Ref: BP/EHS/COM/23/12/10
Date: 29/12/2023

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
F 91 80 2852 3423
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 April 2023 to September 2023.

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 April 2023 to September 2023.

As per the Ministry of Environment Forest & Climate Change (MOEF & CC) Notification published in Extraordinary Gazette No: 5845 dated 28th November 2018 herewith submitting the Half yearly EC compliance report in soft since EC report is not visible in the PARIVESH website hence unable to upload the Half yearly compliance report in the PARIVESH website.

Kindly accept and acknowledge the same.

Thanking You,

Yours Sincerely,
29/12/2023
For Biocon Limited-SEZ

SIX MONTHLY COMBINED ENVIRONMENTAL CLEARANCE COMPLIANCE REPORT
(April 2023- September 2023)

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

[Environmental Clearance issued by MOEF/ SEIAA, Karnataka No J-11011/96/2005-IA II (I) dated 16-08-2005, No SEIAA 30 IND 2016 dated 21-04-2017 & SEIAA 45 IND 2020 dated 03-09-2020]

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 (SO_2, 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 (SO_2, NOx 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 April 2023 to September 2023 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 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 April -2023 to September-2023 is as follows*

Parameter	Std (Nm3/hr)	DG-I		DG-II		DG-III	
		Jun-23	Sep-23	Jun-23	Sep-23	Jun-23	Sep-23
Particulate matter	100	42.5	45.2	50.3	53.4	47.6	49.3
NOx	970	26.3	24.6	29.2	28.6	35.4	26.8
SO2	--	15.1	17.5	17.3	20.2	18.5	19.4
CO	150	22.9	25.4	29.3	29.5	24.7	27.7
NMHC	100	30.2	32.5	33.7	35.4	33.6	34.8

DG's are installed after 2017 EC.

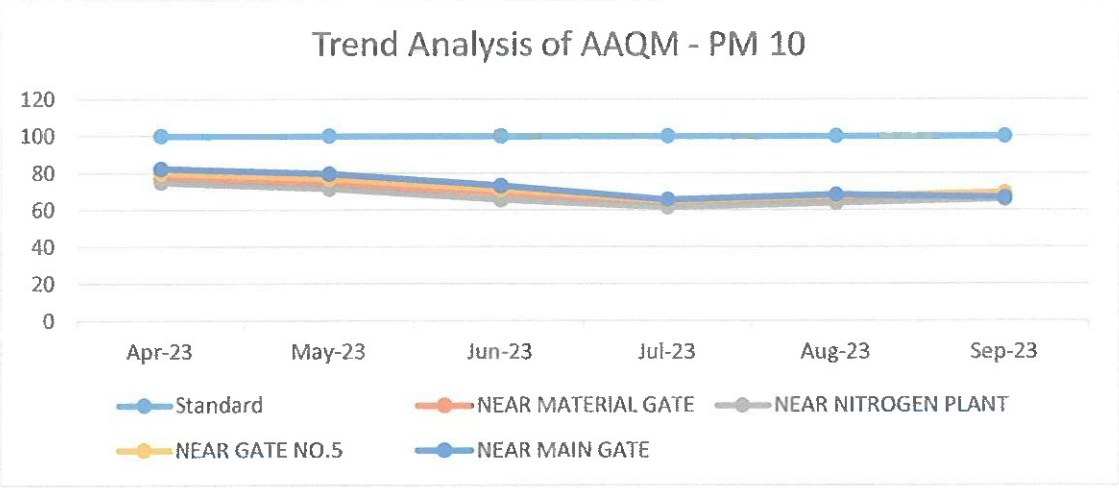
Note: DG no. 4 Installed and under commissioning.

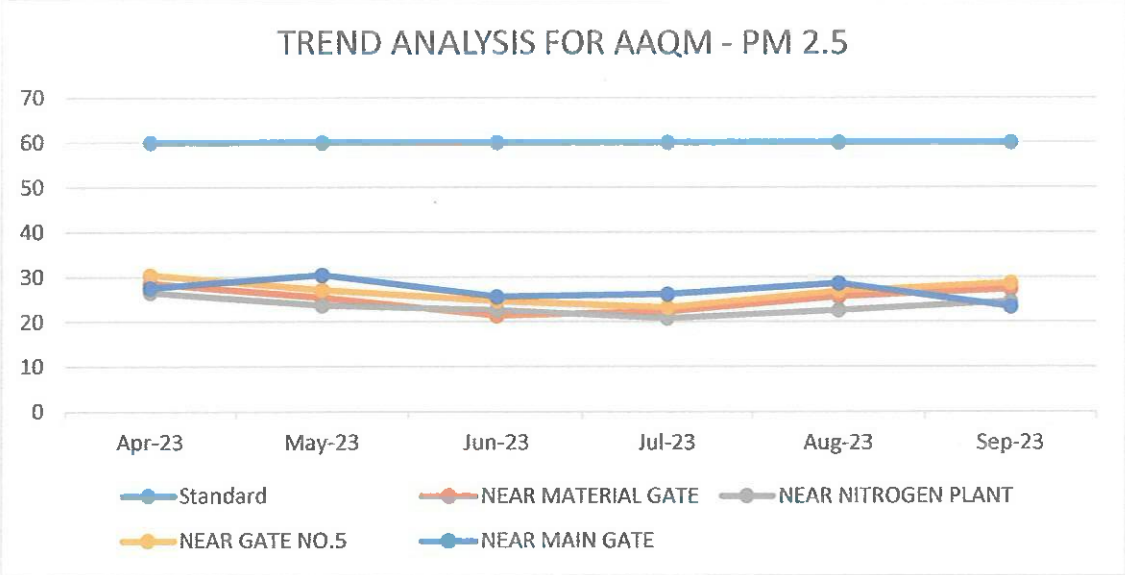
2. **Ambient Air Quality Monitoring Stations should be set up in the down wind direction as well as where maximum ground level concentration of SPM are anticipated in consultation with the State Pollution Control Board. (EC- 2005), (EC- 2020 II. iii)**

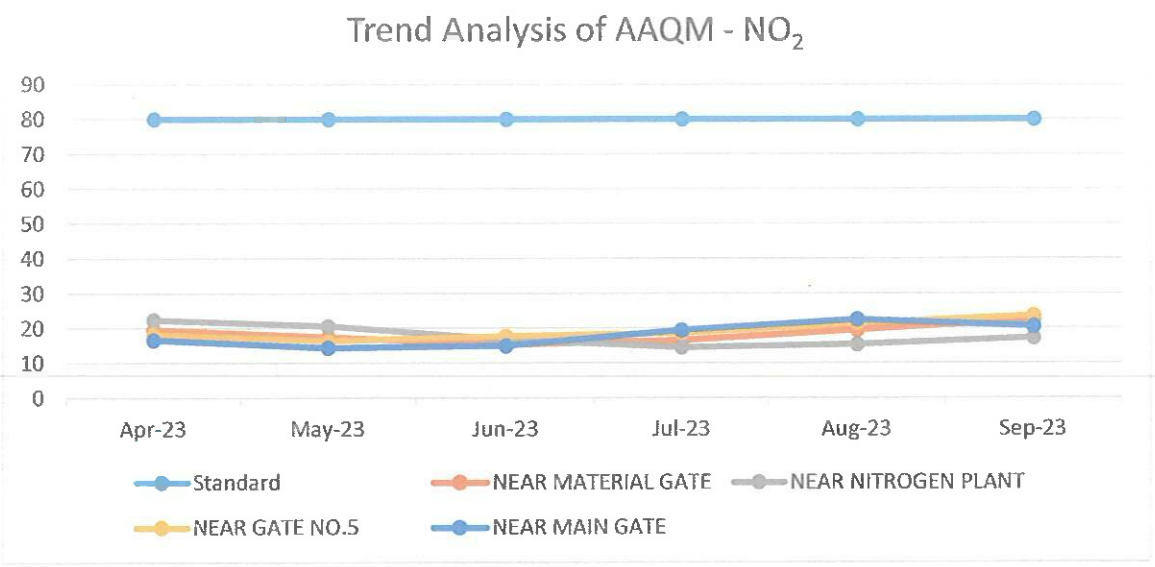
- *Ambient Air Quality monitoring is being carried out at four locations such as Near Material gate, Near Nitrogen plant, Near Gate No.5 & Near Main gate and a continuous Ambient Air Quality Monitoring Station are established in consultation with KSPCB. Air quality is being monitored at all the above 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 PM_{10}, $PM_{2.5}$, NO_X and SO_X. The trend of ambient air quality monitoring for the period April 2023 to September 2023 is as given below.*

