turbines for the period of December 2021 to May 2022 are attached for your reference – *Annexure-1 (Refer Point No. 4).*

EC-2017 (Specific Condition: Point No: 5)

The process emissions from the boiler shall be dispersed through stack of adequate height as per CPCB/KSPCB standards. The gaseous emissions from the DG set shall be dispersed through stack height as per CPCB standards shall be provided. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.

- Noted and shall be complied with. Stacks provided for DG sets as per CPCB/KSPCB standards. DG sets provided with acoustic enclosures.
- The DG Stack Monitoring report for the period December -2021 to May-2022 is as follows

Parameter	Std (Nm ³ /hr)	DG-I		DG-II		DG-III	
		Dec-21	Mar-22	Dec-21	Mar-22	Dec-21	Mar-22
Particulate matter	100	50.2	48.5	52.7	51.2	45.2	46.6
NO _x	970	26.3	28.2	33.4	31.5	37.1	35.5
SO ₂	--	14.7	16.3	16.5	17.8	18.3	19.1
CO	150	21.4	23.4	25.2	26.6	24.4	22.4
NMHC	100	29.7	28.4	28.2	30.5	32.5	33.3

DG's are installed after 2017 EC.

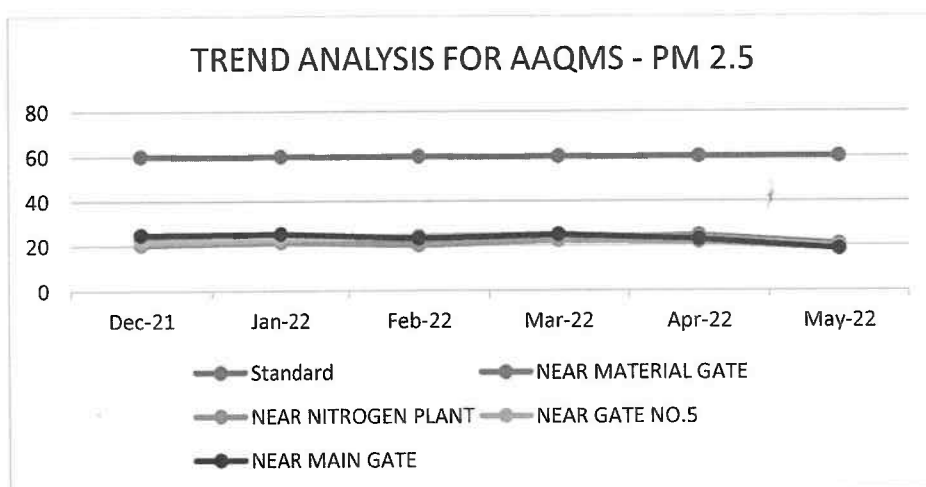
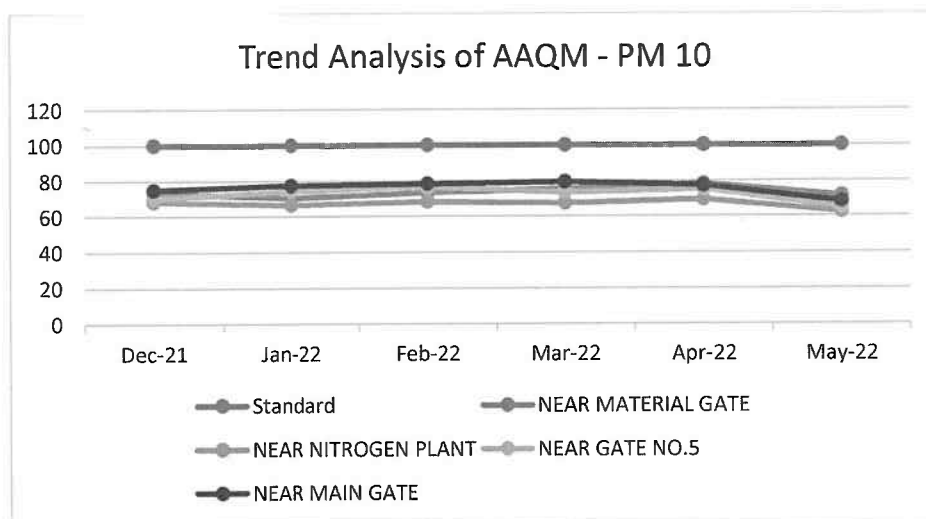
Note: DG no. 4 Installed and under commissioning.

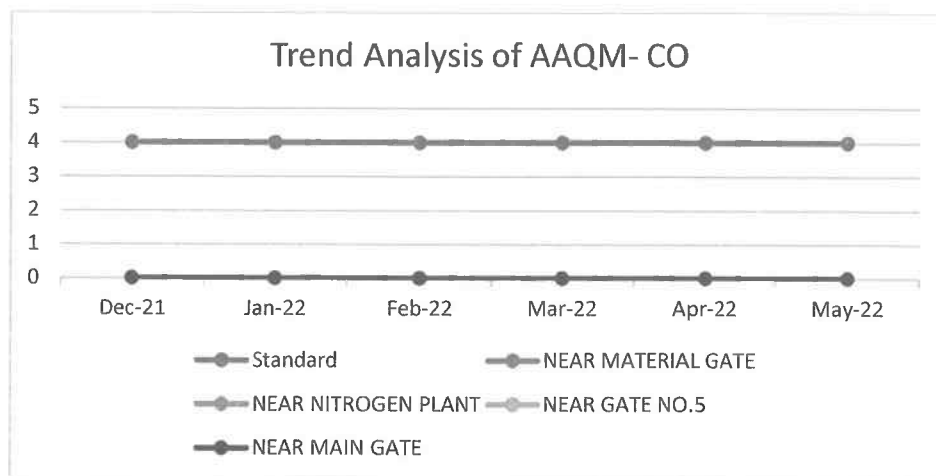
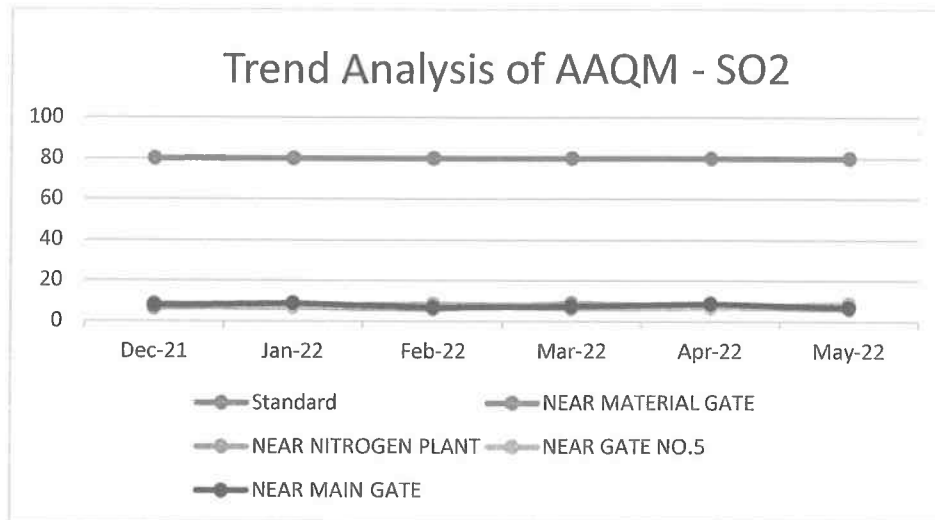
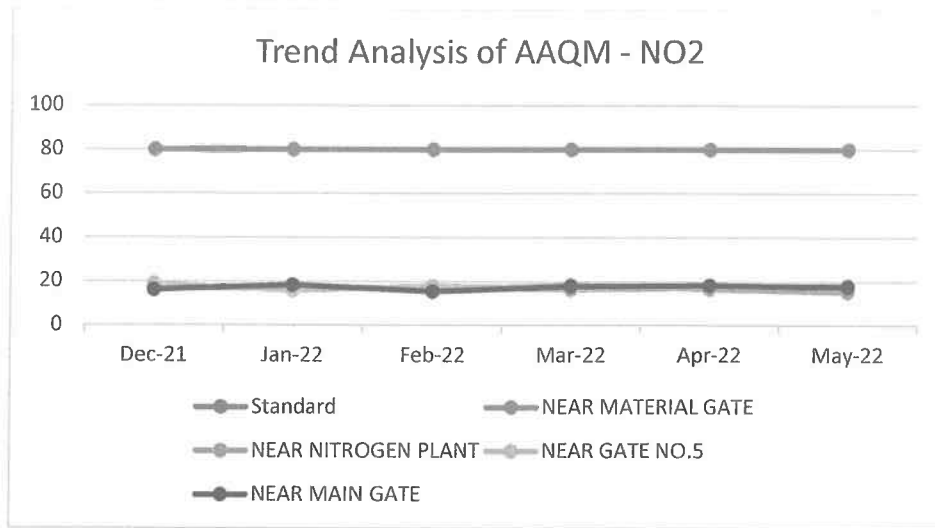
2. Ambient Air Quality Monitoring Stations should be set up in the down wind direction as well as where maximum ground level concentration of SPM are anticipated in consultation with the State Pollution Control Board. (EC- 2005), (EC- 2020 II. iii)

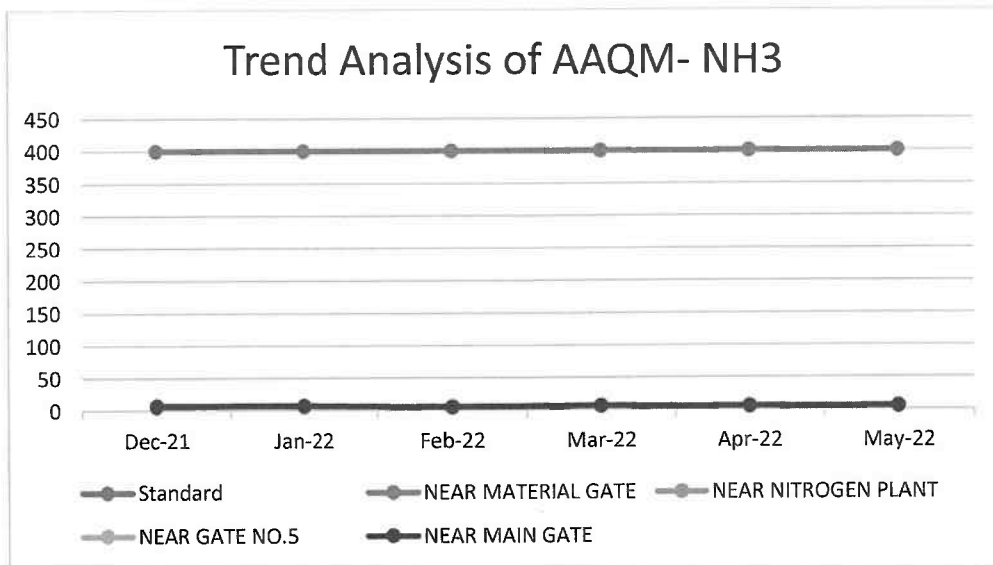
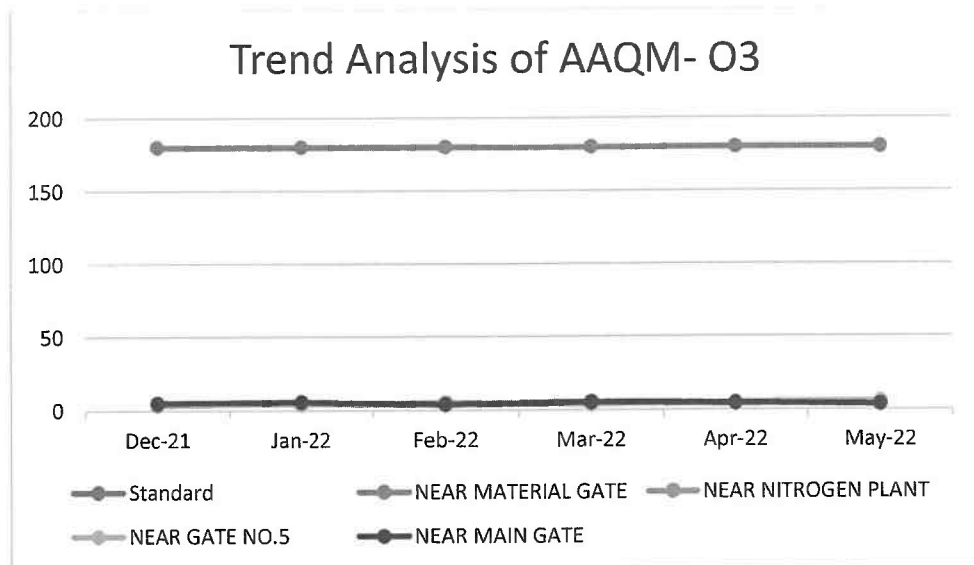
- *Ambient Air Quality monitoring is being carried out at four locations such as Near Material gate, Near Nitrogen plant, Near Gate No.5 & Near Main gate and a continuous Ambient Air Quality Monitoring Station are established in consultation with KSPCB. Air quality is being monitored at all the above said locations once in a month and reports are being submitted to Regional office and Head Office, Karnataka State Pollution Control Board. We have commissioned continuous online ambient air quality monitoring station at site for PM₁₀, PM_{2.5}, NO_x and SO_x. The trend of ambient air quality monitoring for the period December 2021 to May 2022 is as given below.*

Sl No	Month	PM ₁₀	PM _{2.5}	NO ₂	SO ₂	CO	O ₃	NH ₃
December-2021								
1	Near Material Gate	73.6	22.4	17.2	6.5	<1.0	4.4	6
2	Near Nitrogen Plant	68.2	20.4	16.7	7.1	<1.0	3.6	5.1
3	Near Gate No 5	70.2	21.6	18.8	8.6	<1.0	5.2	7.7
4	Near Main Gate	75.1	24.8	16.1	7.9	<1.0	4.8	6.7
January-2022								
1	Near Material Gate	70.4	23.6	16.5	7.7	<1.0	5.2	6.8
2	Near Nitrogen Plant	66.5	21.6	17.8	6.9	<1.0	4.5	5.7
3	Near Gate No 5	74.4	22.8	15.9	7.2	<1.0	3.8	5.1
4	Near Main Gate	77.4	25.2	18.3	8.7	<1.0	5.7	7.2
February-2022								
1	Near Material Gate	73.4	21.7	17.5	8.2	<1.0	4.4	5.7
2	Near Nitrogen Plant	68.2	20.1	16.3	6	<1.0	3.6	4.5
3	Near Gate No 5	76.6	24.2	17.9	7.8	<1.0	5.2	6.6
4	Near Main Gate	78.4	23.3	15.5	6.7	<1.0	4.1	5.2
March-2022								
1	Near Material Gate	75.6	23.2	16.4	7.5	<1.0	5.5	6.3
2	Near Nitrogen Plant	67.4	22.3	18.3	8.8	<1.0	4.4	5.6
3	Near Gate No 5	73.4	25.1	16.9	6.2	<1.0	3.6	5.4
4	Near Main Gate	79.4	24.8	17.7	7.2	<1.0	5.1	6.6

April-2022								
1	Near Material Gate	78.2	24.5	17.1	8.3	<1.0	4.6	5.8
2	Near Nitrogen Plant	69.5	21.6	16.5	7.2	<1.0	3.7	4.6
3	Near Gate No 5	75.2	23.3	17.6	6.8	<1.0	5	6.2
4	Near Main Gate	77.3	22.8	18.1	8.6	<1.0	4.4	5.2
May-2022								
1	Near Material Gate	71.5	20.6	17.2	7.1	<1.0	3.8	4.6
2	Near Nitrogen Plant	62.4	18.6	15.2	6.1	<1.0	4.4	5.7
3	Near Gate No 5	64.8	19.3	18.2	8.6	<1.0	5.6	6.4
4	Near Main Gate	68.3	18.4	17.6	6.7	<1.0	3.5	5.1

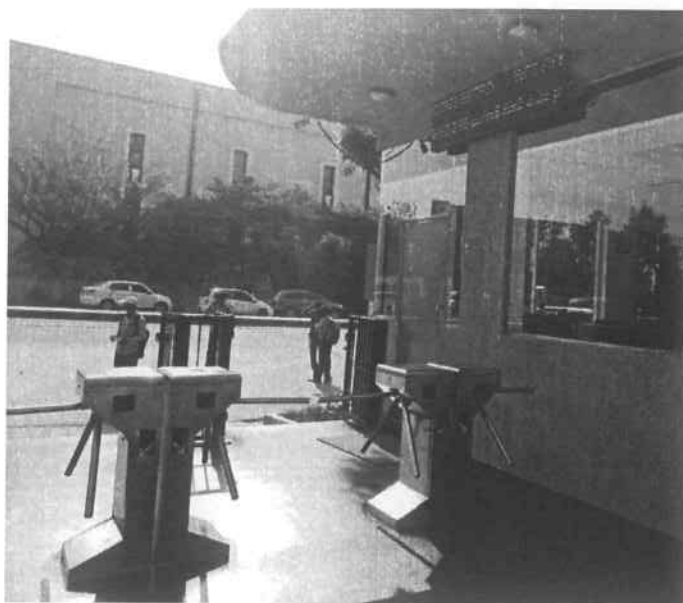








AAQMS System installed to measure ambient air quality at vantage points



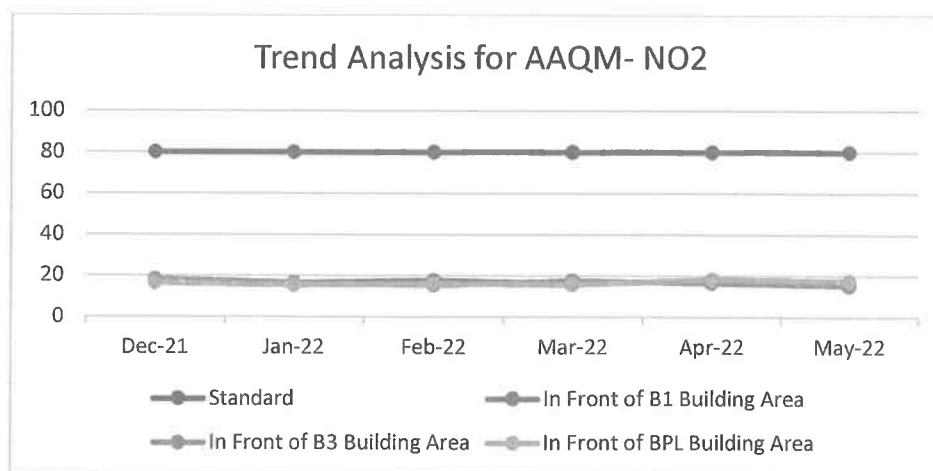
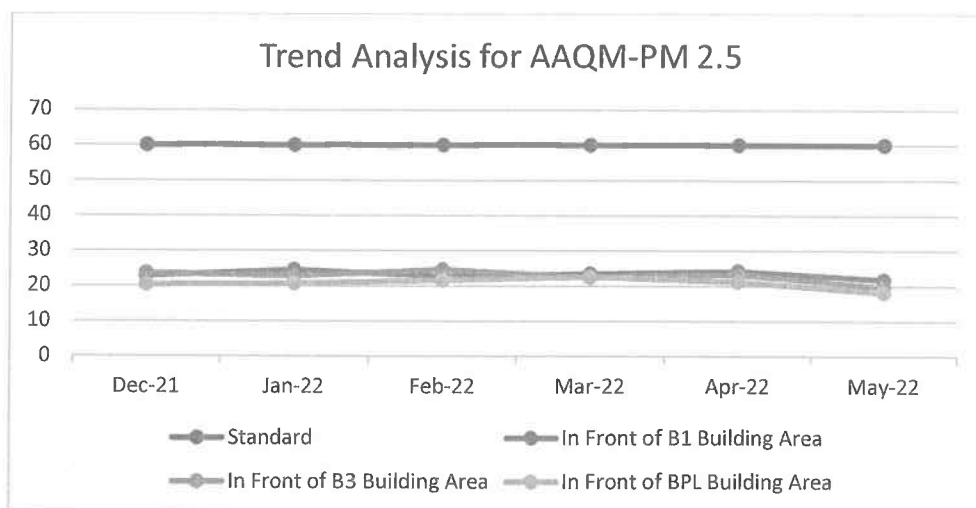
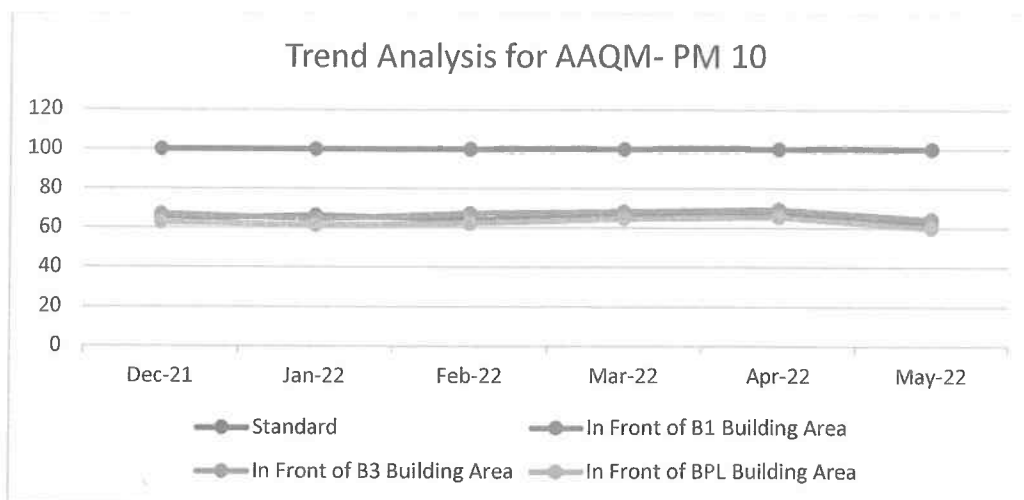
Ambient Air Quality display at Factory Main gate Entrance