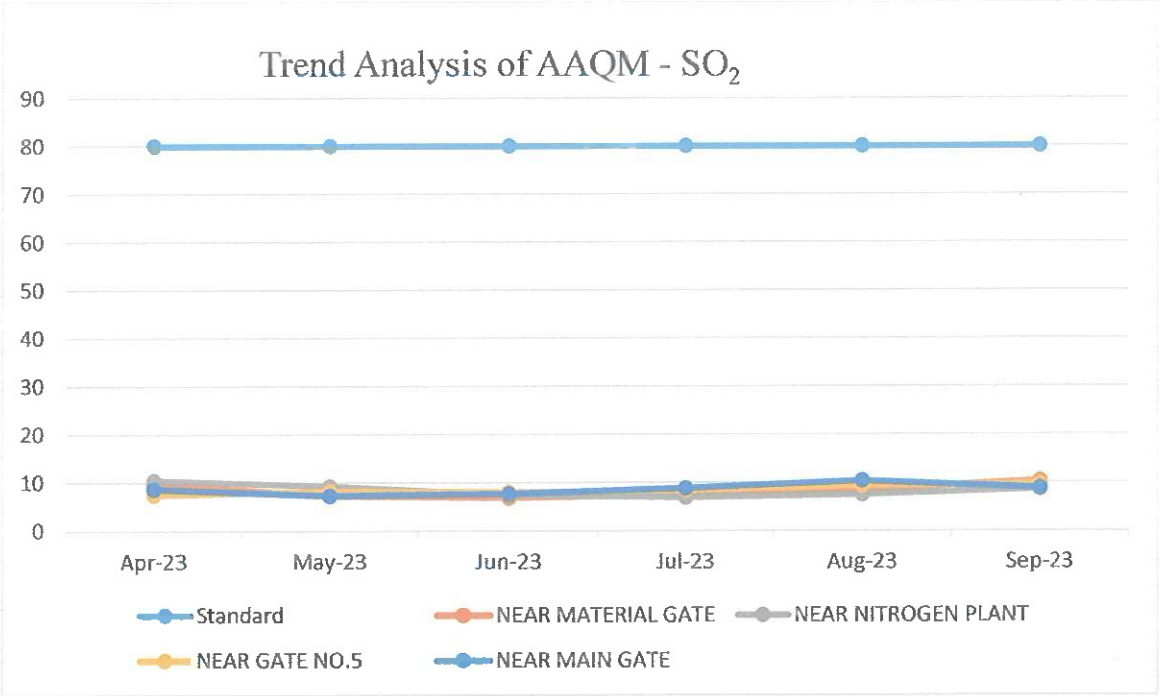
Sl No	Month	PM_{10}	$PM_{2.5}$	NO_2	SO_2	CO	O_3	NH_3
April-2023								
1	**Near Material Gate**	77	28.6	19.5	9.7	<1.0	2.9	4
2	**Near Nitrogen Plant**	74.8	26.5	22.4	10.5	<1.0	6.2	7.4
3	**Near Gate No 5**	79.6	30.4	18.2	7.5	<1.0	5.5	6.8
4	**Near Main Gate**	82.4	27.5	16.6	8.7	<1.0	3.9	5.2
May-2023								
1	**Near Material Gate**	74.3	25.4	17.4	7.3	<1.0	3.2	4.4
2	**Near Nitrogen Plant**	71.5	23.7	20.6	9.3	<1.0	5.5	6.7
3	**Near Gate No 5**	76.6	27.1	16.4	8.3	<1.0	4.2	5.3
4	**Near Main Gate**	79.5	30.5	14.4	7.3	<1.0	4.8	6
June-2023								
1	**Near Material Gate**	69.2	21.4	15.3	6.9	<1.0	4	5.2
2	**Near Nitrogen Plant**	65.5	22.6	16.7	7.4	<1.0	4.8	6.1
3	**Near Gate No 5**	70.8	24.6	17.7	8	<1.0	3.5	4.6
4	**Near Main Gate**	73.2	25.6	15	7.7	<1.0	2.9	4.1
July-2023								
1	**Near Material Gate**	63.5	22.3	16.5	7.4	<1.0	4.3	5.5
2	**Near Nitrogen Plant**	61.4	20.8	14.5	6.9	<1.0	4	5.2
3	**Near Gate No 5**	64.7	23.2	18.6	8.3	<1.0	4.5	6.1
4	**Near Main Gate**	65.6	26.2	19.4	8.8	<1.0	5.1	6.5

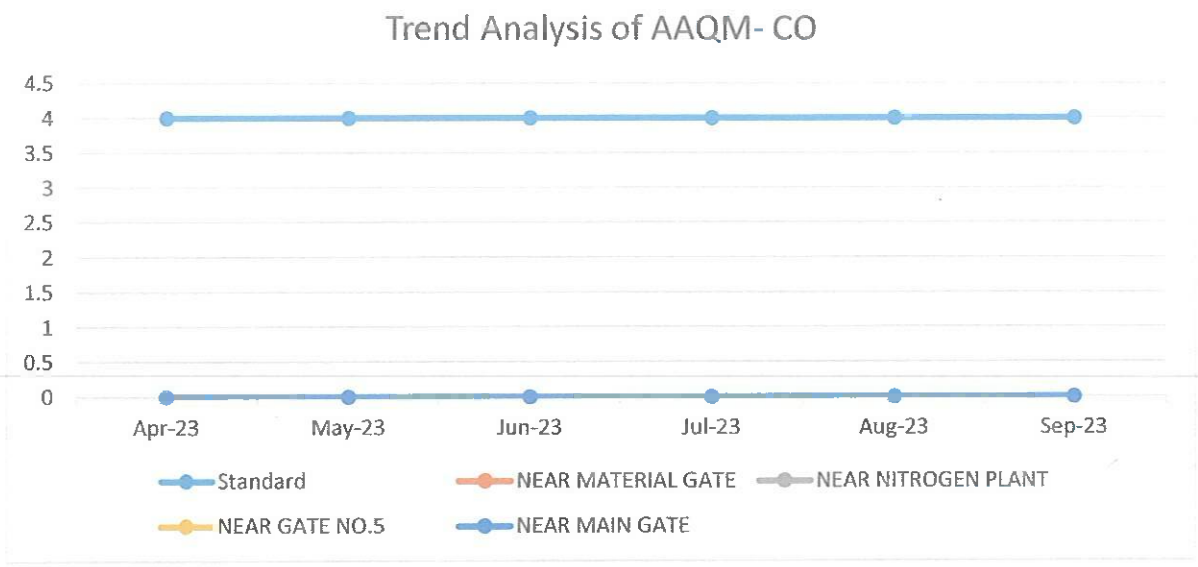
August-2023								
1	**Near Material Gate**	66.4	25.7	19.5	8.6	<1.0	5.2	6.7
2	**Near Nitrogen Plant**	63.7	22.6	15.4	7.5	<1.0	4.6	5.9
3	**Near Gate No 5**	67.5	26.8	21.3	9.2	<1.0	6	7.4
4	**Near Main Gate**	68.3	28.6	22.5	10.4	<1.0	6.5	7.8
September-2023								
1	**Near Material Gate**	68.5	27.3	22.4	10.3	<1.0	5.8	7.2
2	**Near Nitrogen Plant**	65.8	24.5	17.2	8.6	<1.0	5	6.4
3	**Near Gate No 5**	69.4	28.6	23.5	9.7	<1.0	5.5	6.8
4	**Near Main Gate**	66.7	23.4	20.5	8.8	<1.0	6.2	7.5