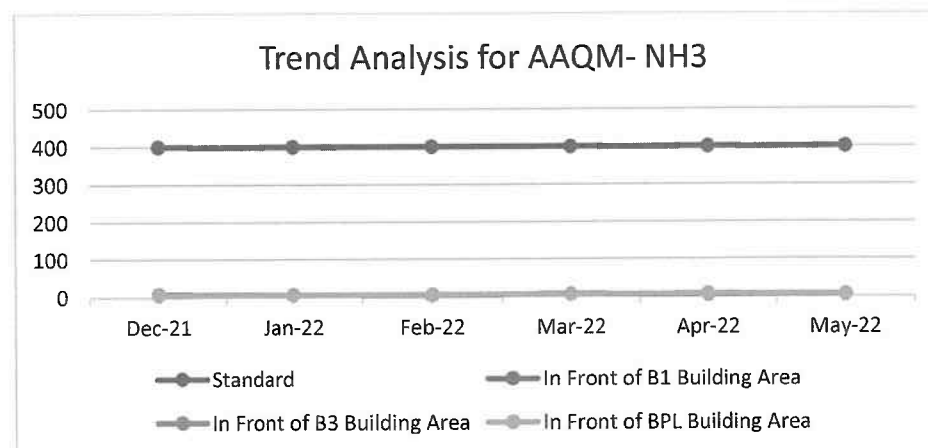
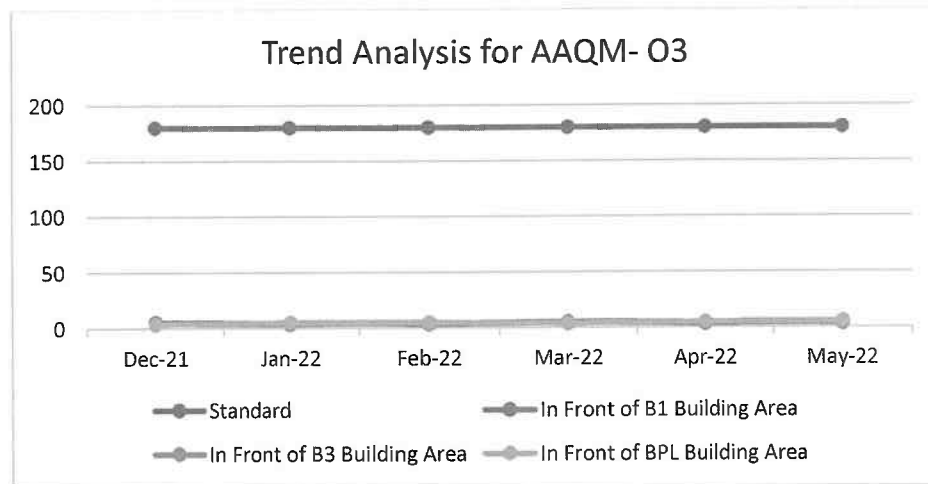
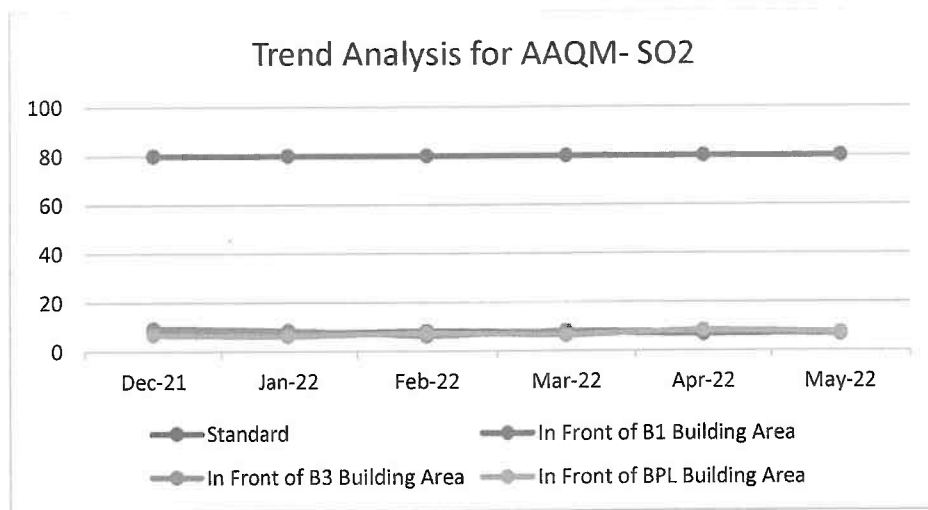
EC-2017 (Specific Condition: Point No: 6), EC-2020(II. vii)

Ambient air quality data shall be collected as per NAAQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM10, PM2.5, SO2, NOX, CO, VOC, BaP, HCL etc., (12 parameters) shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of MoEF – Bangalore, SEIAA – Karnataka, the respective zonal office of CPCB and KSPCB.

- Noted and shall be complied with. Ambient air quality monitoring is carried out at three identified monitoring locations in Biocon Biologics. Air quality is monitored in above said locations and reports are being submitted to Regional office and Head Office, Karnataka State Pollution Control Board. The trend of ambient air quality monitoring for the period December 2022 to May 2022 is as given below.

SI No	Month	PM ₁₀	PM _{2.5}	NO ₂	SO ₂	CO	O ₃	NH ₃
December-2021								
1	In Front of B1 Building Area	64.2	22.8	17.9	8.3	<1.0	5.5	7.3
2	In Front of B3 Building Area	67.2	23.6	18.3	9.4	<1.0	4.3	6.2
3	In Front of BPL Building Area	62.8	20.4	16.5	6.6	<1.0	3.9	5.1
January-2022								
1	In Front of B1 Building Area	66.3	24.5	16.5	7.2	<1.0	4.6	6.2
2	In Front of B3 Building Area	64.4	22.8	16.7	8.5	<1.0	3.7	5.6
3	In Front of BPL Building Area	61.3	20.6	15.4	6.1	<1.0	5.2	6.8
February-2022								
1	In Front of B1 Building Area	64.1	22.7	17.8	8.2	<1.0	3.7	5.2
2	In Front of B3 Building Area	67.5	24.6	15.4	6.2	<1.0	4.3	6.1
3	In Front of BPL Building Area	62.3	21.6	16.3	7.5	<1.0	5.2	7.1
March-2022								
1	In Front of B1 Building Area	66.8	23.5	16.2	7.6	<1.0	4.4	6.1
2	In Front of B3 Building Area	68.2	22.4	17.6	8.2	<1.0	5.5	7.2
3	In Front of BPL Building Area	64.7	22.6	15.8	6.3	<1.0	3.9	5.6
April-2022								
1	In Front of B1 Building Area	67.5	24.2	17.6	6.8	<1.0	3.9	5.3
2	In Front of B3 Building Area	69.4	23.3	16.5	7.7	<1.0	4.6	6.1
3	In Front of BPL Building Area	65.5	21.2	18.3	8.6	<1.0	5	7.4
May-2022								
1	In Front of B1 Building Area	62.3	21.8	16.5	7.2	<1.0	4.5	5.8
2	In Front of B3 Building Area	64.4	19.6	15.2	6.8	<1.0	3.7	4.6
3	In Front of BPL Building Area	59.8	18.2	17.5	7.6	<1.0	5.6	6.3





3. Fugitive emissions in the work zone environment, product, and raw material storage areas must be regularly monitored. The flue gas emissions should confirm to the standards prescribed by the Karnataka State Pollution Control Board. (EC- 2005) (EC-2020 II, ii)

- *We have taken at most care in all the process area, product handling area, and raw material handling area to avoid fugitive emissions. Work place monitoring for fugitive emissions in the work zone is conducted once in six month results are well within the standards.*

Occupational Exposure Limits (OEL's) are designed to protect workers against the health effects of exposure to hazardous substances. OEL is the maximum concentration of any airborne contaminant/fumes/vapours to which an unprotected worker may be exposed during the course of work activities.

Methods and Equipment Adopted: We had adopted sampling and quantification by PID method, which provide online readings at the location. We had used the EVM-7 equipment to conduct the study at different locations. This VOCs monitor has the capacity to measure VOCs in the range of low levels 0 ppm to 2,000 ppm. PID provides a compact, accurate, affordable and reliable real time gas monitoring of Total Volatile Organic Compounds. The Exposure limits of various Volatile Organic Compounds/ Solvents being used in process operation during monitoring of workplace are as presented in the following table:

<i>Sl. No.</i>	<i>Volatile Organic Compounds</i>	<i>Threshold Limit Values As per KFR & OSHA standard</i>
01	Ethyl Acetate	400 ppm
02	Methanol	200 ppm
03	Acetone	50 ppm
04	Petroleum Ether	300 ppm
05	Toluene	100 ppm
06	Acetonitrile	40 ppm
07	N-heptane	400 ppm
08	N-Hexane	50 ppm
09	Ammonia	25 ppm
10	Benzene	0.5 ppm
11	Acetic Acid	10 ppm
12	Cyclohexane	300 ppm
13	Dimethylamine	25 ppm

14	<i>n</i> -Propylamine	01 ppm
15	Thionyl chloride	01 ppm
16	Acetophenone	10 ppm
17	Isopropyl alcohol	400 ppm
18	Carbon monoxide	50 ppm
19	Methyl acrylate	01 ppm
20	Methyl tert-butyl ether	50 ppm
21	Pyridine	05 ppm
22	Methyl Ethyl Ketone	200 ppm

VOC Monitoring Results are as follows:

Sl.No	Location	Measured Area	VOC PPM TWA
1	A1	Ground floor Production	0.012
2	A1	Frist Floor Production	0.011
3	A2	Ground floor Production	0.015
4	A2	Ground floor Panel Room	0.013
5	A2	Ground floor center	0.013
6	A2	Frist Floor Production	0.014
7	A2	Frist floor Production centre	0.013
8	A2	2nd floor Center	0.013
9	A2	3rd floor	0.015
10	A2	3rd floor Center	0.013
11	C1	C1A Change Room	0.519
12	C1	C1B Change Room	0.522
13	C1	C1B-SSR-05	0.493
14	C1	C1B-SSR-02	0.501
15	C1	Fire extinguisher Area- 009	0.523
16	C1	C1B-SSV-03/PG-01	0.524

17	C1	C1B-CST-01	0.542
18	C1	C1B-SSV-01/TI01	0.518
19	C1	C1B-CST-03	0.504
20	C1	C1B-SSR-10	0.512
21	C1	C1B-DPB-03 Area room	0.491
22	C1	C1B-LAF-02	0.481
23	C1	Wash Room	0.623
24	C1	C1B-ANF-01	0.636
25	C1	C1B-VTD-01	0.628
26	C1	Storage Room in	0.467
27	C1	Drying Room	0.407
28	C1	C1B-SSV-07	0.541
29	C1	Control Room -Out	0.486
30	C1	Control Room - In Office	0.842
31	C1	Office	0.481
32	C1	IP-QC-GC-LAB	0.491
33	C1	Office Entry	0.491
34	C1	Rest room	0.514
35	C1	GF Entry	0.508
36	C1C	Entry	0.519
37	C1C	toilet	0.522
38	C1C	Exit	0.493
39	C1C	ANTE room	0.501
40	C1C	Emergency cup board	0.523
41	C1C	office Exit	0.524
42	C1C	Control room	0.542
43	C1C	PH meter room	0.518
44	C1C	Clean room out	0.504
45	C1C	Clean room left	0.512

46	C1C	Wash room	0.491
47	C1C	C1C-WB-06	0.481
48	C1C	RCVD-Clean room out	0.623
49	C1C	VTD room Out	0.636
50	C1C	LAF room in	0.628
51	C1C	Emergency exit	0.467
52	C1C	Fire extinguisher side	0.407
53	C1C	Drain point side	0.541
54	C1C	Milling room	0.486
55	C1C	Emergency exit	0.842
56	C1C	Reactor Room	0.481
57	C1C	Drain point side	0.491
58	C1C	Intermediate room	0.491
59	C1C	Clean room B	0.514
60	C1C	Clean room entrance B	0.508
61	D1	Production entrance right	0.354
62	D1	Production entrance left	0.369
63	D1	Production middle	0.37
64	D1	Production end right	0.358
65	D1	Production end Left	0.351
66	D1	Production end	0.357
67	D1	Production middle	0.354
68	D1	Production entrance	0.357
69	D1	Production end	0.405
70	D1	Production middle	0.454
71	D1	Production entrance	0.357
72	D1	Panel room	0.358
73	D1	Solvent area 1	0.353
74	D1	Solvent area 2	0.355
75	D1	AHU room entrance	0.454

76	D1	AHU room middle	0.357
77	D1	AHU room end	0.358
78	D1	Solvent area tank area 2 Entrance	0.353
79	D1	Solvent area tank area 2 End	0.355
80	D1	Solvent area tank area 1 Entrance	0.344
81	D1	Solvent area tank area 1 End	0.361
82	D1	Aqueous area entrance	0.354
83	D1	Aqueous area Middle	0.348
84	D1	Aqueous area End	0.454
85	D2	ISO-7 room 1	0.357
86	D2	ISO-7 room 2	0.358
87	D2	LAF area	0.353
88	D3	Water Plant (Entrance)	0.43
89	D3	Water Plant (End)	0.431
90	D3	Water Plant (Change room)	0.411
91	D3	In Process lab Q12 R2 (Entrance)	0.351
92	D3	In Process lab Q12 R2 (End)	0.357
93	D3	In Process lab Q12 R3 (Entrance)	0.354
94	D3	In Process lab Q12 R3 (End)	0.357
95	D3	Wet Lab (Entrance)	0.405
96	D3	Wet Lab (End)	0.454
97	D3	Cooling chamber (End)	0.357
98	D3	Cooling chamber (Entrance)	0.358
99	D3	GC Room (End)	0.353
100	D3	GC Room (Entrance)	0.355
101	D3	Fume hood Room	0.354
102	D3	Chemical storage room	0.369
103	D3	Washroom	0.37
104	D3	Q12 Office area	0.358

105	D3	Office area HPLC	0.34
106	D3	HPLC Room	0.342
107	D3	HPLC Room Wet Lab	0.344
108	D3	Panel Room (Entrance)	0.361
109	D3	Panel Room (End)	0.354
110	D3	Panel Room (Left)	0.348
111	D3	Panel Room (Right)	0.348
112	D3	Water Plant (Entrance)	0.466
113	D3	Water Plant (Middle)	0.456
114	D3	Module-1 (Entrance)	0.456
115	D3	Module-1 (Middle)	0.472
116	D3	Near D3-SSR-108	0.52
117	D3	Module-2 (Entrance)	0.343
118	D3	Module-2 (Middle)	0.342
119	D3	Near D3-BV-102	0.362
120	D3	Module-3	0.342
121	D3	Near D3-LC-103	0.342
122	D3	D3-SSR-10	0.361
123	D3	Freezer Room D3-GFD-97	0.372
124	D3	Freezer Room D3-GFD-99	0.344
125	D3	Entrance Lobby	0.148
126	R1	Entrance Left	0.015
127	R1	End left	0.015
128	R1	End left	0.014
129	U1	Near SH 06	0.46
130	U1	RO distribution	0.47
131	U1	Near softener	0.479
132	U1	Panel room left	0.461
133	U1	Panel room right	0.456

134	U1	10 MGF feed pump	0.444
135	U1	MGF feed pump	0.456
136	U1	Near MGF	0.452
137	U1	Near UFM	0.501
138	U1	RO left side	0.503
139	U1	RO housing right side	0.509
140	U1	RO 2	0.491
141	U1	RO 2 MGF	0.505
142	U1	Near MFM	0.533
143	U1	Near MCF	0.558
144	U1	Panel room 3	0.451
145	U1	Panel room 2	0.433
146	U1	MGF - 94KL	0.527
147	U1	High pressure pump	0.501
148	U1	MFM pump area	0.477
149	U1	Tank area LS	0.441
150	U1	Tank area RS	0.429
151	U1	New panel room LS	0.457
152	U1	New panel room RS	0.446
153	U2	Control room RO	0.43
154	U2	Control room RO	0.545
155	U2	MCC Room	0.412
156	U2	MCC room	0.388
157	U2	PLC room	0.371
158	U2	New ETP	0.436

159	U2	New ETP	0.437
160	U2	New ETP	0.432
161	U2	Lime store	0.438
162	U2	Lime store	0.433
163	U2	Lime store	0.445
164	U2	Chemical preparation room 2	0.467
165	U2	Dust collector	0.488
166	U2	Chemical preparation room 3	0.436
167	U2	NaOH dosing tank DT 02	0.486
168	U2	MCC panel U2-MCC-001-01	0.418
169	U2	VFD panel U2-MCC-001-02	0.401
170	U2	High Noise area Pump room	0.46
171	U2	High Noise area Pump room	0.434
172	U2	High Noise area Pump room	0.44
173	U2	High Noise area Pump room	0.43
174	U3	Cartridge filter housing	0.59
175	U3	400-C-KLD-RO-plant	1.024
176	U3	1st blow indicator	1.081
177	U3	FEH 45	0.835
178	U3	Pressure sand filter	0.851
179	U3	Panel room	0.45
180	U3	Panel room	0.462
181	U3	FEH 44	0.762
182	U3	Jockey pump 1	0.785
183	U3	Diesel engine pump 3	0.657

184	U3	Jockey pump 2	0.623
185	U3	Header line A,D .C blocks (1)	0.687
186	U3	Boiler feed pump 1	0.486
187	U3	Tank 9	0.479
188	U3	U3 office	0.426
189	U5	Boiler 3 Front side	0.44
190	U5	Boiler 3 Back side	0.413
191	U5	Boiler 2 back side	0.43
192	U5	Boiler 2 Front side	0.427
193	U5	Boiler 1 back side	0.435
194	U5	Boiler 1 front side	0.437
195	U5	Boiler chimney	0.403
196	U5	Furnace oil terrace area R.S	0.41
197	U5	Calibration 1AB	0.346
198	U5	Instrumentation	0.351
199	U5	Instrumentation	0.359
200	U5	Human Resource	0.353
201	U5	Discussion room	0.37
202	U5	PLC panel HRSG Boiler 2	0.364
203	U5	Control room	0.358
204	U5	Control room	0.361
205	U5	HT panel Room	0.445
206	U5	HT panel Room	0.461
207	U5	HT panel Room	0.455
208	U5	HT panel Room	0.494

209	U5	DG Room	0.469
210	U5	DG Room	0.445
211	U5	DG Room	0.489
212	U5	DG Room	0.442
213	U8(Compressor house)	Refrigerant full cylinders area	0.838
214	U8(Compressor house)	Emergency exit	0.995
215	U8(Compressor house)	U8-PAC-002	0.914
216	U8(Compressor house)	U8-IAC-002-35	0.509
217	U8(Compressor house)	U8-IAC-003-34	0.545
218	U8(Compressor house)	office	0.397
219	U8(Compressor house)	Panel room	0.414
220	U8(Compressor house)	Panel room	0.431
221	U8(Compressor house)	Panel room	0.439
222	U8	FEH 48	0.453
223	U8	Board Room	0.425
224	U8	Board Room	0.439
225	U8	Board Room	0.424
226	U8	Board Room	0.434
227	U8	Fire Exit	0.42
228	U8	Fire Exit	0.424
229	U8	Fire Exit	0.41
230	U8	Training Hall	0.403
231	U8	Safety office	0.359
232	U8	Safety office	0.356
233	U8	Safety office	0.357

234	U8	Safety office	0.352
235	U8	OHC	0.35
236	U8	OHC	0.349
237	U8	OHC	0.354
238	U8	OHC	0.414
239	U17	Entry	0.492
240	U17	U5-SST-001-BC-40	0.464
241	U17	U5-SST-001-BC-40	0.444
242	U17	Panel Feeder no 32	0.428
243	U17	Panel Feeder no 32	0.431
244	U17	Panel Feeder no 32	0.418
245	U17	Battery room	0.366
246	U17	Battery room	0.424
247	W11	W11-CR-02 Entrance	0.44
248	W11	W11-CR-03 Middle	0.413
249	W11	W11-CR-04 End	0.43
250	W11	W11-CR-05 Entrance	0.427
251	W11	W11-CR-06 Middle (Emergency Exit)	0.461
252	W11	W11-CR-01 (1st Row) Entrance	0.509
253	W11	W11-CR-01 (2nd Row) Entrance	0.43
254	W5	W5 warehouse	0.401
255	W1	W1 office	459
256	W1	W1 office	418
257	W1	Material Entry	0.479
258	W1	ACID storage area	0.68

259	W1	CRT area	0.344
260	W1	CRT area	0.353
261	W1	CRT area	0.347
262	W1	Dispensing Room 1	0.545
263	W1	Dispensing Room 2	0.49
263	W1	Sampling Room 1	0.412
265	W1	Sampling Room 2	0.417
266	W1	Dispensing Room 3	413
267	W1	Dispensing sampling area	0.401
268	W1	Material Handling equipment room	0.488
269	W1	W1	0.46
270	W1	W1	0.444
271	W1	W1	0.463
272	W1	W1	0.461
273	W1	W1	0.45

* VOC is monitored during work place monitoring conducted in the month of May 2022.

- Online Continuous VOC Monitoring Instrument installed in the Solvent recovery area. The same will be connected to the CPCB server.

EC-2017 (Specific Condition: Point No: 9)(EC-2020 II. and iv)

In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, bag filters, scrubbers and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area shall be regularly monitored. The emissions shall conform to the limits stipulated by the KSPCB.

- We have taken at most care in all the process area, product handling area, and raw material handling area to avoid fugitive emissions. Work place monitoring for fugitive emissions in the work zone is

conducted once in six month results are well within the standards.

Occupational Exposure Limits (OEL's) are designed to protect workers against the health effects of exposure to hazardous substances. OEL is the maximum concentration of any airborne contaminant/fumes/vapours to which an unprotected worker may be exposed during the course of work activities.

Methods and Equipment Adopted: We had adopted sampling and quantification by PID method, which provide online readings at the location. We had used the EVM-7 equipment to conduct the study at different locations. This VOCs monitor has the capacity to measure VOCs in the range of low levels 0 ppm to 2,000 ppm. PID provides a compact, accurate, affordable and reliable real time gas monitoring of Total Volatile Organic Compounds. The Exposure limits of various Volatile Organic Compounds/ Solvents being used in process operation during monitoring of workplace are as presented in the following table:

SL NO	LOCATION	VOC
		PPM (TWA)
01	B1 2nd Floor Office Area QA	0
02	B1-M -084 Analytical lab 01 GF	0.1
03	B1 Fill Finish (Lyophilization and crystallization Room)	0.1
04	B1 Fill Finish (Nonsterile Corridor) General Used Area	0
05	B1 Fill Finish Sterile Formulation Area	0
06	B1 Fill Finish Vial Washing Area	0.1
07	B1 Inoculum Lab Process Area 01 Room 01	0
08	B1 Kill Plant	0.1
09	B1 M1 Down Stream	0.1
10	B1 M1 Upstream (Fermentation Room)	0.1
11	B1 M2 AHU Area Technical Floor	0
12	B1 M2 Down Stream	0
13	B1 M2 Upstream	0

14	<i>B1 SF QA Office Area</i>	0
15	<i>B1 SF QC Micro Lab</i>	0.3
16	<i>B1 Technical Floor M1 AHU Area</i>	0
17	<i>B1 Water Plant</i>	0
18	<i>B2 Formulation Area</i>	0
19	<i>B2 General Washing Area</i>	0.1
20	<i>B2 GF Office Area</i>	0.1
21	<i>B2 Micro Lab</i>	0.2
22	<i>B2 Pen Packing and Labelling Area</i>	0.1
23	<i>B2 Vial Washing Area</i>	0.1
24	<i>B2 Water Plant</i>	0
25	<i>RND 2nd F POD 01 Lab</i>	0
26	<i>RND 2nd F POD 01 Office Area</i>	0
27	<i>RND 3rd F POD 1 Lab</i>	0
28	<i>RND 3rd F POD 1 Office Area</i>	0
29	<i>RND 3rd F POD 3 Office Area</i>	0
30	<i>RND Basement AHU 03</i>	0
31	<i>RND Basement Car Parking</i>	0
32	<i>RND Basement Chiller Plant</i>	0
33	<i>RND Basement Warehouse</i>	0
34	<i>RND FF POD 01 Lab</i>	0
35	<i>RND FF POD 01 Office Area</i>	0
36	<i>RND FF POD 02 Lab</i>	0
37	<i>RND FF POD 03 Lab</i>	0
38	<i>RND General Corridor FF</i>	0
39	<i>RND GF POD 02 Lab</i>	0
40	<i>RND GF POD 03 Lab</i>	0

41	W20- Ground Floor Warehouse Office	0
42	W20- First Floor AHU area	0
43	W20- First Floor Office area	0
44	W20- Packing area	0
45	W20- Packing & Consumable Storage area (WH 116)	0.9
46	W20- Packing Material Storage area & Consumable Storage area (WH 034)	0
47	W20- QA Documentation area (WH 057)	0
48	W20 Raw Materials, Packing materials and Consumables storage area (WH 051)	0
49	W20 Receipt area	0
50	B3 -Chiller area	0
51	B3-2nd Clean room	0
52	B3-First floor office area	0
53	B3- Ground floor office area	0
54	B3- Ground floor clean room	0.0
55	B3- 1st Floor analytical Lab	0
56	B3- 1st floor RM Lab	0
57	B3- QC washing room	0
58	B3- 2nd floor Office	0.1
59	B3-1st floor technical area	0
60	B3-3rd floor office area	0.8
61	B3-3rd Utility Air compressor	0
62	B5-E & M office	0
63	B5- 1st floor office area	0
64	B5- 1st floor Production area	0

65	B5-Mezzine floor	0
66	B5- 2nd floor Micro Lab	0
67	B5- 2nd floor Office area	0
68	B5- 2nd floor QC office	0
69	B5- 2nd floor washing room	0
70	Q13 QC Office FF	0
71	Q13 Analytical Lab-06	0
72	Q13 Analytical Lab-03	0
73	Q13 Analytical Lab-04	0

4. The process emissions shall be scrubbed through caustic scrubber and confirm to the prescribed standards. The efficiency of the scrubber shall be improved and maintained as per the best practicable technology. VOC emissions shall be monitored and data submitted to the Ministry. (EC- 2005)

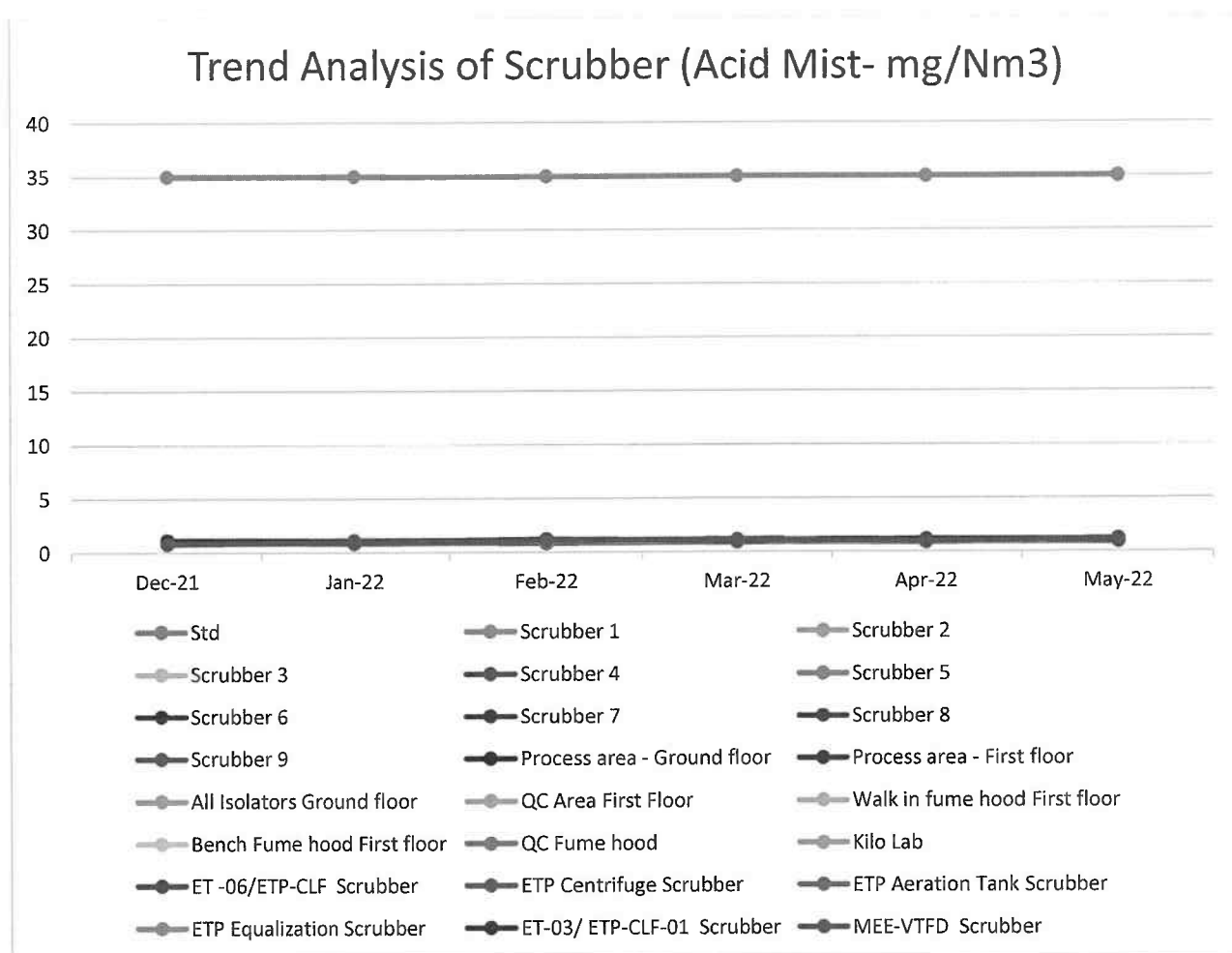
- *We have taken at most care in the designing stage of scrubbers and are well maintained. The sources are storage of VOC components & VOC generating compounds which are being used through closed loop pipes. Controls are Inertization of nitrogen, Sprinkler system and transportation of VOC components through closed loop. As per the consent from KSPCB, emissions are monitored monthly and results are well within the standards. As a part of work place monitoring, VOC is monitored at above said locations once in six month and the results are detailed.*
- *The scrubber emission facts are detailed in Annexure – 1 mentioned below:*

Annexure – 1:

Gaseous Emissions statement from December - 2021 to May -2022 (mg/Nm³)

Name of Stack	Std (mg/Nm ³)	Parameters	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Scrubber 1	35	Acid mist	1.02	1.17	1.06	1.14	1.07	1.15
Scrubber 2	35	Acid mist	0.98	1.05	1.12	1.05	1.12	0.88
Scrubber 3	35	Acid mist	0.84	0.93	0.87	0.95	0.86	0.93
Scrubber 4	35	Acid mist	1.15	0.89	0.92	0.88	0.98	1.04
Scrubber 5	35	Acid mist	0.92	1.09	1.14	0.96	1.14	1.07
Scrubber 6	35	Acid mist	1.12	0.96	0.88	1.04	0.88	0.96

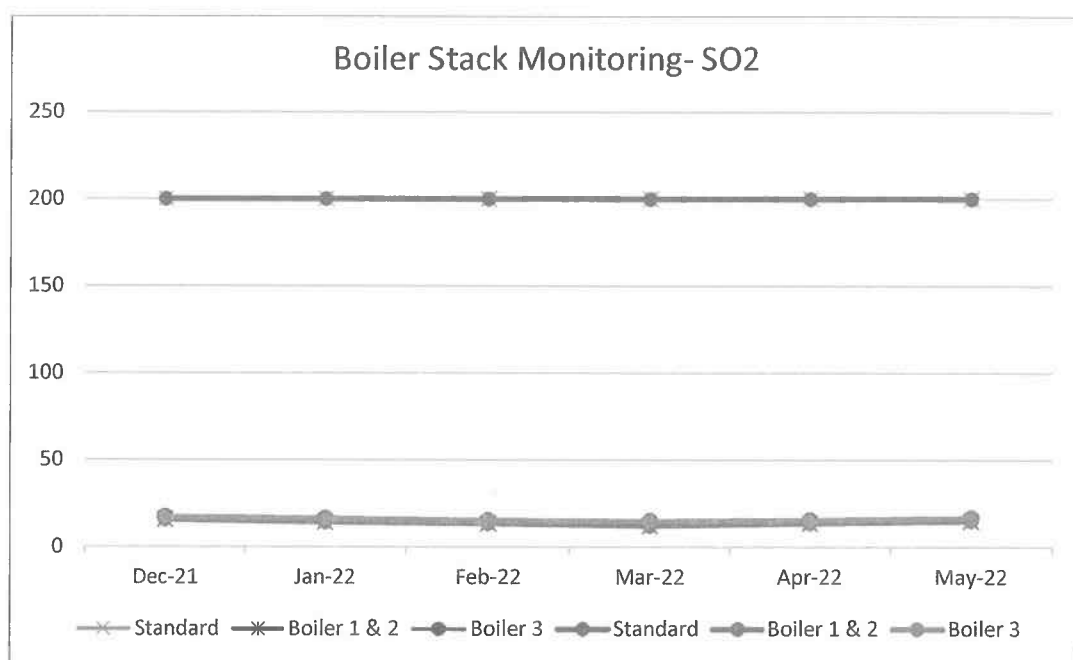
Scrubber 7	35	Acid mist	1.06	0.84	0.91	1.12	1.05	1.13
Scrubber 8	35	Acid mist	0.87	1.02	1.18	1.08	1.12	1.18
Scrubber 9	35	Acid mist	1.08	0.87	1.04	0.95	1.06	0.94
Process area - Ground floor	35	Acid mist	0.85	1.11	1.09	1.15	1.1	1.03
Process area - First floor	35	Acid mist	0.91	1.05	0.86	0.99	0.86	0.96
All Isolators Ground floor	35	Acid mist	1.09	0.93	1.12	1.08	1.07	0.85
QC Area First Floor	35	Acid mist	1.04	0.88	0.93	0.86	0.91	1.04
Walk in fume hood First floor	35	Acid mist	1.16	1.02	1.15	1.03	1.15	0.96
Bench Fume hood First floor	35	Acid mist	0.93	1.13	1.04	1.14	1.09	0.87
QC Fume hood	35	Acid mist	0.83	0.99	0.89	0.97	0.84	1.12
Kilo Lab	35	Acid mist	1.07	1.13	1.01	1.15	1.06	1.15
ET -06/ETP- CLF Scrubber	35	Acid mist	0.86	0.92	0.84	0.95	1.05	1.18
ETP Centrifuge Scrubber	35	Acid mist	1.13	1.06	1.13	1.07	0.91	0.88
ETP Aeration Tank Scrubber	35	Acid mist	0.91	0.85	0.91	0.88	1.15	1.06
ETP Equalization Scrubber	35	Acid mist	1.19	1.12	1.03	1.13	0.86	0.94
ET-03/ETP- CLF-01 Scrubber	35	Acid mist	1.11	1.04	1.16	1.05	1.13	1.03
MEE-VTFD Scrubber	35	Acid mist	0.81	0.98	1.08	1.14	0.97	1.14