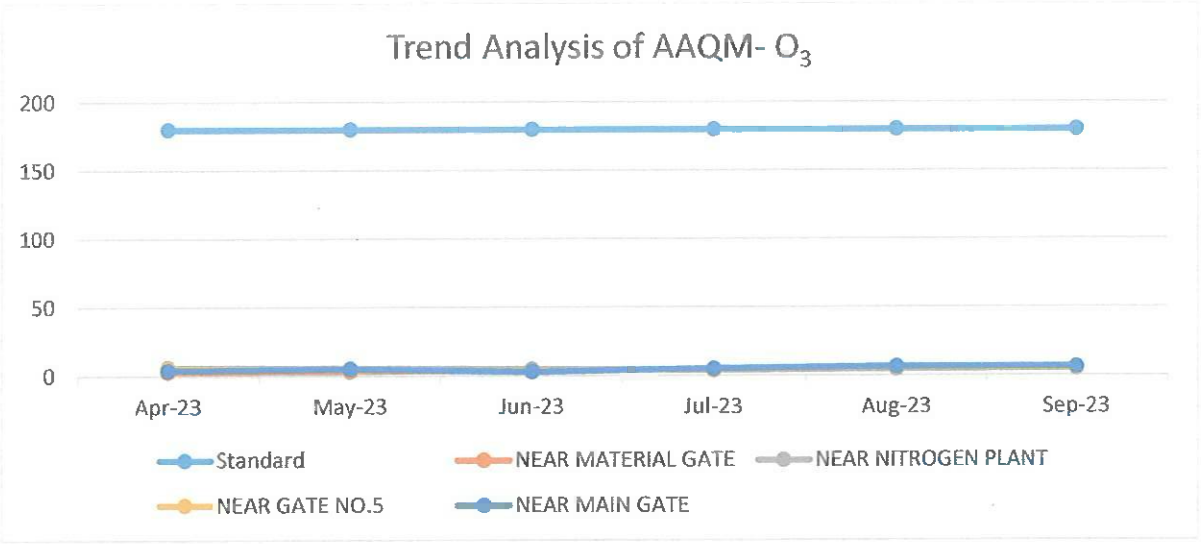


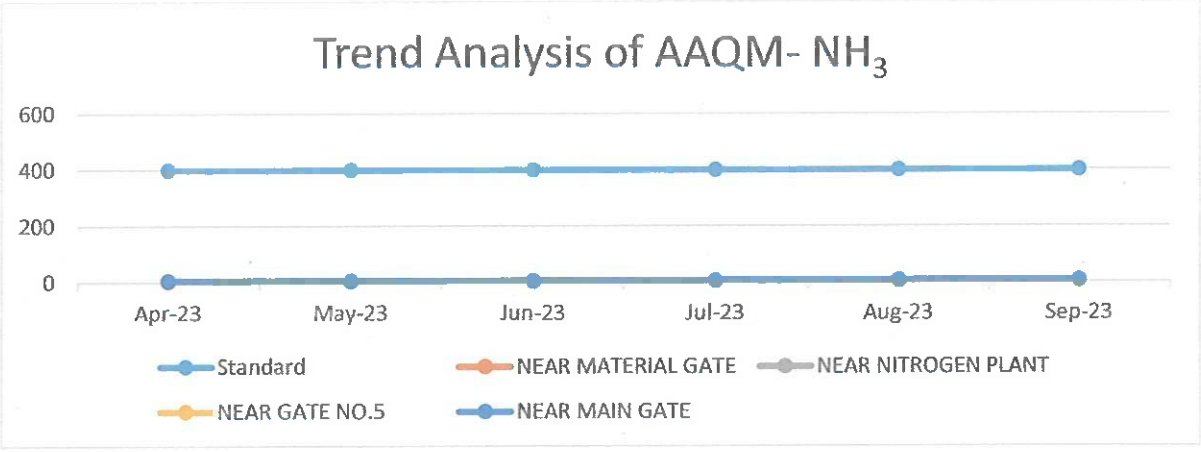



Trend Analysis of AAQM - NO_2
90
80
70
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
NEAR MATERIAL GATE
NEAR NITROGEN PLANT
NEAR GATE NO.5
NEAR MAIN GATE


Trend Analysis of AAQM - SO_2
90
80
70
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
NEAR MATERIAL GATE
NEAR NITROGEN PLANT
NEAR GATE NO.5
NEAR MAIN GATE


Trend Analysis of AAQM- CO
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
NEAR MATERIAL GATE
NEAR NITROGEN PLANT
NEAR GATE NO.5
NEAR MAIN GATE


Trend Analysis of AAQM- O3
200
150
100
50
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
NEAR MATERIAL GATE
NEAR NITROGEN PLANT
NEAR GATE NO.5
NEAR MAIN GATE


Trend Analysis of AAQM- NH3
600
400
200
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
NEAR MATERIAL GATE
NEAR NITROGEN PLANT
NEAR GATE NO.5
NEAR MAIN GATE

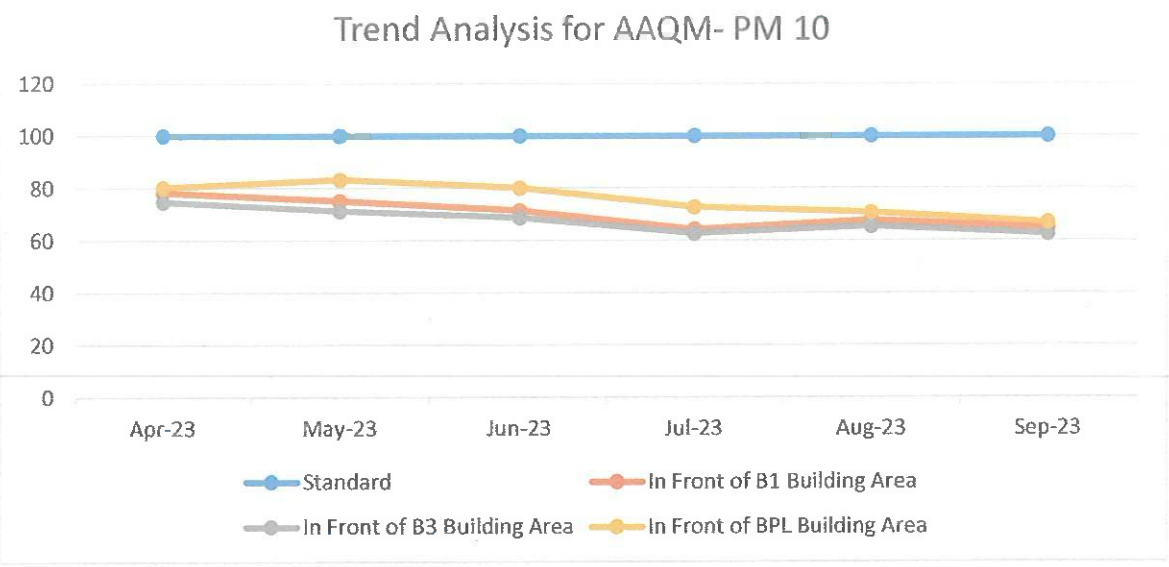
AAQMS System installed to measure ambient air quality at vantage points	*Ambient Air Quality display at Factory Main gate Entrance*

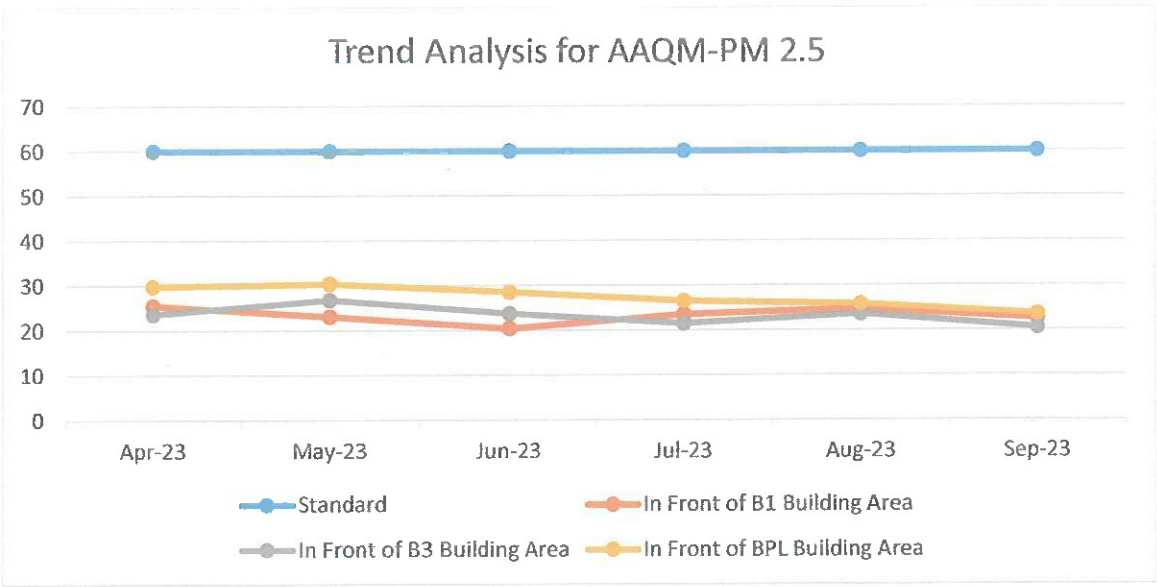
EC-2017 (Specific Condition: Point No: 6), EC-2020(II. vii)

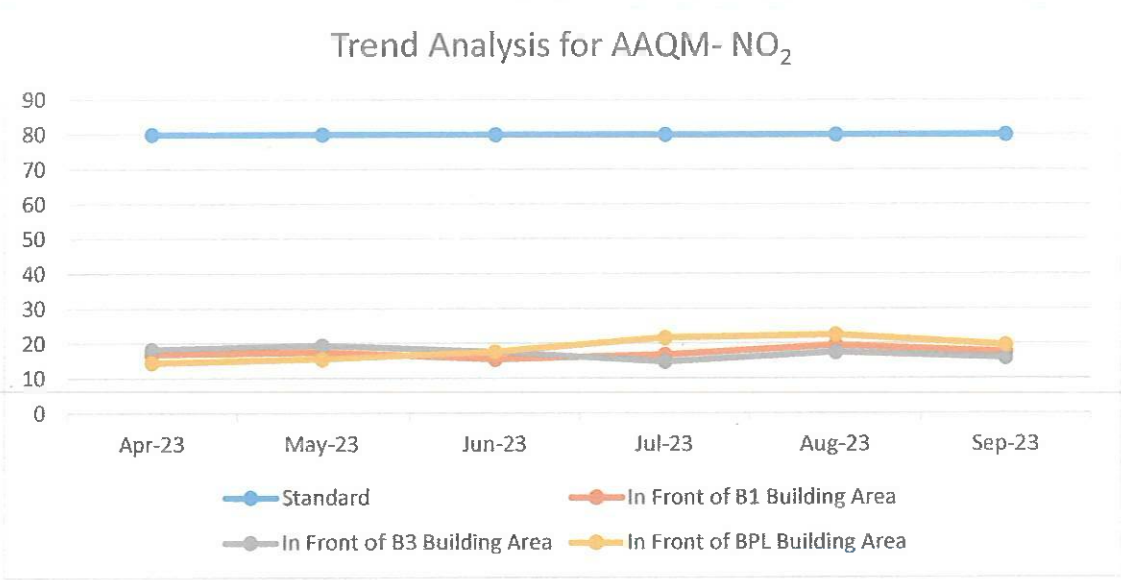
Ambient air quality data shall be collected as per NAAQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM10, PM2.5, SO2, NOX, CO, VOC, BaP, HCL etc., (12 parameters) shall be monitored in the ambient air and emissions from the stacks and displayed 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.