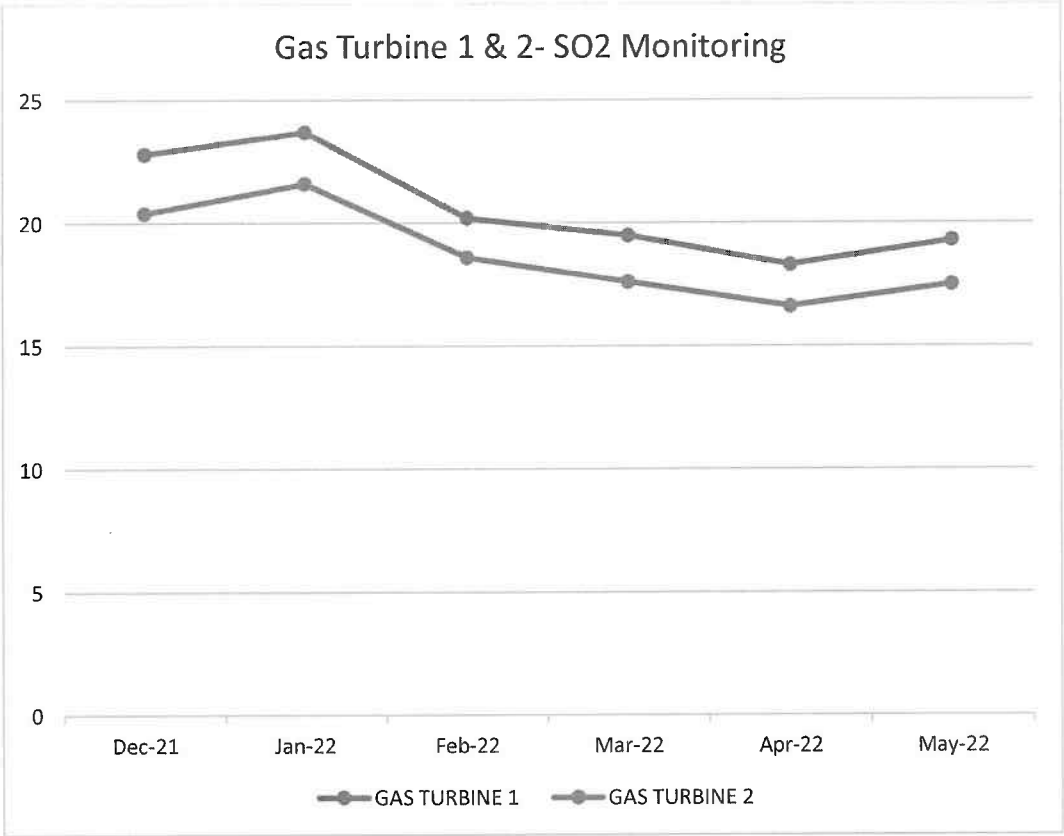


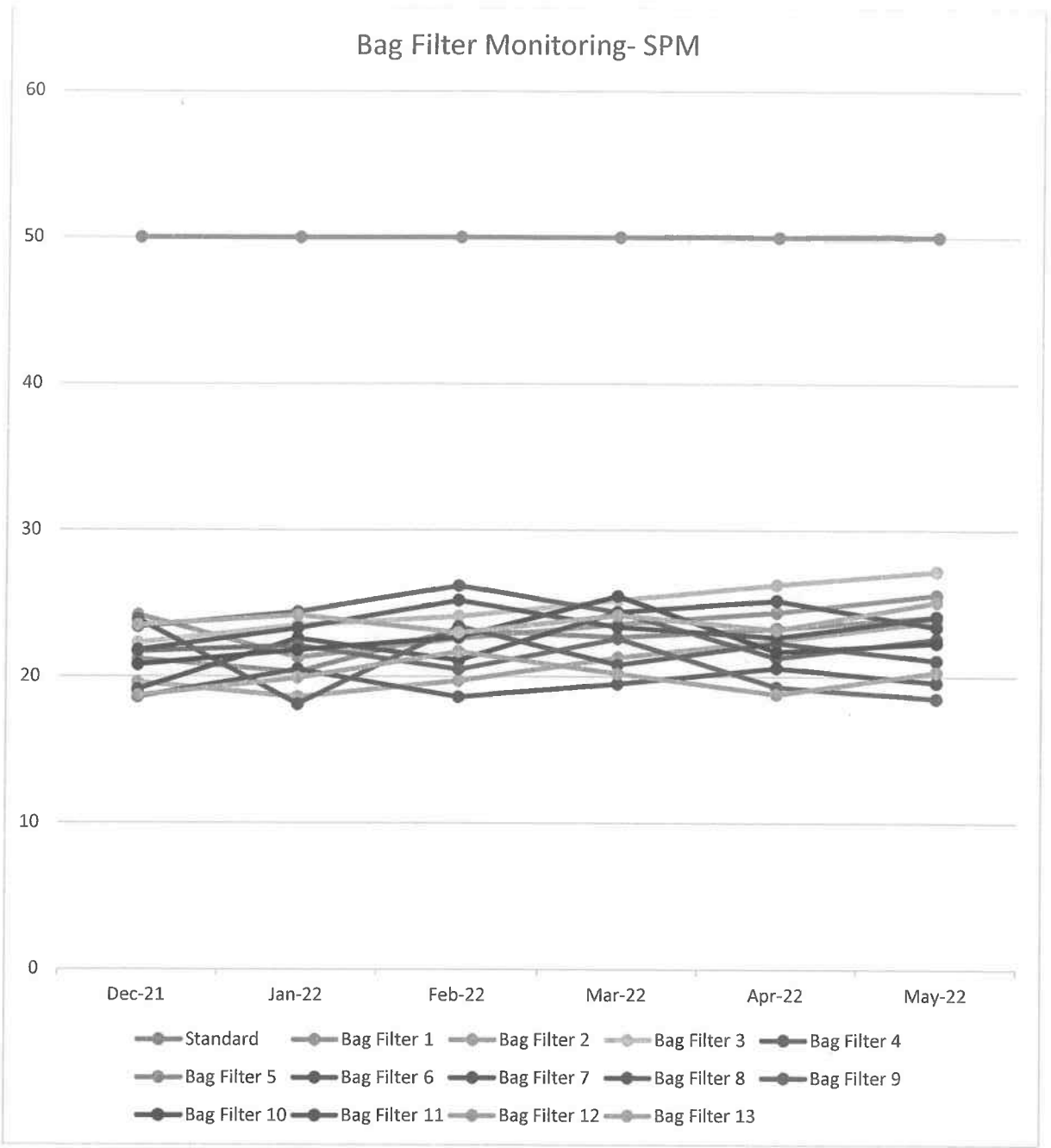
Name of Stack	Std (mg/Nm ³)	Parameters (mg/Nm ³)	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Gas turbine 1	-	SO ₂	22.8	23.7	20.2	19.5	18.3	19.3
Gas turbine 2	-	SO ₂	20.4	21.6	18.6	17.6	16.6	17.5
Boiler 1 & 2	200	SO ₂	15.6	14.2	13.4	12.2	13.6	14.8
Boiler 3	200	SO ₂	17.2	16.3	15.1	14.8	15.2	16.7

Name of Stack	Parameters (mg/Nm ³)	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Bag filter 1	SPM	24.2	21.3	22.6	23.6	24.4	25.6

Bag filter 2	SPM	19.6	18.6	19.7	21.3	22.5	23.8
Bag filter 3	SPM	22.3	23.5	24.1	25.2	26.3	27.2
Bag filter 4	SPM	23.4	24.4	26.2	24.4	21.3	22.6
Bag filter 5	SPM	21.2	20.3	23.2	22.7	23.3	24.1
Bag filter 6	SPM	19.1	22.6	21.1	24.4	25.2	23.4
Bag filter 7	SPM	18.6	20.5	18.6	19.5	20.6	19.6
Bag filter 8	SPM	23.9	18.1	23.4	20.8	22.3	21.1
Bag filter 9	SPM	21.7	22.1	20.5	22.6	19.3	18.5
Bag filter 10	SPM	20.8	21.8	22.7	25.5	21.7	22.3
Bag filter 11	SPM	21.8	23.3	25.2	23.4	22.7	24.1
Bag filter 12	SPM	18.7	19.9	21.7	20.2	18.8	20.3
Bag filter 13	SPM	23.5	24.2	23	24.2	23.2	25.1







Parameter	Std (mg/Nm ³)	DG - I		DG - II		DG - III		DG - IV	
		Dec-21	Mar-22	Dec-21	Mar-22	Dec-21	Mar-22	Dec-21	Mar-22
Particulate matter	100	53.5	51.6	45.2	47.3	48.8	49.5	47.3	45.5
NOx	970	31.2	33.5	44.4	42.5	836.3	38.3	839.4	37.4
SO ₂	--	17.6	16.4	16.1	14.8	18.6	17.4	18.2	20.2
CO	150	23.4	21.3	25.3	24.2	26.7	25.3	26.6	24.3
NMHC	100	32.3	30.4	34.4	32.5	35.2	34.6	34.4	31.4

Parameter	Std (mg/Nm ³)	DG - V		DG - VI		DG - VII		DG - VIII	
		Dec-21	Mar-22	Dec-21	Mar-22	Dec-21	Mar-22	Dec-21	Mar-22
Particulate matter	100	44.5	43.3	51.2	49.5	46.4	48.2	52.2	53.8
NOx	970	37.2	35.2	34.4	33.3	35.2	36.4	33.1	34.6
SO ₂	--	19.5	18.8	21.2	22.2	18.3	19.5	22.8	23.5
CO	150	24.4	22.2	22.8	20.6	22.6	23.1	24.4	25.2
NMHC	100	32.3	34.5	31.6	34.5	35.6	32.5	38.2	36.6

Parameter	Std (mg/Nm ³)	DG - IX		DG - X	
		Dec-21	Mar-22	Dec-21	Mar-22
Particulate matter	100	47.4	46.6	52.2	50.4
NOx	970	30.2	32.3	34.8	32.2
SO ₂	--	20.1	22.8	20.7	19.1
CO	150	20.6	21.5	24.2	22.6
NMHC	100	31.7	30.4	31.2	33.5

Parameter	Std (mg/Nm ³)	DG -XI		DG - XII		DG - XIII	
		Dec-21	Mar-22	Dec-21	Mar-22	Dec-21	Mar-22
Particulate matter	100	48.6	46.5	49.3	48.2	53.3	54.5
NOx	970	31.7	30.3	30.8	33.5	36.4	33.6
SO ₂	--	18.5	17.6	21.6	22.4	17.2	18.8
CO	150	21.3	23.5	20.5	21.5	28.1	26.2
NMHC	100	28.7	30.4	26.5	28.2	30.3	33.3

EC-2017 (Specific Condition: Point No: 16)

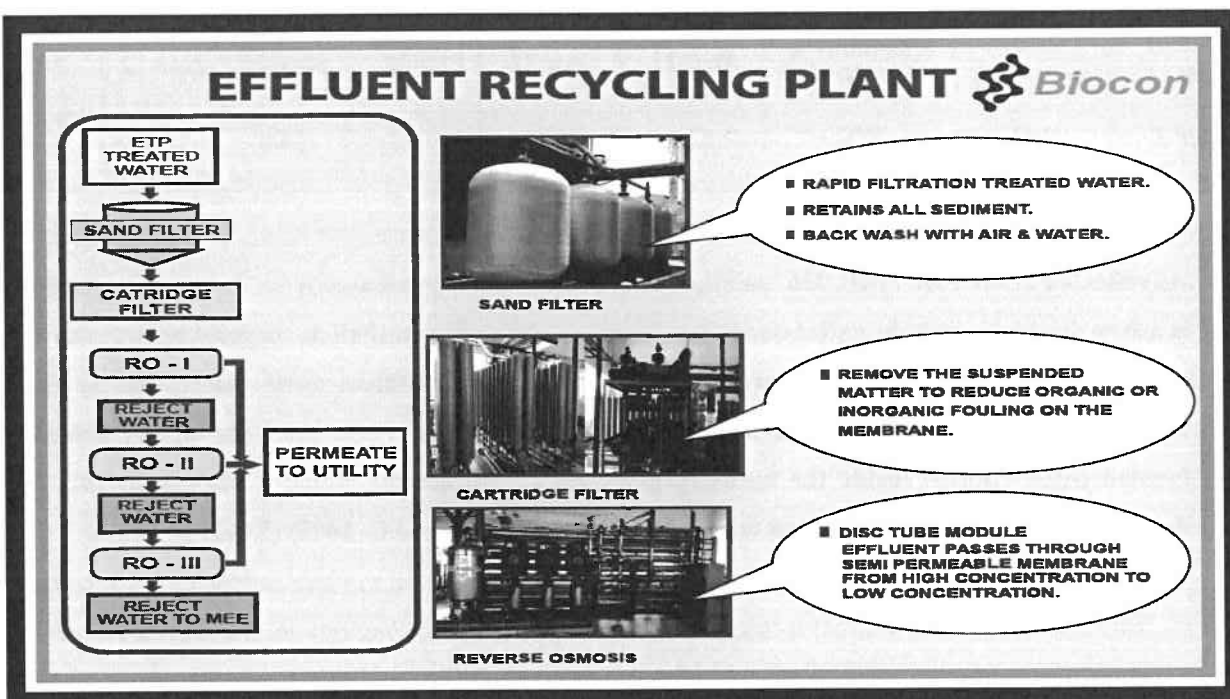
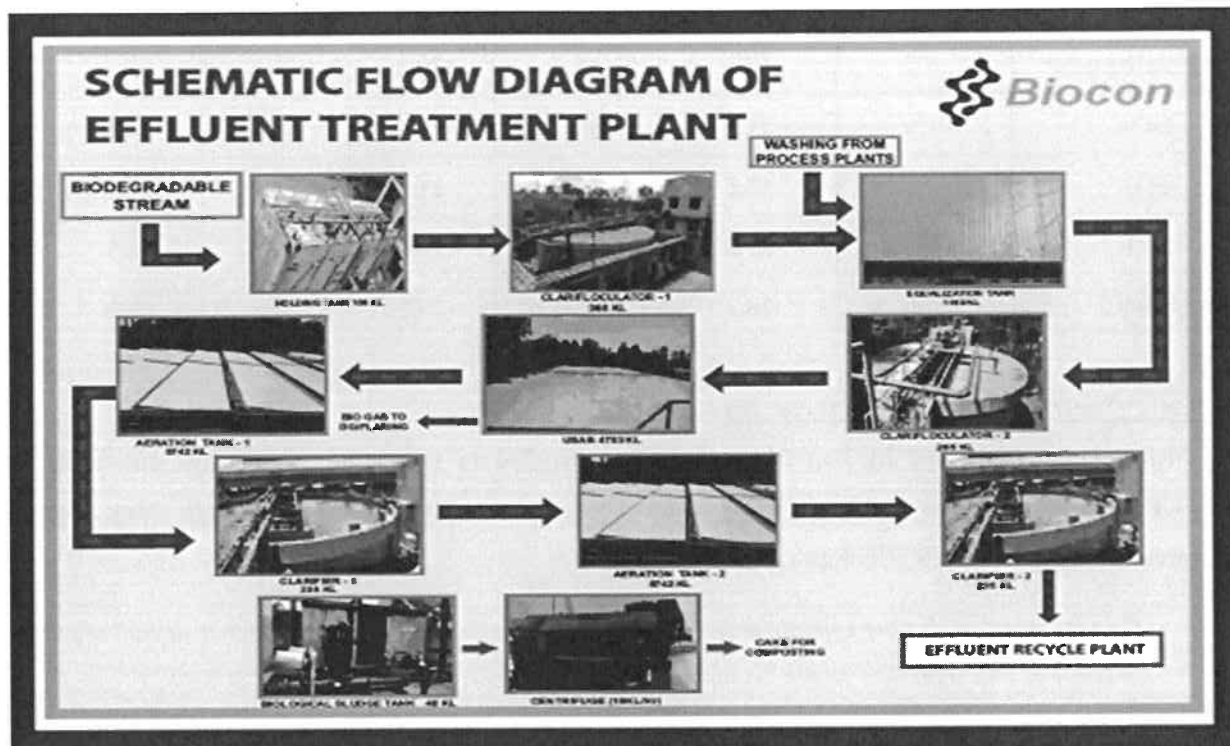
Multi-cyclone followed by bag filter shall be provided to the boilers to control emissions within CPCB/KSPCB prescribed limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/KSPCB guidelines

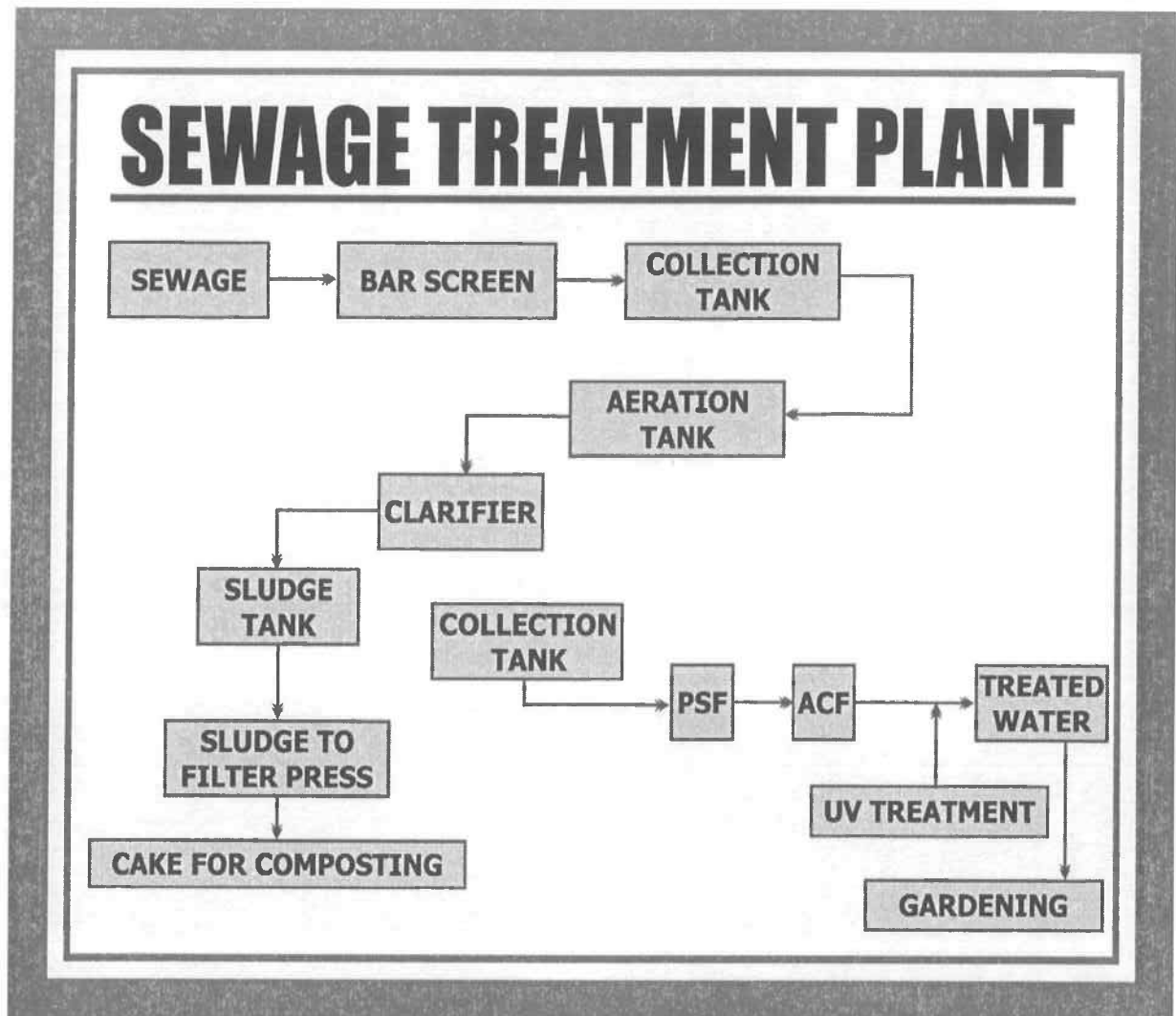
- The fuel proposed for our existing and proposed boilers is piped natural gas which is devoid of particulate emissions. The emission levels is compiled within prescribed limits of CPCB/KSPCB details are as follows:

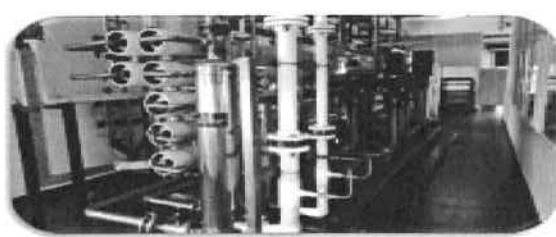
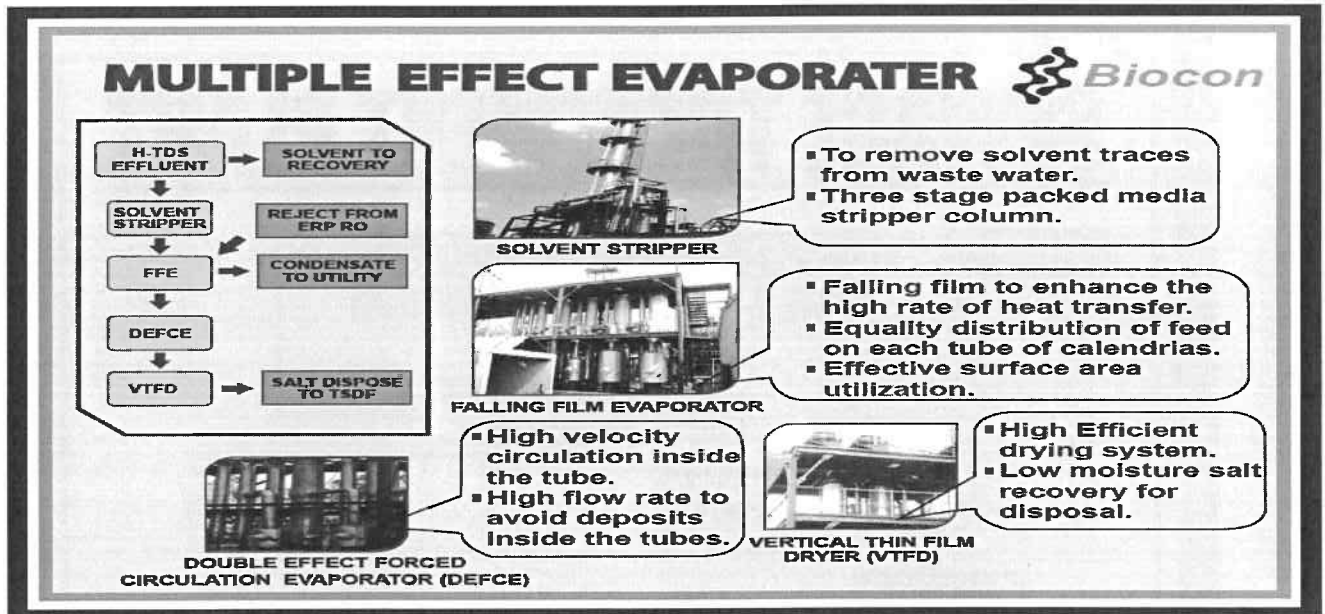
Name of Stack	Std (mg/Nm ³)	Parameters (mg/Nm ³)	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Boiler 3	200	SO ₂	17.2	16.3	15.1	14.8	15.2	16.7

- As reflected in the EIA/EMP, 2367 m³/day wastewater will be generated from the project. As the plant is a zero discharge unit the entire quantity of treated trade effluent shall be recycled back to the process and all the rejects shall be evaporated. The process and treatment units description as given by Karnataka Pollution Control Board should be followed in too. There shall not be any discharge of treated trade effluent inside the industry premises or outside the industry premises. Only treated domestic waste water shall be used for green belt development. (EC- 2005) (EC-2020 III, ii)

- All Treatment units as mentioned in EIA have been established and working satisfactorily. Treated water from Effluent Treatment Plant is again recovered in Effluent recycling system. The recycled water is used for Utility consumption like Boiler, cooling towers and chillers and rejects generated are evaporated. Treated waste water from STP is used for Gardening. OCEMS installed for STP Outlet and is under commissioning, which will be connected to KSPCB server shortly.

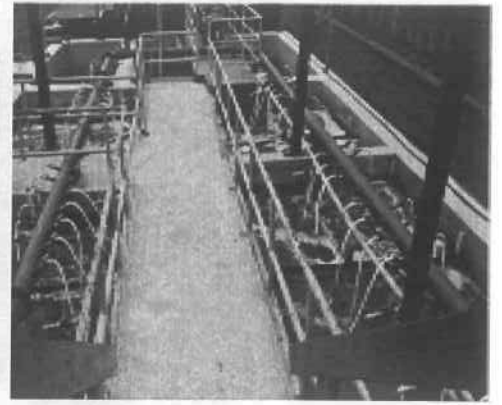
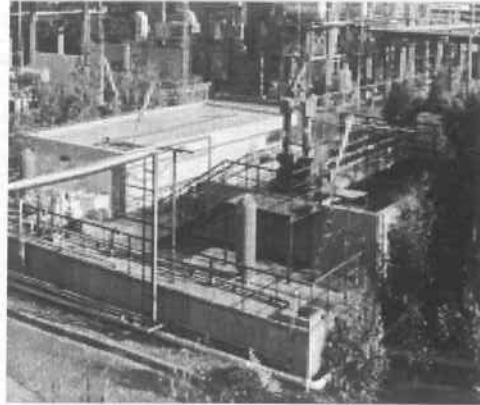




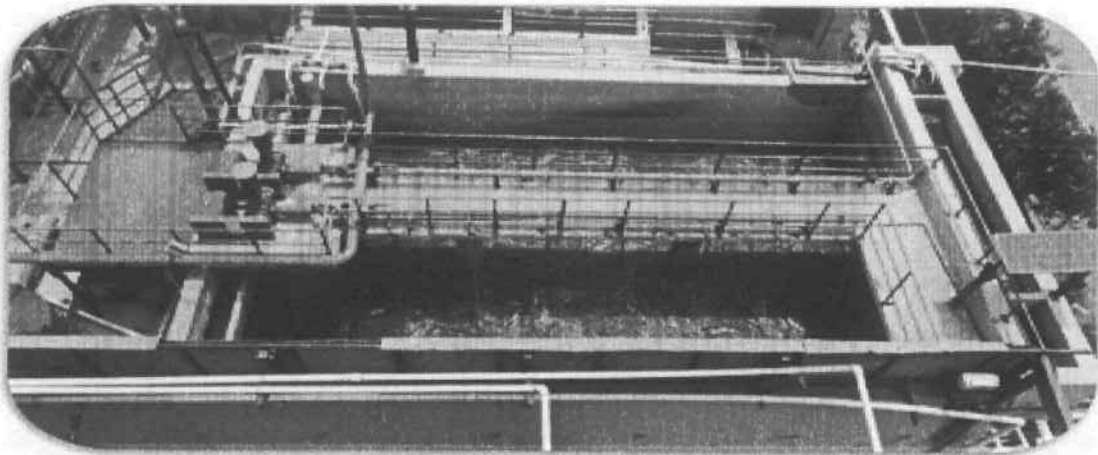


Effluent Treatment Plant & RO Plant

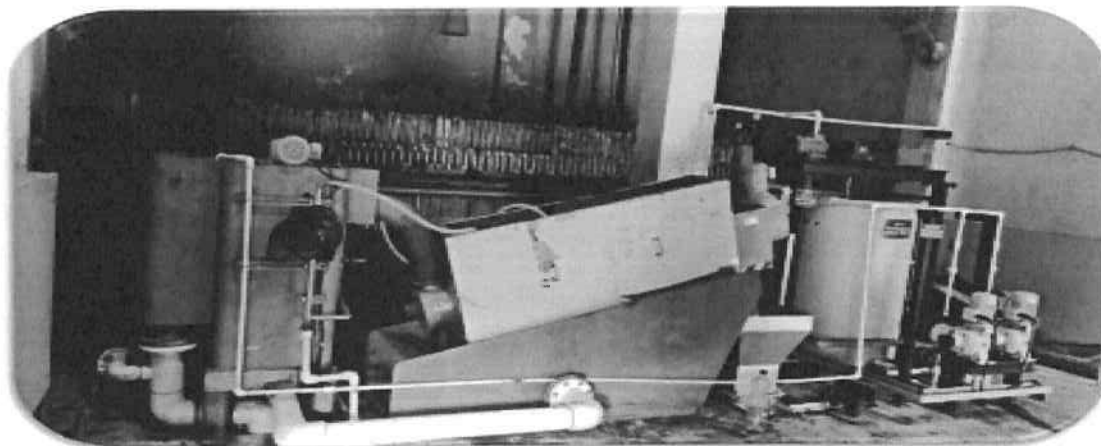
•Domestic effluent (sewage) generated is treated in a specifically designed Sewage Treatment Plant
•Used in Gardening in place of fresh water



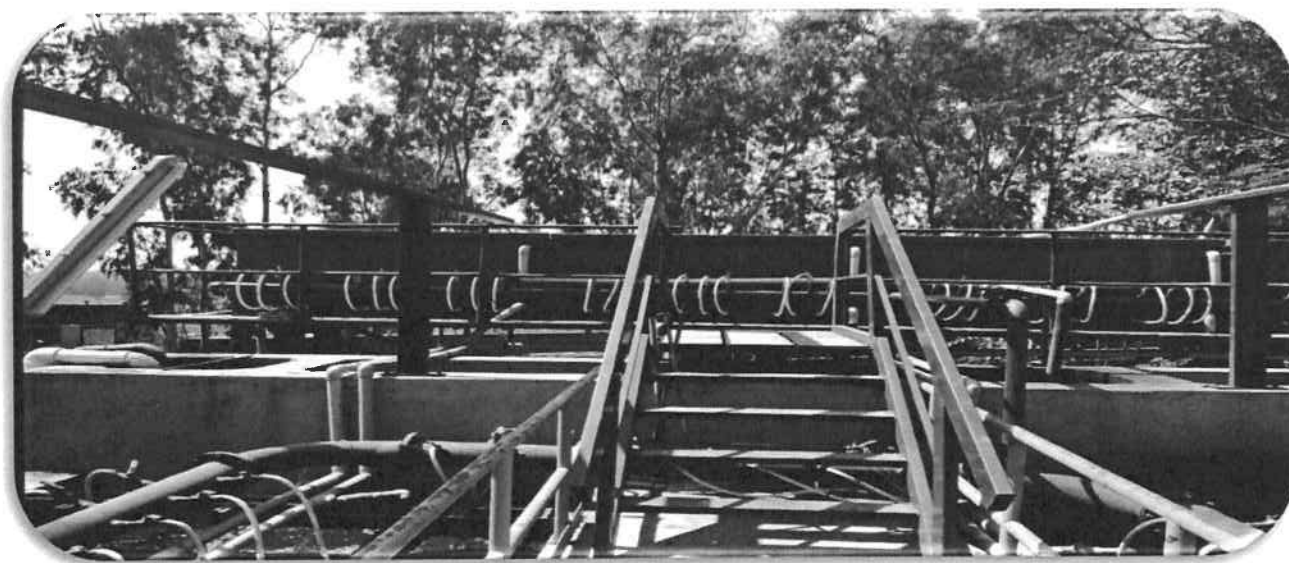
Domestic Effluent Treatment



Membrane Bio Reactor



Volute Centrifuge for Sludge Dewatering



Sewage Treatment Plant

EC-2017 (Specific Condition: Point No: 2)

The total effluent generation shall not exceed 1554 KLD. The trade effluent shall be treated in the effluent treatment plant (ETP) followed by RO & MEE and Treated effluent shall be reused within factory premises.

- *Noted and shall be complied with.*
- *Treated water from Effluent Treatment Plant is again recovered in Effluent recycling system. The recycled water shall be used for Utility consumption like Boiler and cooling towers and rejects generated are evaporated.*



Effluent Treatment Plant

6. The groundwater quality in and around the unit and hazardous waste storage site shall be regularly monitored and the data recorded to ensure that there is no contamination of the ground water. (EC- 2005)

- *As the bore well dried up, we are unable to take sample, hence same is not being monitored.*

7. The company shall collect, treat and dispose off all solid waste generated from the process and from the effluent treatment plant other than wastes covered under Hazardous Waste Management and handling Rules in such manner so as not to cause environmental pollution. (EC- 2005)

- *We follow a well-planned solid waste segregation system and are stored in solid waste storage yard. All the non-hazardous solid wastes generated in the facility are disposed on a regular basis to the recyclers.*
- *The non-hazardous waste from each process area is being collected in waste collection point provided in the respective process area. Segregated waste from the different blocks and departments is being collected on the daily basis by trained Contract personnel and stored in the designated large storage Yard which is located near ETP.*
- *The collection, storage, handling and disposal of solid waste is as per the standard operating procedure*

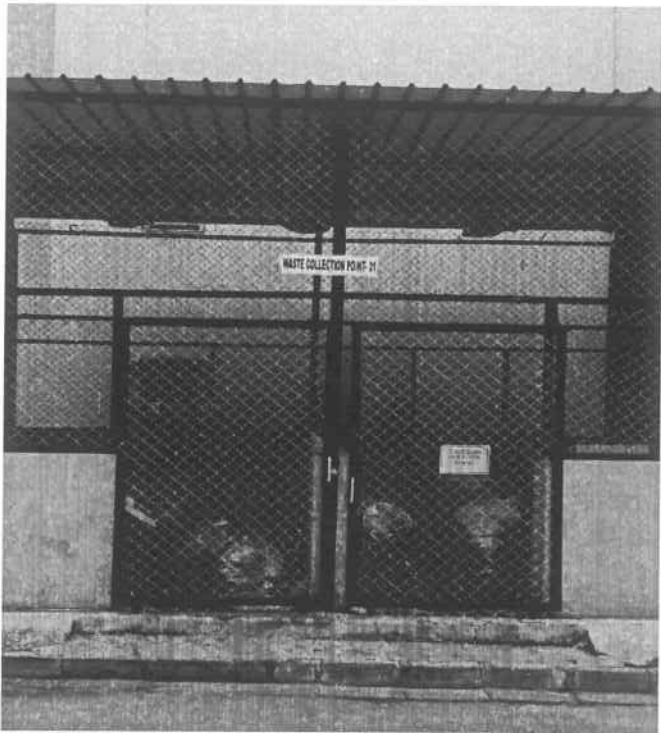
(SOP) S2/SMV/EHS/SOP-ETP/0012

- We have non-hazardous solid waste collection bins placed at all the production units and collected solid waste shall be segregated in scrap yard. The disposal of solid waste shall ensure all the KSPCB regulations
- The non-hazardous waste generation and disposal for the period Dec -2021 to May-2022 is as follows:

<i>Name of the Solid Waste</i>	<i>Quantity in MT</i>	
	<i>Generation</i>	<i>Disposal</i>
<i>Wooden Scrap</i>	<i>57.655</i>	<i>56.95</i>
<i>MS Scrap</i>	<i>88.12</i>	<i>107.85</i>
<i>GI Scrap</i>	<i>28.14</i>	<i>27.24</i>
<i>GI With Puff</i>	<i>Nil</i>	<i>Nil</i>
<i>SS Scrap</i>	<i>10.72</i>	<i>10.65</i>
<i>Aluminium Scrap</i>	<i>5.735</i>	<i>4.76</i>
<i>Aluminium Filter Scrap</i>	<i>Nil</i>	<i>Nil</i>
<i>Aluminium Cable Scrap</i>	<i>Nil</i>	<i>Nil</i>
<i>SS 202 Scrap</i>	<i>Nil</i>	<i>Nil</i>
<i>Machinery Scrap</i>	<i>Nil</i>	<i>Nil</i>
<i>Copper Cable</i>	<i>Nil</i>	<i>Nil</i>
<i>Inert Cell mass – Co-processing</i>	<i>2219.11</i>	<i>2211.36</i>



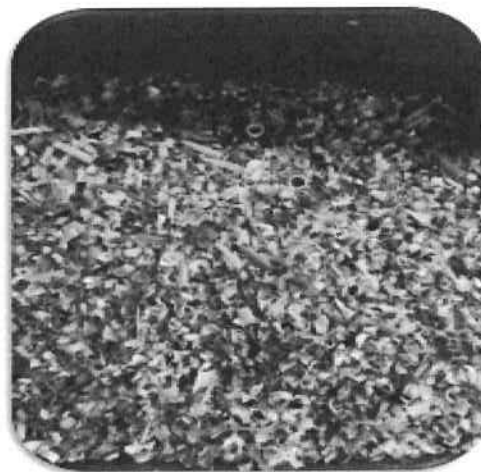
Centralized Non-hazardous Waste Collection Area



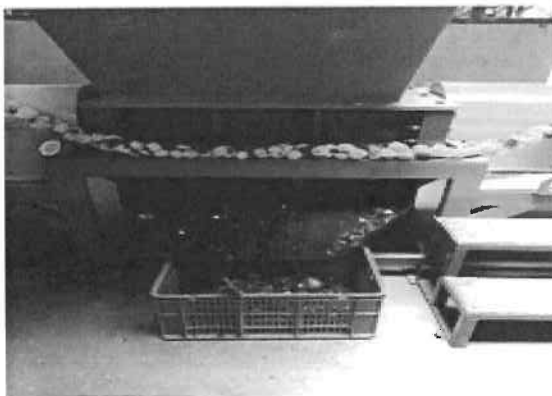
Departmental Non-hazardous Waste Collection



Multi-Purpose Shredder



Multi-Purpose Shredder



Plastic Waste Shredder

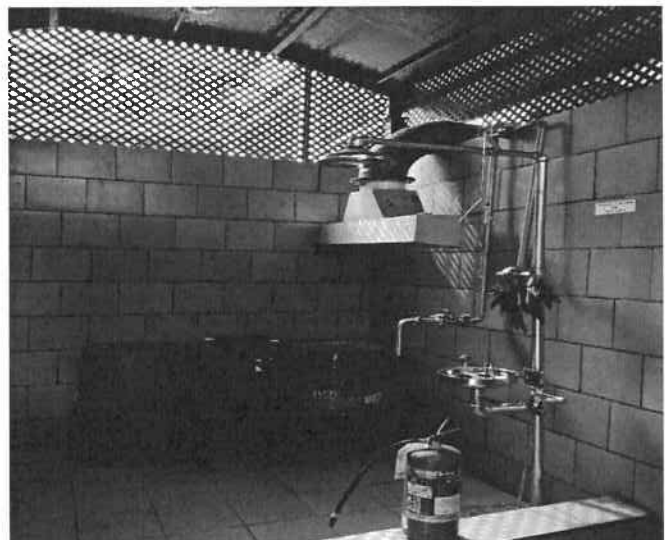
8. As reflected in the EIA/EMP report, the hazardous waste generated from solvent recycling plant as distillation residue, chemical and from ETP and waste oils will be incinerated. Used oils will be sent for recycling to KSPCB/CPCB authorized recyclers. The ash obtained after incineration shall be stored in a covered shed with impervious flooring and leachate collection system within the plant premises for ultimate disposal through KSPCB landfill as and when available. (EC- 2005)

- Hazardous waste generated from each production units is being collected and stored category wise in separate collection yard. The major hazardous waste generated are Used Oil, Waste oil, Spent catalyst, Container, Liners, Process Residues, Concentration or Evaporation residues, Chemical Sludge, Spent Solvent, Off Specification etc.
- The hazardous waste is being disposed to authorized recyclers/ Incinerators Facilities within 90 days in accordance with the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and KSPCB Authorization
- Well planned Hazardous waste storage yard and Decontamination facility is in use for decontamination & storage of Hazardous waste generated from operations and disposal
- The e-manifest is being generated for day to day hazardous waste and the records are in place.





Hazardous waste collection area



Decontamination Facility

Hazardous waste Generation and Disposal for the period December-2021 to May 2022 is as follows

Sl. No	Category Number	Types of hazardous waste as per authorization	Authorization per Annum	Quantity in KL or MT (December - 2021 to May - 2022)			
				Previous Stock	Generated	Dispose	Stock
1	5.1	Used or Spent Oil	50 MT	Nil	7.93	7.93	Nil
2	5.2	Waste or Residue containing oil	18 KL	Nil	Nil	Nil	Nil
3	20.3/28.1	Distillation residue /Process residue and waste	1750 MT	2.65 MT	49.21sss	49.77	2.09
4	28.2	Spent catalyst	110 MT	Nil	0.765	0.765	Nil
5	28.3	Spent carbon	60 MT	4.12 MT	7.17	10.52	0.776
6	28.4	Off specification products	25 MT	Nil	Nil	Nil	Nil
7	28.5	Date expired, discarded Products	25 MT	Nil	0.0167	0.0167	Nil
8	20.2/28.6	Spent Solvent	70,000 MT (10,000 KL/A Disposal)	Nil	8316.97*	2561.92	Nil
9	33.1	Empty barrels /containers	25,000 No's (1500 MT)	4.54 MT	5.25	9.33	Nil
10	37.3	Concentration or Evaporation residue	3000 MT	26.65 MT	1407	1320.78	112.87
11	33.1	Liners contaminated with hazardous chemicals and wastes	50 MT	Nil	0.69	0.69	Nil
12	33.2	Contaminated Cotton rags or other cleaning materials	2.5 MT	Nil	1.47	1.47	Nil
13	35.3	Chemical Sludge from ETP	1800 MT	18.12 MT	572.27	548.25	24.02
14	20.2	Spent Solvent (From Stripper)	2000 MT	3.24 MT	295.77	289.7595	9.25

Note: *The quantity of spent solvent generated is reprocessed through in-house recovery & partially re-utilized and excess quantity disposed to authorised & approved agencies as Spent solvent

** Addendum obtained for Hazardous waste authorisation for disposal of spent solvents from process, Started disposing to reprocessors from March 2020, addendum no. PCB/WMC/2224/HWM(2017)/2019-20/5664 Dated 24 Jan 2020

*** Hazardous waste Authorization renewal obtained on 6th November 2020 with No. 321339 PCB ID:10305 dated 06/11/2020

EC-2017 (Specific Condition: Point No: 8)

The company shall obtain Authorization for collection, storage and disposal of hazardous waste under

the Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016 for management of hazardous wastes and prior permission from KSPCB shall be obtained for disposal of solid/hazardous waste to TSDF. The concerned company shall undertake measures for firefighting facilities in case of emergency

- Noted and shall be complied with. Authorization obtained from KSPCB for collection, treatment, storage and disposal of hazardous wastes.

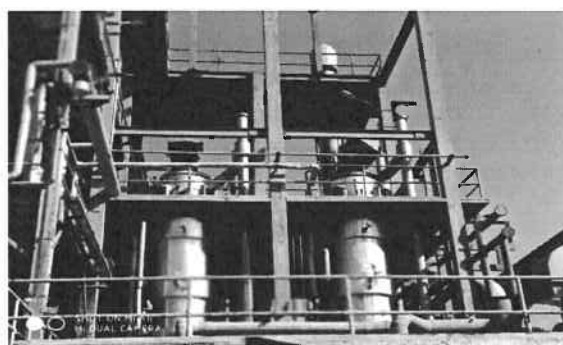
9. Solid waste from fermenters (killed biomass/bacterial mass) shall be disinfected and along with biological sludge from STP and ETP shall be sent to Karnataka compost Development Corporation or M/s Sunrays compost agency for vermin composting. (EC- 2005)

- The cell mass from fermenter is disinfected and killed through steam and concentrated at multiple Effective evaporators. Industry is disposing concentrated liquid to co-processing at cement kilns as an AFR and same is also approved by KSPCB. Biological sludge from ETP and STP is dewatered through Volute centrifuge and sludge generated will be disposed to authorised KSPCB agency for composting. The details of solid waste generation and disposal is as follows;

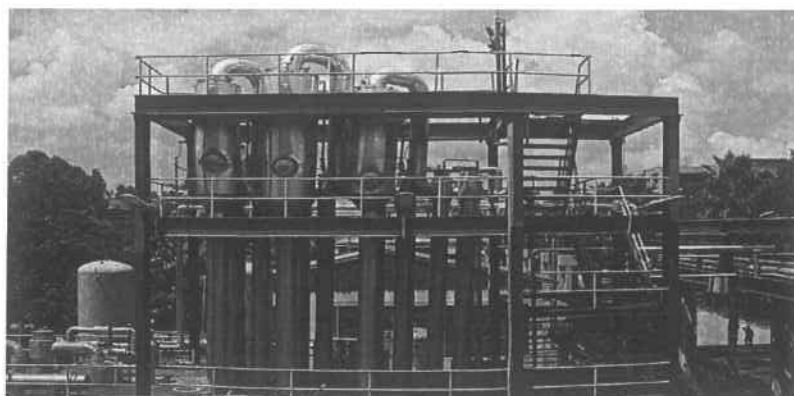
Name of the Solid Waste	Quantity in MT	
	Generation	Disposal
Inert Cell mass – Co-processing	2219.11	2211.36
Biological Sludge- Composting	38.13	31.29



Falling Film Evaporator (FFE)



Vertical Thin Film Dryer (VTFD)



Cell mass plant

10. Commitment made vide letter no. BIL/EHS/04/0105. Dated 28.01.2005 addressed to Deputy Commissioner, Bangalore district (Urban) in response to the Public hearing held on 28.01.2005 shall be followed in to. (EC- 2005)

- *All the commitment made in the above said letter dated 28.01.2005 has been duly followed and all the Pollution control measures have been taken.*

11. Occupational Health Surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act. (EC- 2005) (EC-2020 VIII. Vi)

- *We have occupational health centre in place. Dedicated Doctor and Nurse are available.*
- *Biocon group employees are subjected to Annual health check-up in accordance with the Karnataka Factories Rules 1969.*
- *Periodical Medical Examination is being carried out annually to help in detecting Occupational illness and Health abnormalities. Annual Medical examination shall be conducted in an establishment with all necessary facilities of medical care. The basis of check-up is dependent on the person's age, occupation, and any other case specific examinations respectively on the advice of Director of Factories.*
- *Following tests are recommended for all employees*
 - *Urine Analysis*
 - *CBC (Complete Blood Count)*
 - *FBS (Fasting Blood Sugar)*
 - *Lipid profile: Triglycerides, HDL, LDL, VLDL & Total cholesterol*
 - *Liver function: Bilirubin (Total), SGPT.*
 - *Kidney Function: BUN, Creatinine*
 - *HbA1c*

- *PFT (Pulmonary Function Test)*
- *Skin examination.*
- *Eye Test*
- *ECG for above 35 years employee*
- *Audiometric Test (Personal Expose to High Noise)*
- *Montoux Test*
- *Nasopharyngeal Swab Culture and Sensitivity.*
- *Ophthalmic (vision) test*
- *Chest X- ray*
- *Coprocultative test (Stool Culture, Microscopy and Sensitivity)*
- *Montoux Test*
- *Doctor Consultation & Counselling shall also be ensured for all the employees. The parameters tested results shall be compared with standard values. There were no abnormalities found. Hence we conclude that, there are no occupational health issues found.*



AHC at Biocon



Crush cart and Oxygen Cylinder at OHC



12. The-company shall develop a green belt in 25% of the project area as per the CPCB guidelines and in consultation with the local DFO. (EC- 2005)

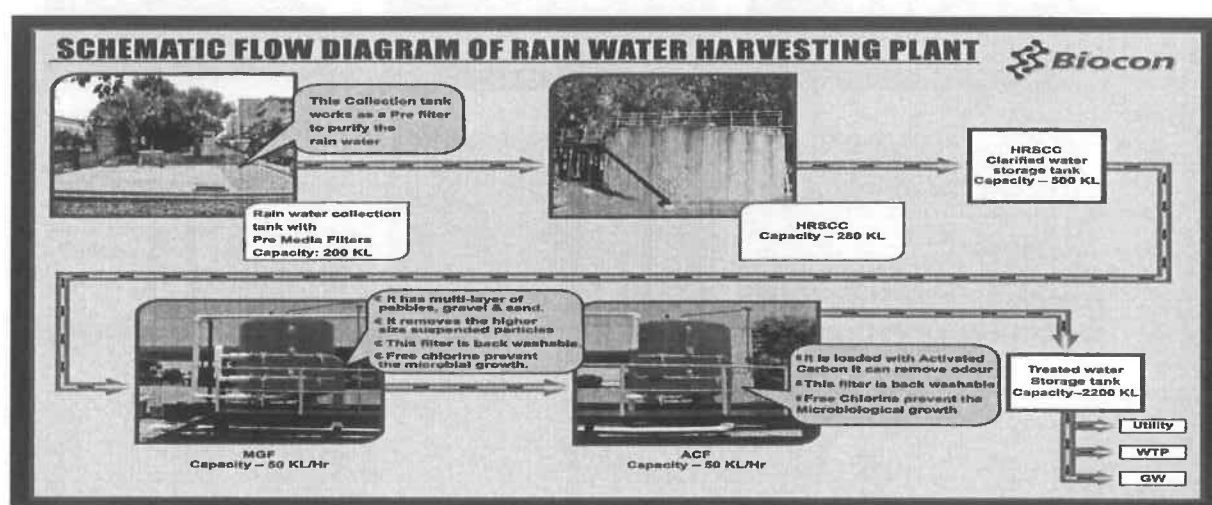
- *The green belt area is covered at our facility is around 29 Acres, Plantation trees are Siris, Neem, Silky Oak, Jack Fruit, Australian Fever, Almond, Indian Beech, Mango, Hibiscus, Tamarinda, Jamaica Cherry, Indian Gooseberry, Soap Nut, Drumstick, Castor Oil Plant, Ajugaparviflora, Oleander Adelfa, Silver Data Palm, Pongemia, Jamoon, Tabubiarosia, Mahagany, Bamboo, Rain Tree etc.*
- *As a part of CSR activity, plantation is carried out at schools and near lake and park areas.*

13. The company shall adopt waste minimization/cleaner production techniques to reduce the pollution load and action plan in this regard shall be submitted to the Ministry. (EC- 2005)

- To minimise the air pollution load, Scrubbers are installed at process handling areas, Aeration tank at ETP and MEE
- Treated water from Effluent Treatment Plant is again recovered in Effluent recycling system. The recycled water is being used for Utility consumption like Boiler and cooling towers
- We have installed triple effect forced circulation evaporator for fivefold concentration of cell mass. Now the plant is successfully under operation for inert cell mass. The plant contains organic removal system, odour control measures and reduction in quantity by evaporating water.
- We have initiated Water conservation projects by reuse or recycling of purified and WFI rejects from process.

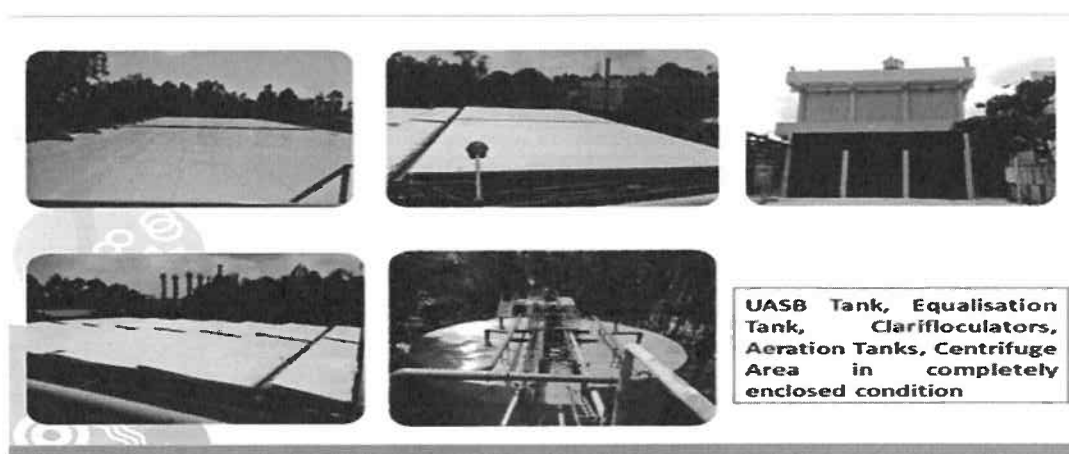
14. The Company shall undertake rain water harvesting measures and action plan in this regard shall be submitted to the Ministry. (EC- 2005) (EC-2020 III, vi)

- Rain water from all rooftops and surface runoff water are collected in collection tank. The water which received during rainfall will be collected after passing media filter which is fixed in line with collection sump.
- Water from the collection sump shall be pumped to the high rate solid contact clarifier to remove TSS and collected in the clarified water storage tank.
- Water from the clarified water storage tank shall be passed through MGF and ACF for further treatment and collected in a treated water tank for future use. Snapshot of rain harvesting system is as follows

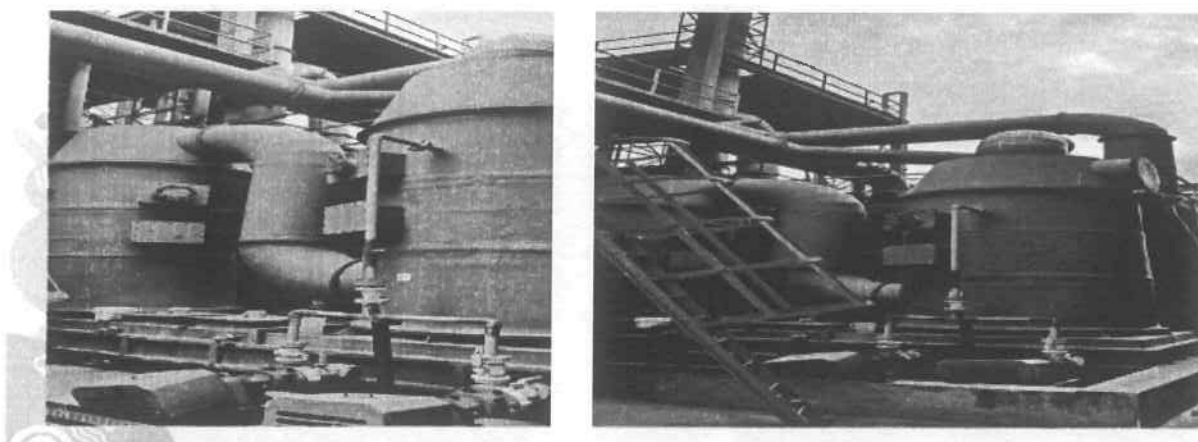


15. The project proponent shall comply with the environmental protection measures to safeguards as recommended in EIA/EMP/Risk analysis reports as well as recommendations of the public hearing panel. (EC- 2005)

- All the Environmental protection measures and safeguards as recommended in EIA/EMP/ Risk Analysis reports as well as recommendations of the public hearing panel were taken in to due consideration and all the efforts are made for effective Environmental management. Flow chart of Effluent treatment plant as recommended in EIA/EMP/ Risk Analysis reports.
- The flow chart of ETP, ERP, STP and MEE is as explained in the Question no.05

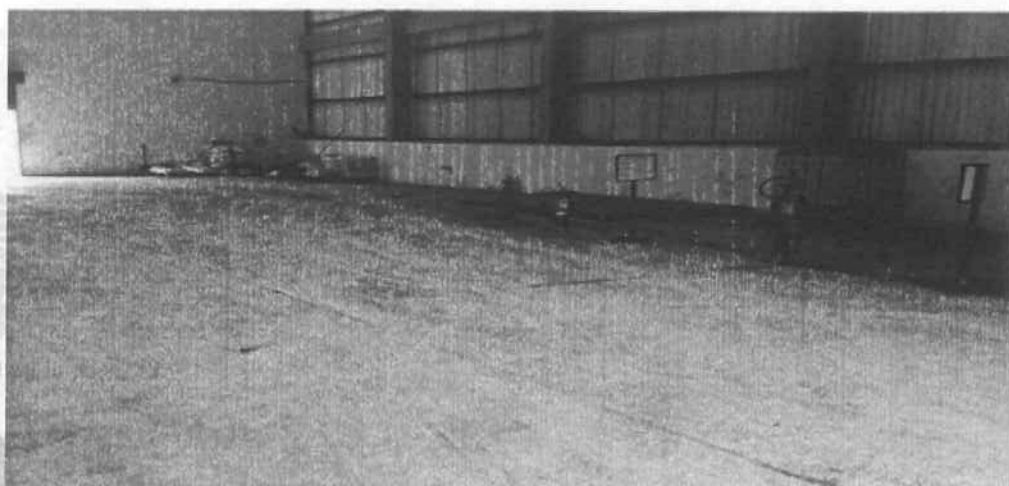


Enclosed Biological Treatment Process



Double Scrubber System in MEE Plant

Hazardous Storage Area for Collection and Storage of the MEE Salt and Chemical Sludge



Scrubbing System in ETP and Odour Control Measures for Aeration Tanks



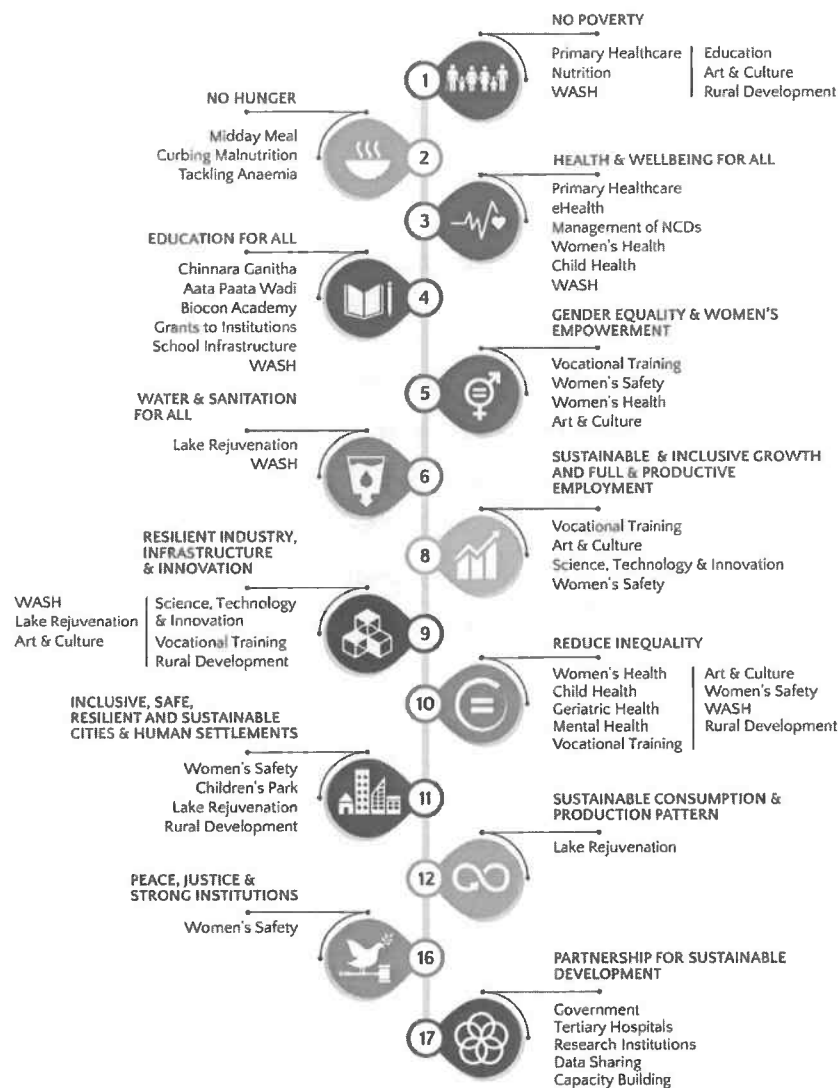
Scrubber System in ETP and Odour Monitoring System

16. The company shall undertake eco-development measures including community welfare measures in the project area for the overall implement of the environment. The eco-development plan shall be submitted to the KSPCB within three months of receipt of this letter for approval. (EC- 2005)



SUSTAINABLE DEVELOPMENT GOALS & BIOCON FOUNDATION PROGRAMS

Sustainable Development Goals are a set of 17 goals set by the UN to transform the world by 2030.