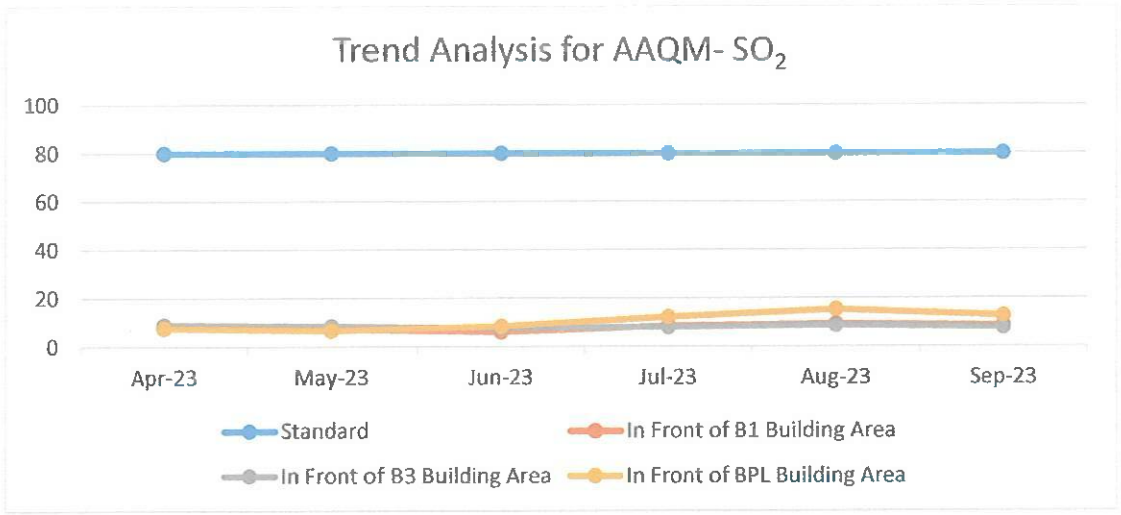
- *Noted and complied with. Ambient air quality monitoring is carried out at three identified monitoring locations in Biocon Biologics. Air quality is monitored in above said locations and reports are being submitted to Regional office and Head Office, Karnataka State Pollution Control Board. The trend of ambient air quality monitoring for the period April 2023 to September 2023 is as given below.*

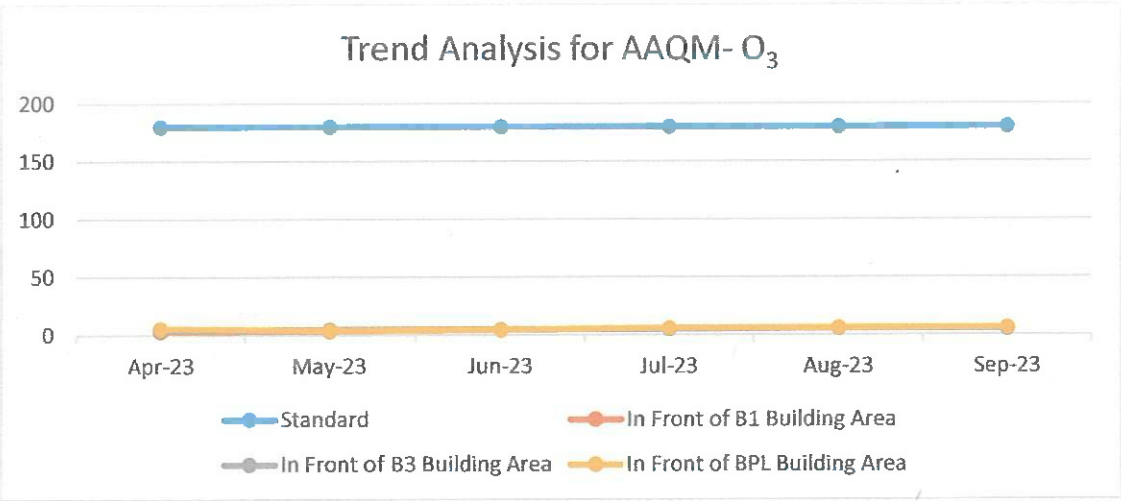
Sl No	Month	PM_{10}	$PM_{2.5}$	NO_2	SO_2	CO	O_3	NH_3
April-2023								
1	In Front of B1 Building Area	78.3	25.5	16.9	8.5	<1.0	3.2	4.8
2	In Front of B3 Building Area	74.7	23.6	18.3	9	<1.0	4.1	5.6
3	In Front of BPL Building Area	80.2	29.8	14.5	7.7	<1.0	5.6	7.2
May-2023								
1	In Front of B1 Building Area	75	23.1	17.5	7.3	<1.0	3.6	5.2
2	In Front of B3 Building Area	71.2	26.8	19.4	8.5	<1.0	4.7	6
3	In Front of BPL Building Area	83.3	30.4	15.5	6.6	<1.0	3.9	4.8
June-2023								
1	In Front of B1 Building Area	71.3	20.4	15.5	6.1	<1.0	4.5	6
2	In Front of B3 Building Area	68.6	23.7	17.6	7.5	<1.0	4.7	6.5
3	In Front of BPL Building Area	80	28.5	17.6	8.3	<1.0	4.5	5.7
July-2023								
1	In Front of B1 Building Area	64.2	23.5	16.7	8.5	<1.0	5.2	6.8
2	In Front of B3 Building Area	62.6	21.5	14.8	8	<1.0	5	6.3
3	In Front of BPL Building Area	72.7	26.5	21.6	12.2	<1.0	5.8	7.1
August-2023								
1	In Front of B1 Building Area	67.5	24.7	19.4	9.3	<1.0	6.2	7.9
2	In Front of B3 Building Area	65.3	23.6	17.5	8.7	<1.0	5.8	7.3
3	In Front of BPL Building Area	70.6	25.8	22.5	15.3	<1.0	6.2	8.5
September-2023								
1	In Front of B1 Building Area	64.8	22.6	17.5	8.4	<1.0	5.6	7.3
2	In Front of B3 Building Area	62.4	20.5	15.8	7.8	<1.0	5.2	6.8
3	In Front of BPL Building Area	66.8	23.5	19.5	12.5	<1.0	6	7.8

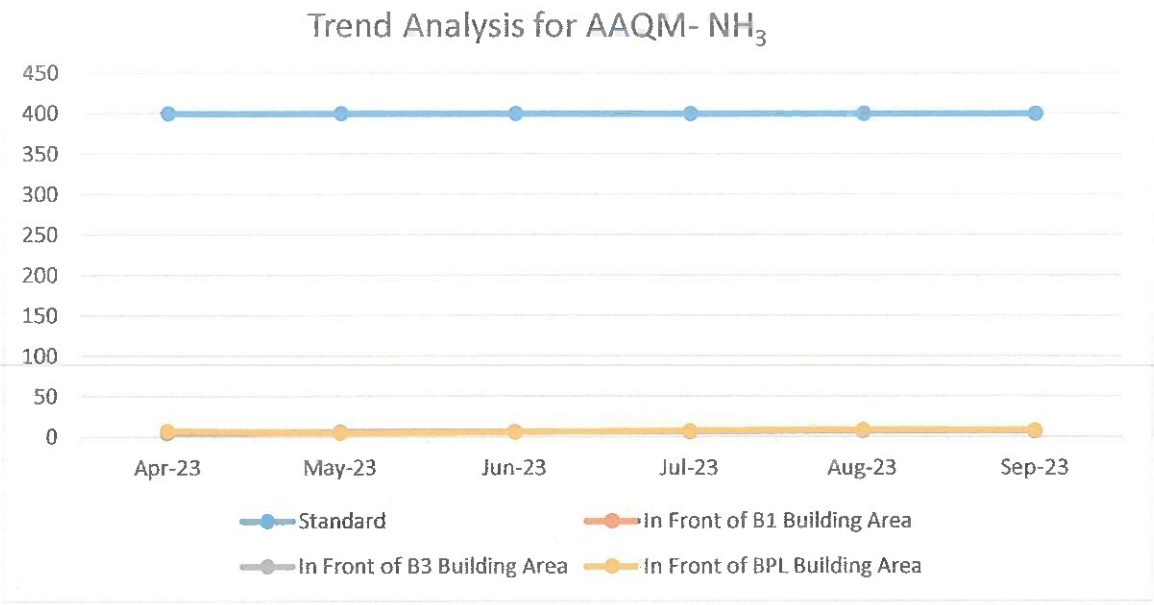

Trend Analysis for AAQM- PM 10
120
100
80
60
40
20
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area


Trend Analysis for AAQM-PM 2.5
70
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area


Trend Analysis for AAQM- NO_2
90
80
70
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area


Trend Analysis for AAQM- SO_2
100
80
60
40
20
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area


Trend Analysis for AAQM- O_3
200
150
100
50
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area



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:

Sl. No.	*Volatile Organic Compounds*	*Threshold Limit Values As per KFR & OSHA standard*
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	*n-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*	*0*
2	*A1*	*First Floor*	*0*

3	A1	GF Control Room	0
4	W1	Near Rack A	0
5	W1	Between Rack F & G	0
6	W1	Near Rack T	0
7	W1	Near Rack J	0
8	W1	Rejected material Area	0
9	W1	Dispensing room 1 (W1-DH-020)	0
10	W1	Dispensing Room 2 (W1-DH-021)	0
11	W1	Sampling room (W1-DH-022)	0
12	W1	Dedusting Area	0
13	W1	Acid Storage Area	0
14	W1	Rack B	0
15	W1	Office Area	0
16	A2	3rd Floor 100KL Fermenter-1	0
17	A2	3rd Floor 100KL F104-B	0
18	A2	Between Fermenter F104 C & D	0
19	A2	2nd Floor F102B	0
20	A2	2nd Floor: F103-A & F103B	0
21	A2	2nd Floor: B/w F103 C & F103 D	0
22	A2	1st Floor: D106-F & D106 H	0
23	A2	1st Floor: D106-B & D106 D	0
24	A2	1st Floor: D105-B & D105-D	0
25	A2	GF: F104D – 100Kl	0
26	A2	GF F104 C	0
27	A2	B/w D105 C &D105 A	0
28	A2	LAF II (Microbiology lab)	0
29	A2	LAF I	0
30	A2	LAF III	0
31	A2	LAF IV	0

32	A2	Incubator Room	0
33	A2	Culture Storage Room	0
34	A2	Incubation Room	0
35	A2	Media Preparation Room	0
36	A2	Qc Lab	0
37	A2	PE-AL	0.1
38	A2	PE Lab	0.1
39	A2	Media Preparation Room	0
40	A2	Kilo Lab	0
41	A2	Kilo Lab Washing Area	0
42	A2	Media Preparation Room	0
43	A2	GF – PE Office Area	0
44	D1	SF Control Panel Room	0.1
45	D1	SF T403-H	0.1
46	D1	TF T403-H	0.1
47	D1	TF T403 D	0.1
48	D1	GF T403 E & F	0.1
49	D1	GF T408 A	0.1
50	D1	GF T409 A	0.1
51	R1	GF Near PlC	0
52	R1	FF Batch Recovery columns	0
53	R1	FF R1-E-602 Condenser	0
54	R1	3rd Floor Tank Storage Area	0
55	C3	GF Cryogenic Room	0
56	C3	GF VTD Loading	0
57	C3	FF AJM Room	0
58	C3	FF C3 SSR 08	0
59	C3	FF Centrifuge Room	0.2
60	C3	FF Loading	0
61	C3	SF Cryogenic Room	0

62	C3	SF N-Butyl Lithium tank	0.1
63	C3	SF Reactor Room	0
64	C3	TF Washroom	0
65	C3	FF C3 SSR 07	0
66	C3	GF Centrifuge C3-CFG-05	0
67	C3	GF RCVD	0
68	C3	GF RCVD	0
69	D3	Freeze Drying Room	0
70	D3	GF Module 3	0
71	D3	GF Module 3 SSR 106	0
72	D3	GF Module 3 D3 SSR 110	0.1
73	D3	GF Module 3 Washroom	0
74	D3	Module 4 Process Area	0.1
75	D3	Module 4 SSR 104	0
76	D3	Qc Chemical Storage area	0
77	D3	Qc Gc Room	0
78	D3	Qc In process Lab 2	0
79	D3	Qc In process Lab	0
80	D3	Qc Wet lab	0
81	C2A	FF Centrifuge Room	0.1
82	C2A	FF Drying room	0
83	C2A	FF Milling Room	0
84	C2A	FF Washroom	0.2
85	C2A	GF Drying room	0
86	C2A	SF Reactor room	0
87	C2A	SF Washroom	0
88	C2	FF Process Area	0
89	C2	GF Process Area	0
90	C2	GF Hydrogenation Room	0

91	C2B	SF Combustible Storage Room	0
92	C2B	SF Reactor Room	0
93	C2B	GF Centrifuge Room	0
94	C2B	GF Packing Room	0
95	C1C	FF Production	0
96	C1C	GF Resin Unloading	0
97	C1C	SF Production	0
98	C1CA	FF Centrifuge Room	0
99	C1CA	FF Washroom	0
100	C1CA	GF Lyophilizer Room	0
101	C1CA	GF RCVD Room	0
102	C1CA	GF VTD Room	0
103	C1CA	SF SSR Reactor Room 5 Kl	0
104	C1CA	SF Milling room	0
105	C1CA	TF Intermediate Storage Room	0
106	C1CB	FF Centrifuge Room	0
107	C1CB	5Kl Reactor Room	0
108	C1CB	TF 15 KL Reactor Room	0
109	C1A	GF Drier Room	0
110	C1A	GF Drying Room	0
111	C1A	GF RCVD Room	0
112	C1A	SF Reactor room	0
113	C1B	FF Process Area SSR 04	0
114	C1B	FF SSV 03	0
115	C1B	GF ANF 01	0
116	C1B	GF Centrifuge Unloading	0
117	C1B	SF C1B SSR 01	0
118	C1B	SF Centrifuge Bag Storage area	0
119	Q1	Lab	0

120	*Q1*	*Lab*	*0.1*
121	*Q1*	*FF HPLC Room*	*0*
122	*Q1*	*Fume Hood Room*	*0.1*
123	*Q1*	*Chemical Storage Room*	*0*
124	*W5*	*Solvent unloading*	*0*
125	*Utility*	*Compressor House*	*0*
126	*Utility*	*Boiler House*	*0*
127	*Utility*	*Nitrogen plant*	*0*
128	*Utility*	*Powerhouse*	*0*
129	*Utility*	*ETP*	*0*
130	*Utility*	*MEE plant*	*0*
131	*Utility*	*Water plant*	*0*
132	*D5*	*Entrance Reception*	*0*
133	*D5*	*Change Room*	*0*
134	*D5*	*GF Lift corridor*	*0*
135	*D5*	*Raw material entry*	*0*
136	*D5*	*Control room*	*0*
137	*D5*	*Lyophilizer area*	*0*
138	*D5*	*Office -primary change room*	*0*
139	*D5*	*Office*	*0*
140	*D5*	*Document room*	*0*
141	*D5*	*Washroom*	*0*
141	*D5-L1*	*VTD area*	*0*
142	*D5-L1*	*VTD service area*	*0*
143	*D5 -L1*	*Raw material storeroom*	*0*
144	*D5-L2*	*Side chain & acylation room*	*0*

145	D5-L2	Clean room	0
145	D5-L2	Clean room washroom	0
146	D5-L2	Passenger lift Exit	0
147	D5-L3	Staircase	0
148	D5-L3	Production corridor	0
149	D5-L3	IPQC room	0
150	D5-L3	Cleavage room	0
151	D5-L3	Passenger lift corridor	0
152	D5-L3	Staircase	0
153	D5-L3	AHU area End	0
154	D5-L3	AHU area Middle	0
155	D5-L3	AHU area and DCS entrance	0
156	D5-L3	AHU area Middle	0
157	D5-L4	Staircase	0
158	D5-L4	Mezzanine floor utility area staircase	0
159	D5-L4	Utility Entrance	0
160	D5-L4	PCC panel room	0
161	D5-L4	AC power system panel room	0
162	D5-L4	Utility area middle	0
163	D5-L4	Utility area end	0
164	D5-L4	Utility washroom	0
165	D5-L5	Staircase	0
166	F3	Entrance	0
167	F3	Centre	0
168	F3	Corridor Near ATM	0

169	*F3*	*Dining Hall-1*	*0*
170	*F3*	*Dining Hall-2*	*0*
171	*F3*	*Kitchen*	*0*
172	*F3*	*Utility Corridor*	*0*
173	*F3*	*Storeroom*	*0*
174	*F3*	*Fine Dining Entrance*	*0*
175	*F3*	*Fine Dining End*	*0*
176	*U8*	*Casual Canteen Entrance*	*0*
177	*U8*	*Casual Canteen End*	*0*
178	*SEZ*	*Office Entrance*	*0*
179	*SEZ*	*Office End*	*0*
180	*W5*	*Entrance Gate*	*0*
181	*W5*	*Gas Cylinder Storage Room Entry*	*0*
182	*W5*	*Gas Cylinder Storage Room Exit*	*0*
183	*W5*	*Sampling Point*	*0*
184	*W5*	*Near Gate No-4*	*0*
185	*W6*	*Entrance*	*0*
186	*W6*	*Inside Left*	*0*
187	*W6*	*Inside Right*	*0*
188	*W6*	*Gate No-6 Near R1*	*0*
189	*W6*	*Gate No-7 Near R1 Day Tank*	*0*

** VOC is monitored during work place monitoring conducted in the month of May 2023.*

- *Online Continuous VOC Monitoring Instrument installed in the Solvent recovery area.*

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)
1	B1 SF corridor	0
2	B1-M GF-084 Analytical lab 01	0.1
3	B1 Fill Finish (lyophilisation and crystallization Room)	0.1
4	B1 Fill Finish (Non sterile Corridor) General Used Area	0
5	B1 Fill Finish Sterile Formulation Area	0
6	B1 Fill Finish Vial Washing Area	0.1
7	B1 Kill Plant	0.1
8	B1 M1 Down Stream	0.1