EC-2017 Part A- Specific Conditions, (EC-2020 II.vi)

1. National Emission standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.

- *Noted the content.*

3. In ETP shall ensure to prevent ground water contamination due to leakage from unlined tanks

- *Noted and all the tanks are above ground level, complied with*

4. Total fresh water requirement from BWSS&B water supply shall not exceed 2806 KLD and prior permission shall be obtained from the concerned authority. No ground water shall be used. (EC-2020 III.vi)

- *Noted and shall be complied with. Permission from BWSS&B for up to 3000 KLD of fresh water supply is available. There is no usage of ground water in BSEZ currently and also for the project.*

7. The company shall upload the status of compliance of the stipulated environmental clearance conditions, including results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF – Bangalore, SEIAA - Karnataka, the respective zonal office of CPCB and the KSPCB. The levels of PM10, PM2.5, SO2, NOX, CO, VOC (ambient levels) and emissions from the stacks shall be monitored and displayed at a convenient location near the main gate of the company and at important public places.(EC-2020 X.iii)

- *Environmental Clearance document and Compliance report is uploaded in the website. Link to view the document in website is as follows:
<https://www.biocon.com/responsibility/sustainability/environmental-clearance/>*

The data related to PM10, PM2.5, SO2, NOx, CO, monitored and displayed in the Main Gate.

10. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.(EC 2020 VI. Waste management 2020)

- *Noted and shall be complied with.*
- *In Biologics the solvent usage in the manufacturing process is very minimum and is mainly through small containers. The solvent drums are stored in Warehouse with all safety protection system. Hazardous chemicals like acid, Hypo, Caustic are being stored in Carbouys. Acid carboys are stored in secondary container with dyek with sand. Acid Bottles are stored in Acid cabinets and solvents are kept in fire*

retardant cabinets. Necessary training imparted to the employees to handle the chemicals and necessary PPE's are issued for safe handling of chemicals. Required engineering controls are in place. Spill kit available to mitigate emergency spills if any.

11. The hazardous and solid waste shall be disposed as per proposed EIA/EMP and the details of hazardous & solid waste is provided in the Annexure – ii along with the quantity and disposal mechanism.

- Separate Hazardous waste authorization is obtained for Biocon Biologics location. The details of Hazardous waste are mentioned below:

Sl. No	Category Number	Types of hazardous waste as per authorization	Authorization per Annum	Quantity in KL or MT (December - 2021 to May - 2022)			
				Previous Stock	Generated	Dispose	Stock
1	28.1	Process residues and waste	6 MT	Nil	0.594	0.594	Nil
2	20.2/28.6	Spent Solvent	50 KL	0.304 MT	1.0665	1.3705	Nil
3	33.1	Discarded Containers, Used barrels (MS Drums, HDPE barrels/ Carboys)	60 MT	0.01808 MT	Nil	0.01808 (Sent along with Biocon Waste)	Nil
4	33.1	Discarded Liners	30 MT	Nil	Nil	Nil	Nil
5	28.4	Off Specification Products	75 MT	Nil	Nil	Nil	Nil
6	28.5	Date Expired Products	25 MT	Nil	Nil	Nil	Nil
7	33.2	Contaminated Cotton rags or other cleaning materials	2 MT	Nil	2	2	Nil
8	5.1	Used Oil	5 KL	Nil	Nil	Nil	Nil
9	Schedule III, Part D, B 3020	Paper Waste	10 MT	Nil	Nil	Nil	Nil
10	Schedule III, B 3030	Textile Wastes	2 MT	Nil	1.84	1.84	Nil
11	Schedule III-B 3050	Wood Scrap	400 MT	Nil	18.55	18.55	Nil
12	Schedule III-DB 1010	MS Scrap	48 MT	Nil	7.72	7.72	Nil

Hazardous waste Generation and Disposal for the period December-2021 to May 2022 is as follows

- *The Hazardous Waste are disposed to authorized recyclers, authorized incinerators, authorized reprocessors, authorized TSDF/SLF as per the Annexure II of EC obtained during 2017 from SELAA*

12. The company shall undertake following waste minimization measures: (EC-2020 VI. Waste management condition III)

- 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/fermenters**
- e. **Venting equipment through vapour recovery system**
- f. **Use of high pressure hoses for equipment cleaning to reduce wastewater generation**

S.I No.	Condition	Control Measures
a.	Metering and Control of quantities of active ingredients to minimize waste	Measurement and metering are in place for Waste minimization
b.	Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.	Noted
c.	Use of automated filling to minimize spillage	Automated Filling system are available wherever required
d.	Use of close feed system into batch reactors/fermenters	Closed feed system available for reactors and fermenters
e.	Venting equipment through vapour recovery system	Vapour recovery system are in place
f.	Use of high pressure hoses for equipment cleaning to reduce wastewater generation	High pressure hoses and spray balls are being used in cleaning of equipment for reduce waste water generation

13. For control of fugitive emission following steps shall be followed:

- a. **Closed handling system shall be provided for chemicals**
- b. **Reflux condenser shall provide over reactor**
- c. **System of leak detection and repair of pump/pipeline based on preventive maintenance**
- d. **The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks**

shall be vented through trap receiver and condenser operated on chilled water

S.I No.	Condition	Control Measures
a.	Closed handling system shall be provided for chemicals	Closed loop system available
b.	Reflux condenser shall provide over reactor	Reflux condensers are provided over the reactor
c.	System of leak detection and repair of pump/pipeline based on preventive maintenance	Preventive maintenance procedure and system in place
d.	The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water	Acids are handled in closed loop system and required systems are in place.

14. Solvent management shall be as follows:

- a. Solvent used in the process shall be completely recovered and reused
- b. Efforts are to be made to recover inorganic salts
- c. Reactor shall be connected to chilled brine condenser system
- d. Reactor and solvent handling pump shall have mechanical seals to prevent leakages
- e. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
- f. Solvents shall be stored in a separate space specified with all safety measures
- g. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done
- h. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses
- i. Fugitive emission in the work zone environment, product, raw materials storage areas etc. shall be regularly monitored. The emissions shall conform to the limits imposed by KSPCB.

S.I No.	Condition	Control Measures
a.	Solvent used in the process shall be completely recovered and reused	Solvent used in the process is recovered Inhouse and reused
b.	Efforts are to be made to recover inorganic salts	Noted
c.	Reactor shall be connected to chilled brine condenser system	Reactors are connected to condenser system

d.	Reactor and solvent handling pump shall have mechanical seals to prevent leakages	Mechanical Seals available to prevent leakage
e.	The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery	Shell and tube condensers used to achieve more than 95% recovery
f.	Solvents shall be stored in a separate space specified with all safety measures	Solvent stored separately in storage tanks and safety measures are provided like flame arrestor, flame proof electrical fittings, fire protection system.
g.	Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done	Double earthing is provided for all electrical equipment's where solvent handling is done
h.	Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses	All electrical installation in the plant is of flame proof and breather valves provided to prevent losses
i.	Fugitive emission in the work zone environment, product, raw materials storage areas etc. shall be regularly monitored. The emissions shall conform to the limits imposed by KSPCB.	Emissions are monitored as specified by KSPCB norms and ensured emissions are well within the limits.

15. No effluent shall be discharged outside the factory premises and “Zero” discharge concept shall be adopted (EC-2020 III. Water quality monitoring and preservation)

- ZLD system, Treated water from Effluent treatment is again recovered in Effluent recycling system. The Recycled water shall be used for Utility consumption like Boiler and Cooling towers and rejects generated are evaporated using Multiple Effect Evaporator.

17. Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubbers with caustic lye media solution shall be provided to process vents to control SO₂. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.

- There are no stacks planned for the project in process area since the manufacturing process is fermentation based and completely done under closed loop. Emissions from lab areas and warehouse are controlled with wet scrubbers and will be complied with prescribed CPCB/KSPCB standards.

18. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic waste and storm drains.

- *Closed loop transfer system available for transferring of Chemicals from storage tanks to process equipment.*

19. The company shall harvest surface as well as rainwater from the rooftops of the buildings and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water,(EC-2020 III, vi).

- *Rain water from all rooftops and surface runoff water are collected in collection tank. The water which received during rainfall will be collected after passing media filter which is fixed in line with collection sump.*
- *Water from the collection sump shall be pumped to the high rate solid contact clarifier to remove TSS and collected in the clarified water storage tank.*
- *Water from the clarified water storage tank shall be passed through MGF and ACF for further treatment and collected in a treated water tank for future use.*

20. 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 OISD 117 norms, (EC-2020 VIII. i)

- *All process equipment is being inertized with nitrogen during process operation.*
- *Closed loop solvent transfer system available.*
- *Earthing and Bonding to equipment's is provided.*
- *Adequate quantity of fire extinguishers installed at manufacturing and storage area.*
- *Fire Hydrant system and Foam Monitors installed at manufacturing and storage area.*
- *Medium velocity water spray (Deluge System) installed for solvent storage tanks.*

- *Portable Dry sprinkler aerosol system installed at operational area.*
- *Emergency Safety Cupboard (which includes SCBA, Fire Suite, Spill Control Kits and PPE's Available)*
- *Aerial Ladder Platform (Foam Tender) and Emergency Response Vehicle available at the site.*

21. Training shall be imparted to all employees on safety and health aspects of chemical 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. (EC-2020 VIII, iii)

- *All new joiners must undergo pre-employment medical check-up and all employees and contract workers have to undergo comprehensive annual health check-up every year and records of the same are maintained.*
- *Following Trainings are provided for employees handling chemicals*
 - *Chemical Safety Training*
 - *Laboratory Safety Training*
 - *Fire Fighting Training*
 - *Emergency Preparedness and Response*
 - *Electrical Safety Training*
 - *Process Safety Training*

22. Usage of PPEs by all employees/workers shall be ensured. (EC-2020 VIII.iii)

- *Activity based PPE usage Matrix is prepared and made effective. All Employees and contract workers comply to the requirement.*
- *PPE's like Safety Helmet, Safety Goggles, Half Face Cartridge Mask/ Dust Mask, Safety Gloves, Chemical Suit and Safety Shoe used during activity.*

23. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the factories act.(EC-2020 VIII. Vii)

- *All employees and contract workers undergo comprehensive annual health check-up every year and records maintained.*
- *7 Bed Full-fledged Occupational Health Centre available at site.*
- *Round the clock Doctors and Paramedical staff available at OHC.*

- *Advanced Life support Ambulance available at site.*
- *Biocon has Tie up with Referral Hospital (Vijayashree Hospital & Kaveri Hospital)*

24. Green belt shall be developed in at least 33% of area with suitable species of the plants as per the CPCB guidelines to mitigate the effects of fugitive emissions. Selection of plant species shall be as per the CPCB guidelines. (EC-2020 Point-vii)

- *The green belt area is covered at our facility is around 29 Acres. Plantation trees are Siris, Neem, Silky Oak, Jack Fruit, Australian Fever, Almond, Indian Beech, Mango, Hibiscus, Tamarinda, Jamaica Cherry, Indian Gooseberry, Soap Nut, Drumstick, Castor Oil Plant, Ajugaparviflora, Oleander Adelfa, Silver Data Palm, Pongemia, Jamoon, Tabubiarosia, Mahogany, Bamboo, Rain Tree etc.*
- *As a part of CSR activity, plantation is carried out at schools and near lake and park areas.*

25. The adequate financial provisions shall be made in the budget of the project for implementation of the above suggested environmental safeguards. Fund so earmarked shall not be diverted for any other purposes.

- *Noted the content. The funds approved for wastewater treatment facility has been utilised for the construction of ETP and MEE for the project. Fund provision will be made as envisaged in EIA report for capital /recurring cost.*

26. The company shall comply with the recommendations made in the EIA/EMP report. Risk assessment shall be included in the safety manual.

- *The environmental protection measures as proposed in EIA/EMP report is complied with Risk assessments and the same is being included in the safety manual.*

27. Recovers lithium salts from the effluents wherever lithium compounds are used in the reactions

- *Noted the content*

28. Treatment of recalcitrant's to be documented and kept at all times

- *Noted the content*

29. Adopts good management practices (GMP) & green chemistry

- *Noted and shall be complied with.*
- *Good Manufacturing Practices is being established in all aspects of product manufacturing and is practiced in all support functions*
- *Green Chemistry.*

<ul style="list-style-type: none"> - <i>Prevention</i> 	<ol style="list-style-type: none"> 1. <i>Introduction of vent gas system</i> 2. <i>Liquid – Liquid extraction column for Mother liquor treatment</i> 3. <i>To install new Economizer to improve the thermal efficiency of the boiler For reduction of CO₂</i>
<ul style="list-style-type: none"> - <i>Less Hazard chemical</i> 	<ol style="list-style-type: none"> 1. <i>Introduction of new filtration methodology by elimination of vacuum filtration.</i> 2. <i>Replacement of hazardous chemical (acetic anhydride vs propanic anhydride at the R& D stage itself.</i> 3. <i>Introduction of butane troch instead of LPG for strille operation</i>
<ul style="list-style-type: none"> - <i>Designing of safety chemical</i> 	<ol style="list-style-type: none"> 1. <i>Elimination of PET ether usage by introduction of agitated thin film evaporator.</i> 2. <i>overflow protection interlock for day tank</i> 3. <i>Ammonia leak detection system in process area.</i>

<ul style="list-style-type: none"> - <i>Energy efficiency</i> 	<ol style="list-style-type: none"> 1. <i>Replacement of 160 W to 36 W LEB light in manufacturing unit (550 Nos)</i> 2 <i>Pilot trail for Power generation from cyclone separator exhaust – Achieved single phase power</i> 3. <i>Installed the Economizer of capacity 16 TPH boiler 3 nos to save the fuel and reduced the emission</i>
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30. Storage facilities for the fuel shall be made in the plant area in consultation with department of explosives, Nagpur. Disaster management plan shall be prepared to meet any eventuality in case of an accident taking place due to storage of fuel.

- *Dedicated Fuel storage facility available at site which is approved by PESO. Onsite emergency preparedness and response plan already in place.*
- *Onsite Emergency Plan available at site which is prepared as per the requirement of Department of Factories.*
- *Since the site does not come under MAHU unit Disaster Management plan is not considered.*
- *Mutual Aid*



31. The proposed proponent shall use piped natural gas (PNG) as fuel for the proposed 1 No x 16 TPH boiler and convert the existing 2 No's x 16 TPH boilers from furnace oil to PNG as fuel

- *The Piped Natural Gas (PNG) lines are available to the individual Boiler and the Boilers are operated with the Natural Gas.*

32. The project proponent also shall earmark at least 2.5 % of the total cost of the project towards the corporate social responsibility and item-wise details along with the time bound action plan shall be prepared and submitted to the authority.