9	B1 M1 Upstream (Fermentation Room)	0.1
10	B1 M2 AHU Area Technical Floor	0
11	B1 M2 Down Stream	0
12	B1 M2 Upstream	0
13	B1 SF QC MicroLab	0.3
14	B1 TF M1 AHU Area	0
15	B1 Water Plant	0
16	B2 Formulation Area	0
17	B2- General Washing Area	0.1
18	B2- GF Office Area	0.1
19	B2-GF Lyophilization area	0
20	B2- Micro Lab	0.2
21	B2 Pen Packing and Labelling Area	0.1
22	B2- Vial Washing Area	0.1
23	B2-Water Plant	0
24	RND TF POD-1 office	0
25	RND TF POD-1 Lab	0
26	RND TF POD-3 Office Area	0
27	RND SF POD-1 office	0
28	RND SF POD-1 Lab	0
29	RND Basement AHU 03	0
30	RND Basement Chiller Plant	0
31	RND Basement Warehouse	0
32	RND FF POD-1 Office	0
33	RND FF POD-1 Lab	0
34	RND FF POD-2 Office	0
35	RND FF POD-2 Lab	0

36	RND FF POD-3 Office	0
37	RND FF POD-3 Lab	0
38	RND GF POD-2 Office	0
39	RND GF POD 02 Lab	0
40	RND GF POD-3 Office	0
41	RND GF POD-3 Lab	0
42	B4 FF Purification	0
43	B4 FF Reaction room	0
46	B4 FF Fermentation room	0
47	B4 FF Media room	0
48	B4 FF Harvest room	0
49	B4 FF Return corridor	0
50	B4 FF AHU area	0
51	B4 FF E&M office	0
52	B4 SF Water plant	0
53	B4 SF Buffer preparation area	0
54	B4 SFM Buffer preparation area	0
55	B4 TF AHU area	0
56	W20- Packing materials and storage consumables area (WH051)	0.7
57	W20 Raw materials and consumables storage area (WH O34)	0
58	W20 Receipt area	0
59	W20-Packing area	0
60	W20- Packing & Consumable storage area (WH 116)	0
61	W20- GF warehouse office	0
62	W20-FF office area	0

63	W20- FF AHU area	0
64	W20 GF QA documents area	0
65	B3 -GF office	0
66	B3-FF office	0
67	B3-SF office	0.1
68	B3- TF office	0.8
69	B3- TF Technical area	0
70	B3- TF Chiller area	0
71	B3- SF Air compressor area	0
72	B3- FF QC Analytical lab	0
73	B3- FF QC RM lab	0
74	B3-FF Washing area	0
75	B3-GF Warehouse	0
76	B3-GF Warehouse W21	0
77	B3- SF Production area	0
78	B3- SF Clean room	0
79	B5- FF E&M office	0
80	B5-FF office area	0
81	B5- Mezzanine floor	0
82	B5- SF office area	0
83	B5- SF QC Analytical lab	0
84	B5- SF Microbiology lab	0
85	B5 SF Washing area	0
86	Q13 QC Office FF	0
87	Q13 Analytical Lab-06	0
88	Q13 Analytical Lab-03	0
89	Q13 Analytical Lab-04	0

90	*B1 TF office area*	*0*
91	*B1 TF office area*	*0*

** VOC is monitored during work place monitoring conducted in the month of May 2023 for Biocon Biologics Limited.*

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)**

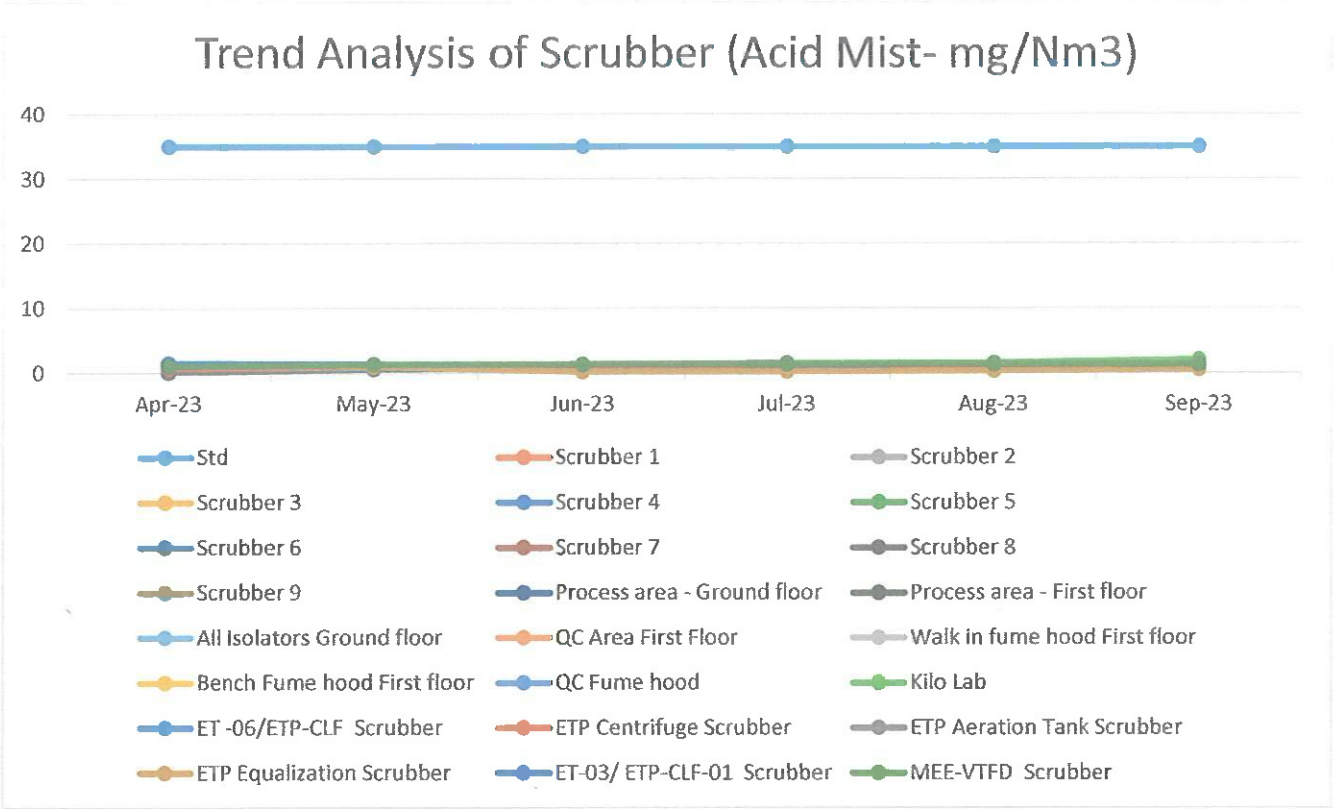
- *We have taken at most care in the designing stage of scrubbers and are well maintained. The sources are storage of VOC components & VOC generating compounds which are being used through closed loop pipes. Controls are Inertization of nitrogen, Sprinkler system and transportation of VOC components 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 April 2023 to September -2023 (mg/Nm^3)

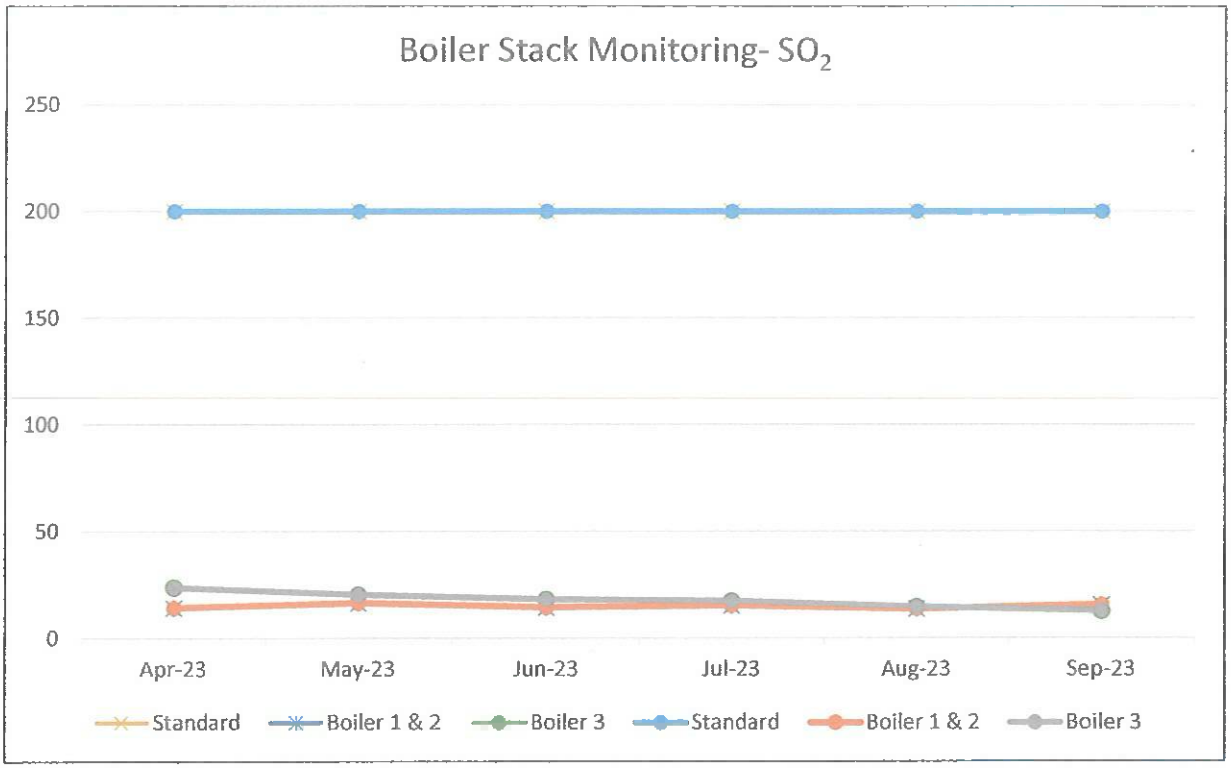
Name of Stack	Std (mg/Nm^3)	Parameters	April-23	May-23	June-23	Jul-23	Aug-23	Sep-23
Scrubber 1	35	Acid mist	0.97	1.03	1.06	1.32	1.35	1.4
Scrubber 2	35	Acid mist	1.06	1.12	0.95	0.9	0.94	1.05
Scrubber 3	35	Acid mist	1.1	0.92	1.12	1.2	1.26	1.32
Scrubber 4	35	Acid mist	0.91	0.85	1.23	1.27	1.31	1.35
Scrubber 5	35	Acid mist	1.15	1.21	1.32	1.38	1.36	1.33
Scrubber 6	35	Acid mist	1.08	1.16	1.03	1.02	1.08	1.15
Scrubber 7	35	Acid mist	0.97	0.81	0.9	0.95	1.05	1.1
Scrubber 8	35	Acid mist	0.1	0.59	0.76	0.82	0.88	0.9
Scrubber 9	35	Acid mist	1.23	0.77	0.81	0.85	0.92	0.96
Process area - Ground floor	35	Acid mist	1.27	1.32	1.25	1.47	1.5	1.47
Process area - First floor	35	Acid mist	1.11	0.88	0.92	0.95	1.15	1.2
All Isolators Ground floor	35	Acid mist	1.2	1.17	1.22	1.36	1.4	1.34

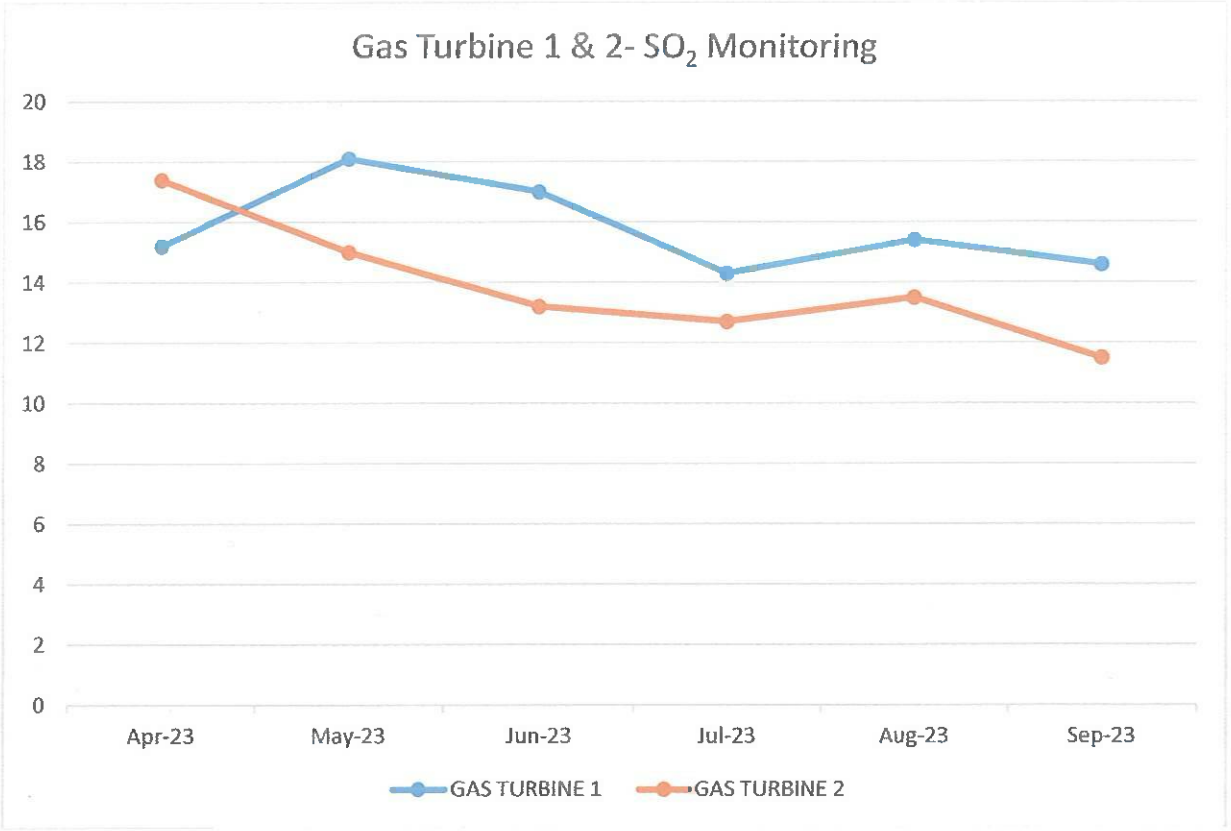
QC Area First Floor	35	Acid mist	0.81	0.99	1.07	1.44	1.47	1.44
Walk in fume hood First floor	35	Acid mist	0.7	0.88	0.91	1.31	1.34	1.38
Bench Fume hood First floor	35	Acid mist	0.55	0.91	1.11	1.37	1.42	1.46
QC Fume hood	35	Acid mist	0.87	1	1.24	1.4	1.45	1.5
Kilo Lab	35	Acid mist	1.19	1.02	1.09	1.42	1.5	2
ET -06/ETP-CLF Scrubber	35	Acid mist	0.55	0.72	0.86	1.2	1.23	1.27
ETP Centrifuge Scrubber	35	Acid mist	0.64	0.87	0.99	1.24	1.28	1.31
ETP Aeration Tank Scrubber	35	Acid mist	1.22	1.16	1.29	1.3	1.36	1.41
ETP Equalization Scrubber	35	Acid mist	0.95	0.9	0.2	0.25	0.32	0.52
ET-03/ ETP-CLF-01 Scrubber	35	Acid mist	1.47	1.32	1.27	1.35	1.33	1.29
MEE-VTFD Scrubber	35	Acid mist	0.99	1.25	1.32	1.42	1.39	1.33