- *The Corporate Social Responsibility recommendations as proposed in EIA Report is complied and total cost for corporate social responsibility*
- *For Hebbagodi Lake Development Total amount spent is Rs. 1.18 cr.*
-

- *For BMRCL Development Total amount spent is Rs. 13 Cr.*
- *For Biocon Hebbagodi Metro Station Development Total amount spent is 65 Cr.*

B. General conditions

1. The project authorities must strictly adhere to the stipulations made by the Karnataka State Pollution Control Board. (EC-2005, EC-2017)

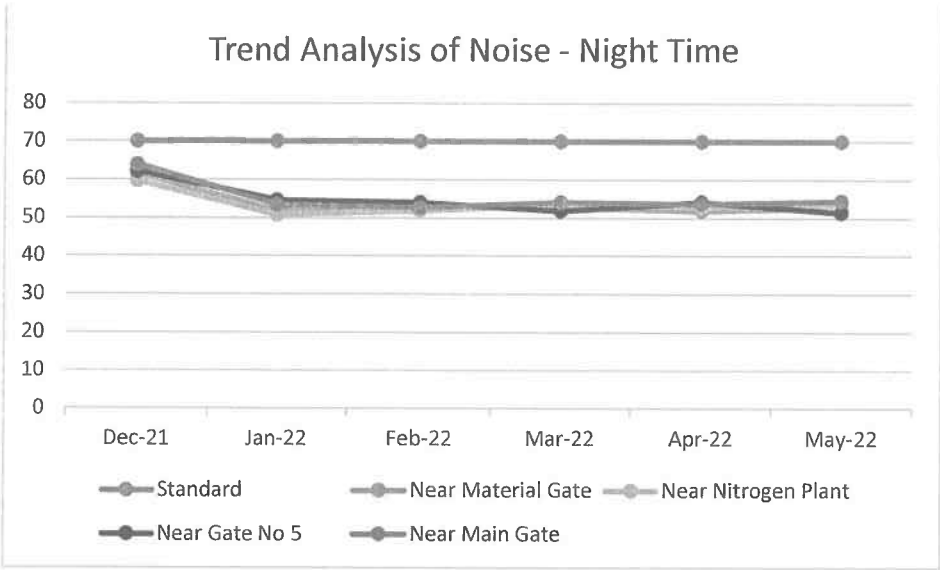
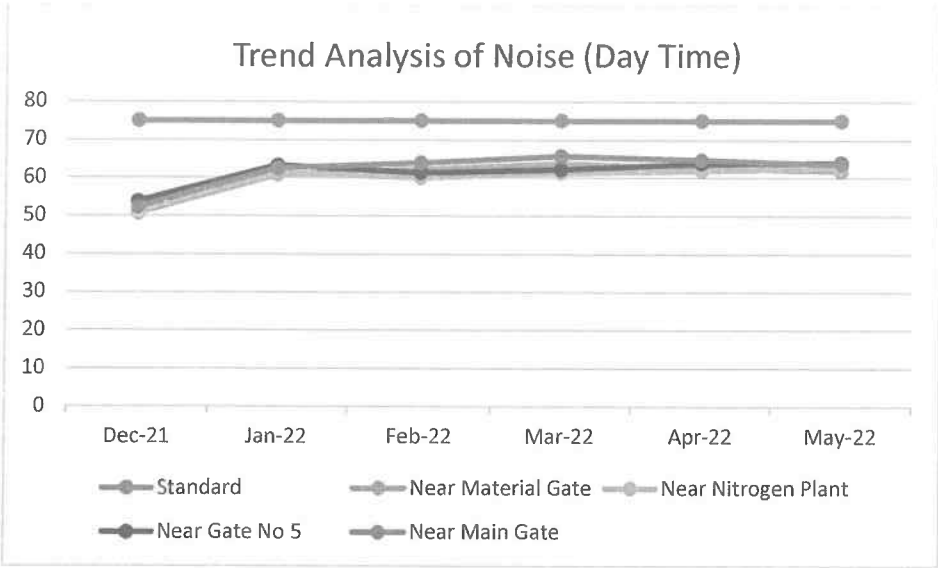
- *Biocon has adhered to all the guidelines prescribed by the KSPCB.*

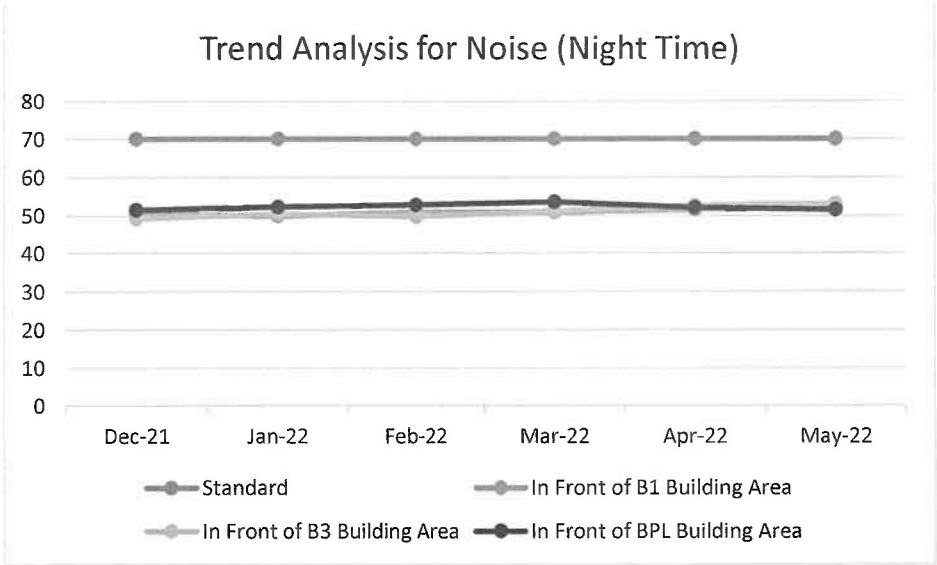
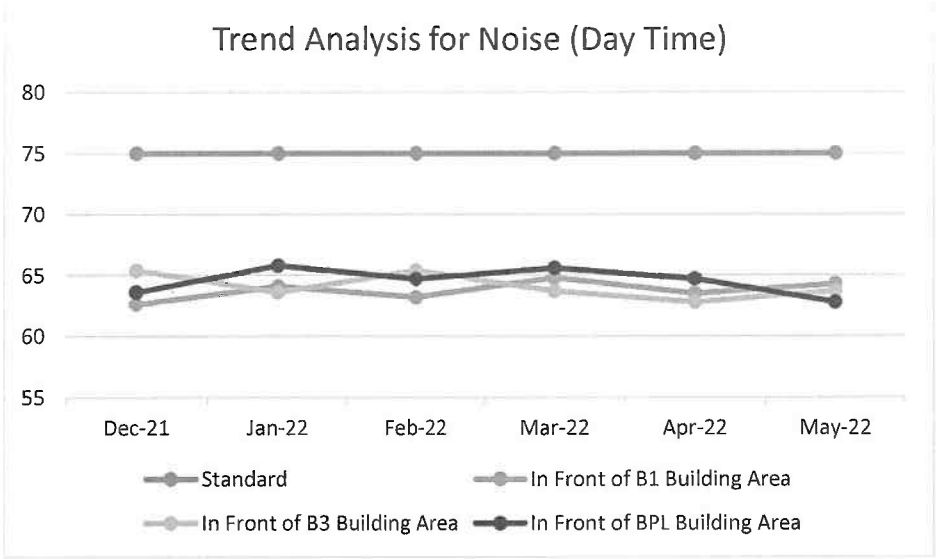
2. At no time, the emissions should go beyond the prescribed standards. In the event of failure of any pollution control system adopted by the units, the respective unit should be immediately put out of operation and should not be restarted until the desired efficiency has been achieved. (EC-2005, EC-2017)

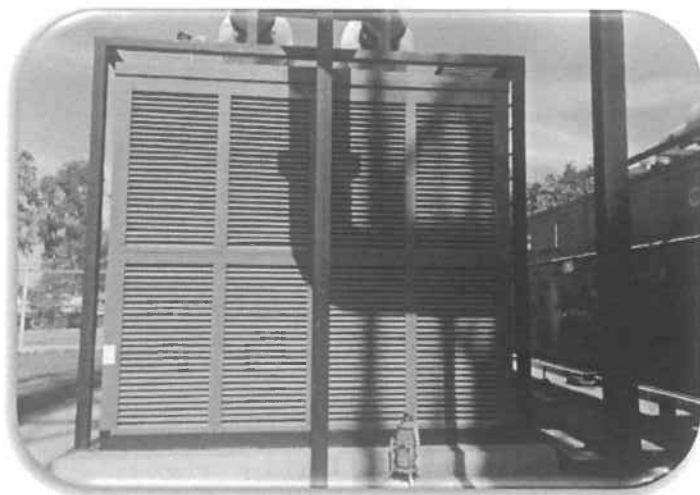
- *In case of power failure, the DG shall be operated continuously for the operation of plant as well as pollution control system*
- *In the event of failure of any pollution control system, Biocon follows the predefined procedures in anticipating to the problem. KSPCB will be informed of the situation and the system will be put off operation and will be restarted after achieving the desired efficiency.*

3. The overall noise levels in and around the plant area should be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures etc., on all sources of noise generation. The ambient noise levels should conform to the standards prescribed under EPA Rules, 1989 viz. 75 dBA(daytime) and 70 dBA(night time). (EC-2005, EC-2017 General Condition Pt. no. 8) (EC-2020 IV, iii)

- *We have taken all the possible measures to avoid noise pollution and noise levels in all the areas are well within the stipulated standards. Noise level is being monitored monthly and reports are available for the same. The trend analysis of Noise from December 2021 to May 2022 is as follows.*







Acoustic enclosure for DG

4. **The project authorities will provide adequate funds both recurring and non-recurring to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so provided should not be diverted for any other purposes. (EC-2005)**
 - *Biocon has invested on adequate infrastructure facilities for effective Environmental management (Waste water treatment plant, waste water recycling plant, waste water evaporation systems, Domestic waste water treatment plant, Scrubbers, Bag filters, etc.) and is investing around 150 Lakhs/month of recurring cost on EHS activities and invested around 30 Cr. for the proposed expansion project i.e. Stream 1, 2 and 3 for ETP, ERP and MEE.*
5. **The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the hazardous wastes (Management & Handling) Rules, 2000. Authorization from the State Pollution Control Board must be obtained for collection/treatment/storage/disposal of hazardous wastes. (EC-2005)**
 - *We are strictly complying with the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016*
6. **The stipulated conditions will be monitored by Regional office of this Ministry at Bangalore/State Pollution Control Board. A six monthly compliance report and the monitored data should be**

submitted to them regularly. (EC-2005)

- *Noted the content*

7. The project proponent should inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the State Pollution Control Board/Committee and may also be seen at website of the Ministry of Environment and Forests at Error! Hyperlink reference not valid. this should be advertised within seven days from the date of issue of the clearance letter at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same should be forwarded to the regional Office. (EC-2005) (EC-2020 X, i)

- *Environmental Clearance document and Compliance report is uploaded in the website. Link to view the document in website is as follows:*

<https://www.biocon.com/responsibility/sustainability/environmental-clearance/>

8. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory. (EC-2005) (EC-2020 X. xiii)

- *Noted the content*

9. The Ministry reserves the right to stipulate additional conditions if found necessary. The company will implement these conditions in a time bound manner. (EC-2005)

- *Noted the content*

10. The above conditions will be enforced, inter-alia under the provisions of the water (Prevention and control of pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and the public liability insurance Act, 1991 along with their amendments and rules. (EC-2005, EC- 2017)

- *Noted the content*

EC-2017 General Conditions

3. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA/Ministry of Environment and Forests as the case may be. In case of deviations or alterations in the project proposal from those submitted to this authority for clearance, a fresh reference shall be made to the authority to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.(EC-2020 X, xi)

- *Noted the content. Any expansion, modernization or changes in the proposed project will be done after obtaining prior approval from MoEF & CC.*
4. The gaseous emissions (PM10, PM2.5, SO2, NOX, CO, VOC) and particulate matter along with RSPM levels from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency. Stack monitoring for PM10, PM2.5, SO2, NOx, CO, VOC shall be carried.
- *Noted and shall be complied with. Air polluting sources are identified such as Gas turbine, Boiler, DG sets. The emissions from the stacks are monitored monthly and reports are submitted to Regional office and Head Office, Karnataka State Pollution Control Board.*
5. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. All transportation of hazardous chemicals shall be as per the MVA, 1989. Authorization from the KSPCB shall be obtained for collection, treatment, storage and disposal of hazardous wastes
- *Noted the content. Authorization obtained from KSPCB for collection, treatment, storage and disposal of hazardous wastes*
6. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. All transportation of hazardous chemicals shall be as per the MVA, 1989. Authorization from the KSPCB shall be obtained for collection, treatment, storage and disposal of hazardous wastes
- *Noted the content. Authorization obtained from KSPCB for collection, treatment, storage and disposal of hazardous wastes*
7. Application of solar energy should be incorporated for illumination of common areas, lighting for gardens and street lighting in addition of provision for solar water heating. A hybrid system or fully solar system for lighting and heating should be provided. Details in this regards should be submitted to the SEIAA.
- *Noted and feasibility study shall be done for the same.*

9. The project proponent shall also comply with all the environmental protection measures and safeguards as per the information provided.

- *The environmental protection measures as proposed in EIA/EMP report is complied.*

10. The implementation of the project vis-à-vis environmental action plans shall be monitored by MoEF, Regional Office at Bangalore/ KSPCB/CPCB and the Department of Environment & Ecology, Bangalore. A six monthly compliance status shall be submitted to monitoring agencies.

- *Noted. A six monthly compliance status report shall be submitted to monitoring agencies.*

11. The project proponent shall inform the public that the project has been accorded environmental clearance by the SEIAA and copies of the clearance letter are available with the KSPCB and may also be seen at website of the Authority at <http://www.seiaa.karnataka.gov.in> and <http://environemntclearance.nic.in/>. This shall be advertised within seven days from the date of issue of the clearance letter, at lease in two local newspapers that are widely circulated in the region of which one shall be in vernacular language of the locality concerned and a copy of the same shall be forwarded to the MoEF regional office at Bangalore/KSPCB/CPCB and the Department of Environment & Ecology, Bangalore(EC-2020 X.i)

- *Noted and complied. Public notice has been given through advertisement in two local newspapers in English and Kannada. Copy of the same was forwarded to MoEF & CC regional office and Minstry of Environment and Ecology office vide letter dated 03/05/17*

12. The project authorities shall inform the MoEF Regional Office at Bangalore/KSPCB/CPCB and the Department of Ecology and Environment, Bangalore the date of financial closure and final approval of the project by the concerned authorities and the date of the start of the project.

- *Noted the content.*

13. The SEIAA, Karnataka may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory (EC-2020 X, xiii)

- *Noted the content.*

14. The SEIAA, Karnataka reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions. (EC 2020, X xiv)

- *Noted the content.*

15. The above conditions will be enforced, inter-alia under the provisions of the Water (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

- *Noted the content.*

16. The issue of Environment Clearance doesn't confer any rights to the project proponent to operate/run the project without obtaining statutory clearances/sanctions form all other concerned authorities.

- *Noted the content.*

17. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environmental (Protection) Act, 1986.

- *Noted the content.*

18. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010 (EC-2020 X. xvii)

- *Noted the content..*

19. Officials from the Department of the Environment and Ecology, Bangalore/ Regional Office of MoEF, Bangalore who would be monitoring the implementation of Environmental Safeguards should be given full cooperation, facilities and documents/data by the project proponents during their inspections. A complete set of all the documents submitted to MoEF/SEIAA should be forwarded to the APCC, Regional Office of MoEF, Bangalore/Department of Ecology and Environment, Bangalore / Regional Officer, KSPCB Bangalore.

- *Noted the content.*

20. In the case of any change(s) in the scope of the project, the project would require a fresh appraisal by this Authority.

- *Noted the content.*

21. The authority reserves the right to add additional safeguard measures subsequently, if found necessary to take action including revoking of the environment clearance under the provisions of the Environment (Protection) Act, 1986 to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.

- *Noted the content.*

22. All other statutory clearances such as the approvals for storage of diesel from the chief controller of explosives, Fire Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wildlife (Protection) Act, 1972 etc. shall be obtained, as applicable by project proponents from the competent authorities.

- *Noted the content. Relevant Statutory clearance obtained.*

23. These stipulators would be enforced among others under the provisions of water (Prevention and control of pollution) Act 1974, the Air (Prevention and control of Pollution) act 1981, the Environment (Protection) Act, 1986 and the Public Liability (insurance) Act 1991 and EIA notification, 2006.(EC-2020 X. xvi)

- *Noted the content.*

24. Under the provisions of Environment (Protection) Act, 1986, legal action shall be initiated against the project proponent if it is found that construction of the project has been started without obtaining environmental clearance.

- *Noted the content.*

Environmental Clearance SEIAA 45 IND 2020 dated 03-09-2020**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.**
 - *EC obtained in 2005 and Industry established in Bommasandra and Jigani Industrial Area. No Forest land is utilized for the Project.*
- ii. **The project proponent shall obtain clearance from the National Board for Wildlife, if applicable.**
 - *Noted the content.*
- 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 six monthly compliance report. (In case of the presence of schedule -1 species in the study area).**
 - *Noted the content.*
- 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.**
 - *Noted the content. Consent to Establish under the Air and Water Act obtained.*
- v. **The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.**
 - *Noted the content*
- 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.**
 - *Noted the content*

II .AIR QUALITY MONITORING AND PRESERVATION

- i. **The project proponent shall install 24*7 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.**
 - *Noted the content.*
- ii. **Storage of raw materials coal etc. shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.**
 - *Raw Materials are stored in the covered areas to prevent the dust pollution and other fugitive emissions.*
- iii. **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.**
 - *Noted the content.*
- iv. **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 content.*

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 project achieving ZLD)**
 - *Online continuous effluent monitoring system installed with web camera/ flowmeters and connected to CPCB server.*
- 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 a Committed.**

-RO Permeates are utilized for the Utilities. Sewage Treated water is used for the Inhouse Gardening Purpose.

- 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.**

- ZLD System, Treated water from Effluent treatment is again recovered in Effluent recycling system. The Recycled water shall be used for Utility consumption like Boiler and Cooling towers and rejects generated are evaporated using Multiple Effect Evaporator.

- 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.**

- Noted and shall be complied with. Permission from BWSS&B for up to 3000 KLD of fresh water supply is available. There is no usage of ground water in BSEZ.

- 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.**

- Separate dedicated drain lines are provided for storm water & effluent water to avoid mixing of storm water & effluent

- 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.**

- Rain water from all rooftops and surface runoff water are collected in collection tank. The water which received during rainfall will be collected after passing through media filter which is fixed in line with collection sump.

- Water from the collection sump shall be pumped to the high rate solid contact clarifier to remove TSS and collected in the clarified water storage tank.

- Water from clarified water storage tank shall be passed through MGF and ACF for further treatment and collected in a treated water tank for further use.

- 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.**

-- DG sets are equipped with pollution control equipment and monitoring reports are submitted to Regional Office KSPCB.

IV. NOISE MONITORING AND PREVENTION

- i. **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.**

- We have taken all the possible measures to avoid noise pollution and noise levels in all the areas are well within the stipulated standards.

V. Energy Conservation Measures

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

-Noted and shall be complied with. LED based lightings are provided inside the campus.

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.**

-Noted and complied.

- ii. **Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP Sludge, process inorganic & evaporation salt shall be dispose off to the TSDF.**

-Noted and shall be complied with

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.**

-Emergency Preparedness plan available and implemented in the site.

- ii. **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, crèche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.**

-Noted the content.

- iii. **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**

-Noted and complied.

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.

For Hebbagodi Lake Development Total amount spent is Rs. 1.18 cr.

For BMRCL Development Total amount spent is Rs. 13 Cr.

For Biocon Hebbagodi Metro Station Development Total amount spent is 65 Cr.

- 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 regards shall be submitted to the MoEF&CC as a part of six- monthly report.

-Noted and complied. Environmental Policy duly signed by Chairman and Managing Director Displayed.

- 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.

- Well qualified Environmental chemist /engineers have been appointed for effective environment management in the factory. A fully fledged EHS Dept is active under the Joint M.D.

- 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.

-Noted the content

- v. Self-environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out.

-Noted the content.

Miscellaneous

- i. **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 the content.

- ii. **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.**

- Environmental Clearance document and Compliance report is uploaded in the website. Link to view the document in website is as follows:

<https://www.biocon.com/responsibility/sustainability/environmental-clearance/>

- iii. **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.**

- Environmental Clearance document and Compliance report is uploaded in the website. Link to view the document in website is as follows:

<https://www.biocon.com/responsibility/sustainability/environmental-clearance/>

- iv. **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 the 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 in hard copy of HYCRs shall not be acceptable.**

-Noted and complied.

- v. **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.**

-Environmental Statement in Form V submitted on 23/09/2021.

- vi. **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 the content

- vii. **The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.**

-Noted the content

- viii. **The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP reports, commitment made during public hearing and also that during their presentation to the Expert Appraisal Committee.**

-Noted the content.

- ix. **No further expansion or modifications in the plant shall be carried out without prior approval of this authority or the Ministry of Environment, Forest and Climate Change (MoEF& CC).**

--Noted the content

- x. **Concealing factual data or submission of false/ fabricated data may result in the revocation of this environmental clearance and attract action under the provisions of Environmental (Protection) Act, 1986.**

--Noted the content

- xi. **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 the content

- xii. **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 Environmental (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 the content

- xiii. **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 conditions in accordance with the mechanism evolved by MoEF & CC.**

- *Noted the content*

- xiv. 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.

- *Noted the content*

OTHER INFORMATION

- | | |
|------------------------------------|--|
| 1. Latitude of the Site | - 12°48'18'' N |
| 2. Longitude of the Site | - 77 °39'51''E |
| 3. Project (Capital) Cost | - Total fixed assets is 1094.09 Crores |
| 4. Year of Commencement of project | - 2005 |

For Biocon Limited-SEZ



Authorized Signatory

Date: 29.06.2022

Place: Bangalore