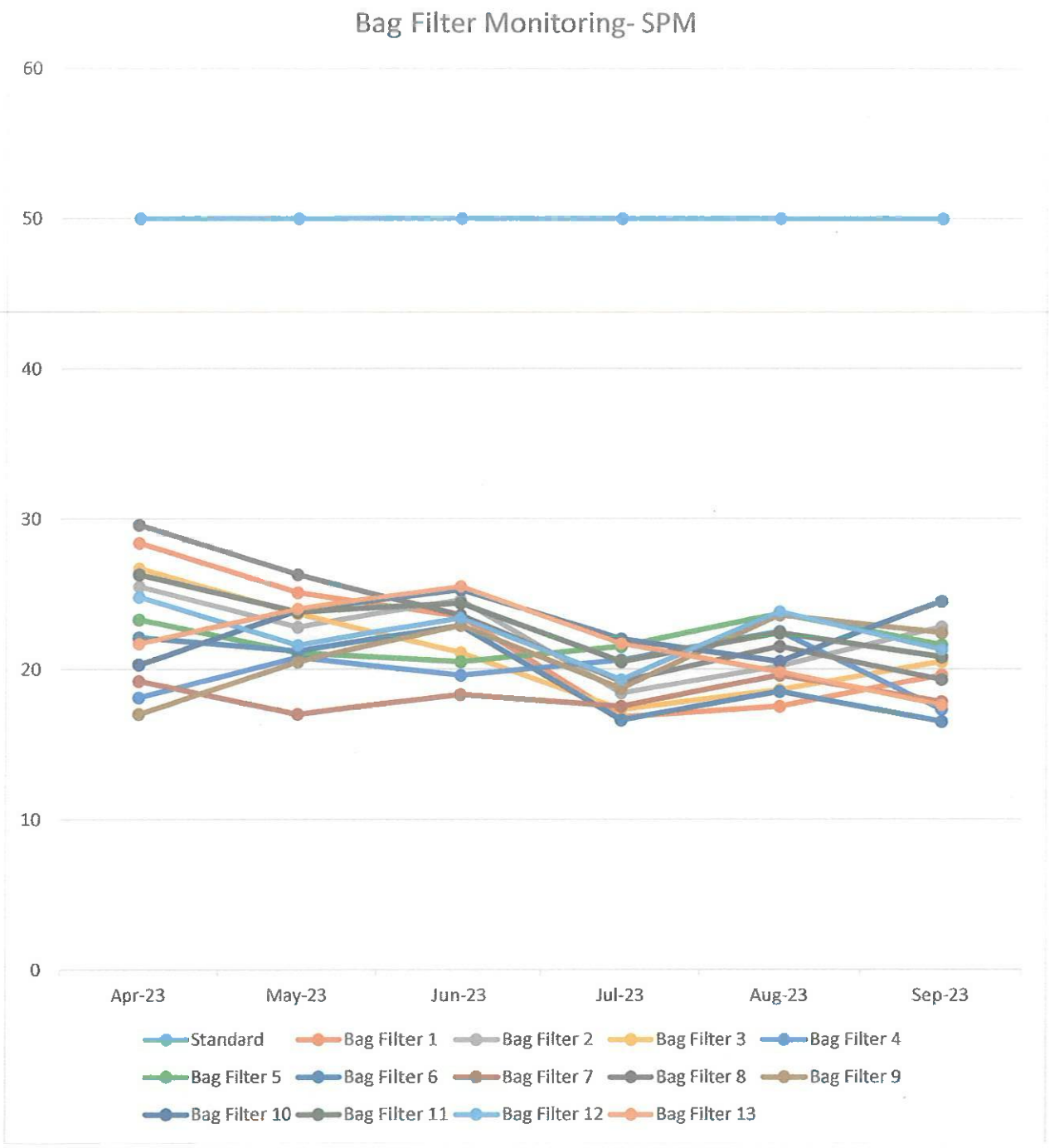


Name of Stack	Std (mg/Nm^3)	Parameters (mg/Nm^3)	April-23	May-23	June-23	Jul-23	Aug-23	Sep-23
Gas turbine 1	-	SO_2	15.2	18.1	17	14.3	15.4	14.6
Gas turbine 2	-	SO_2	17.4	15	13.2	12.7	13.5	11.5
Boiler 1 & 2	200	SO_2	14.2	16.5	14.3	15.2	13.7	15.6
Boiler 3	200	SO_2	23.8	20.4	18.1	17.4	14.6	12.8

Name of Stack	Parameters (mg/Nm^3)	April-23	May-23	June-23	Jul-23	Aug-23	Sep-23
Bag filter 1	SPM	28.4	25.1	23.5	16.8	17.5	19.6
Bag filter 2	SPM	25.5	22.8	24.6	18.4	20.2	22.8
Bag filter 3	SPM	26.7	23.7	21.1	17.3	18.6	20.5
Bag filter 4	SPM	18.1	20.8	19.6	20.6	22.5	17.3
Bag filter 5	SPM	23.3	21.1	20.5	21.5	23.7	21.6
Bag filter 6	SPM	22.1	21.2	22.9	16.6	18.5	16.5
Bag filter 7	SPM	19.2	17	18.3	17.5	19.6	17.8
Bag filter 8	SPM	29.6	26.3	23.6	19.2	21.5	19.3
Bag filter 9	SPM	17	20.5	22.9	18.7	23.6	22.4
Bag filter 10	SPM	20.3	23.9	25.3	22	20.5	24.5
Bag filter 11	SPM	26.3	23.8	24.4	20.5	22.4	20.8
Bag filter 12	SPM	24.8	21.6	23.4	19.3	23.8	21.3
Bag filter 13	SPM	21.7	24	25.5	21.7	19.8	17.6


Boiler Stack Monitoring- SO_2
250
200
150
100
50
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
Boiler 1 & 2
Boiler 3
Standard
Boiler 1 & 2
Boiler 3


Gas Turbine 1 & 2- SO_2 Monitoring
20
18
16
14
12
10
8
6
4
2
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
GAS TURBINE 1
GAS TURBINE 2


Bag Filter Monitoring- SPM
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
Bag Filter 1
Bag Filter 2
Bag Filter 3
Bag Filter 4
Bag Filter 5
Bag Filter 6
Bag Filter 7
Bag Filter 8
Bag Filter 9
Bag Filter 10
Bag Filter 11
Bag Filter 12
Bag Filter 13

Parameter	Std (mg/Nm³)	DG -I		DG - II		DG - III		DG -IV	
		June-23	Sep-23	June-23	Sep-23	June-23	Sep-23	June-23	Sep-23
Particulate matter	100	49.2	51.5	45.6	48.2	51.7	53.4	42.8	46.5
NOx	970	35	32.4	38.7	29.5	31.6	33.5	33.6	31.8
SO2	--	16.6	17.6	17.8	16.5	13.7	19.3	16.8	15.3
CO	150	21.5	23.5	23.6	21.6	25.8	26.4	22	24.6
NMHC	100	30.6	34.2	33.8	32.4	34.5	36.8	31.5	33.2

Parameter	Std (mg/Nm³)	DG - V		DG - VI		DG - VII		DG - VIII	
		June-23	Sep-23	June-23	Sep-23	June-23	Sep-23	June-23	Sep-23
Particulate matter	100	40	43.8	47.1	50.4	46.4	49.8	49.7	52.4
NOx	970	34.8	27.4	30.2	32.6	34	32.5	28.3	31.8
SO2	--	18	13.6	15.7	18.5	16.2	17.8	17.5	19.5
CO	150	25.4	22.5	26.8	25.3	27	29.5	23.1	25.6
NMHC	100	33.7	31.8	34.9	35	35.8	32.3	33	35.6

Parameter	Std (mg/Nm³)	DG - IX		DG - X	
		June-23	Sep-23	June-23	Sep-23
Particulate matter	100	45	45	51.8	54.6
NOx	970	24.8	24.8	30.4	33.5
SO2	--	12	14	18.2	20.4
CO	150	21.1	21.1	25	27.6
NMHC	100	29.7	29.7	34.8	36.3

Parameter	Std (mg/Nm^3)	DG -XI		DG - XII		DG - XIII	
		June-23	Sep-23	June-23	Sep-23	June-23	Sep-23
Particulate matter	100	45.6	45.8	44	49.5	49	46.5
NOx	970	26.8	25.7	23.1	27.6	25.4	23.4
SO2	--	15.5	16.5	14.8	18.3	12.6	13.8
CO	150	23.6	25.6	25	26.2	29.8	26.2
NMHC	100	31.9	30.4	34.6	35.4	38.4	32.6

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

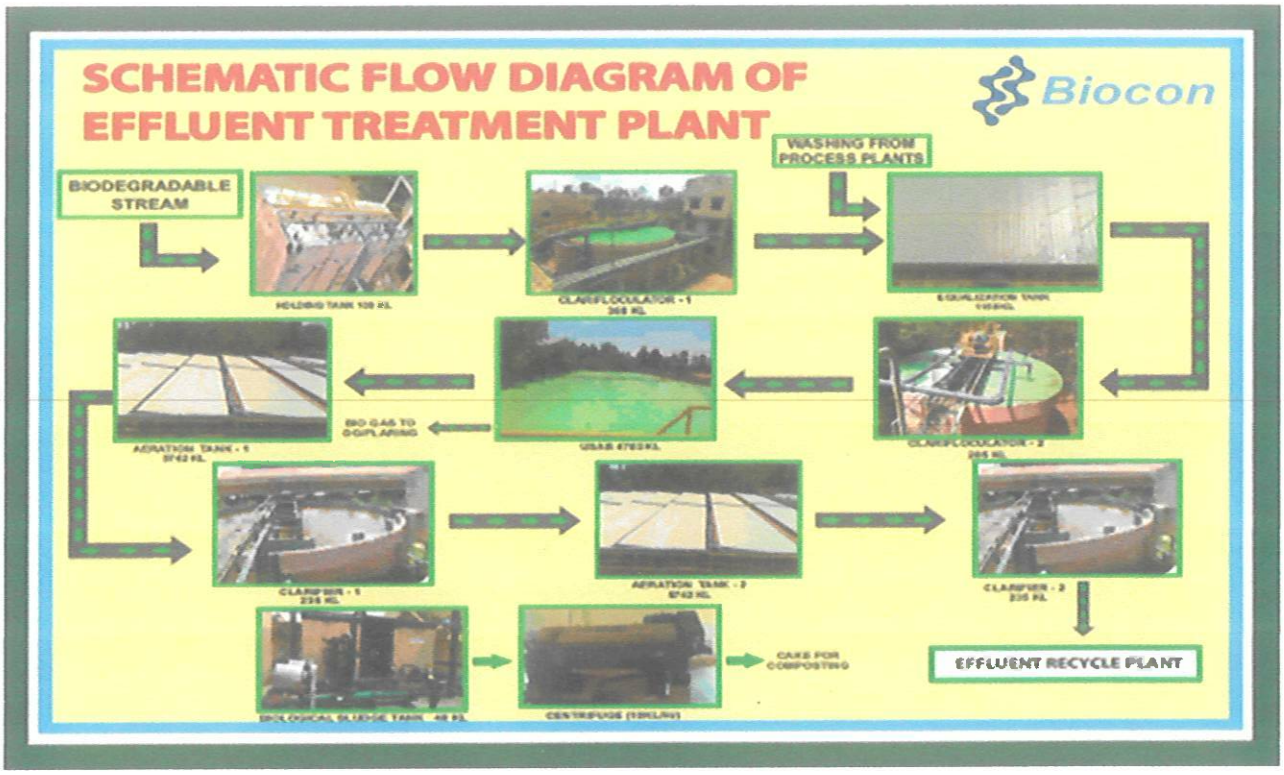
Multi-cyclone followed by bag filter shall be provided to the boilers to control emissions within CPCB/KSPCB prescribed limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/KSPCB guidelines

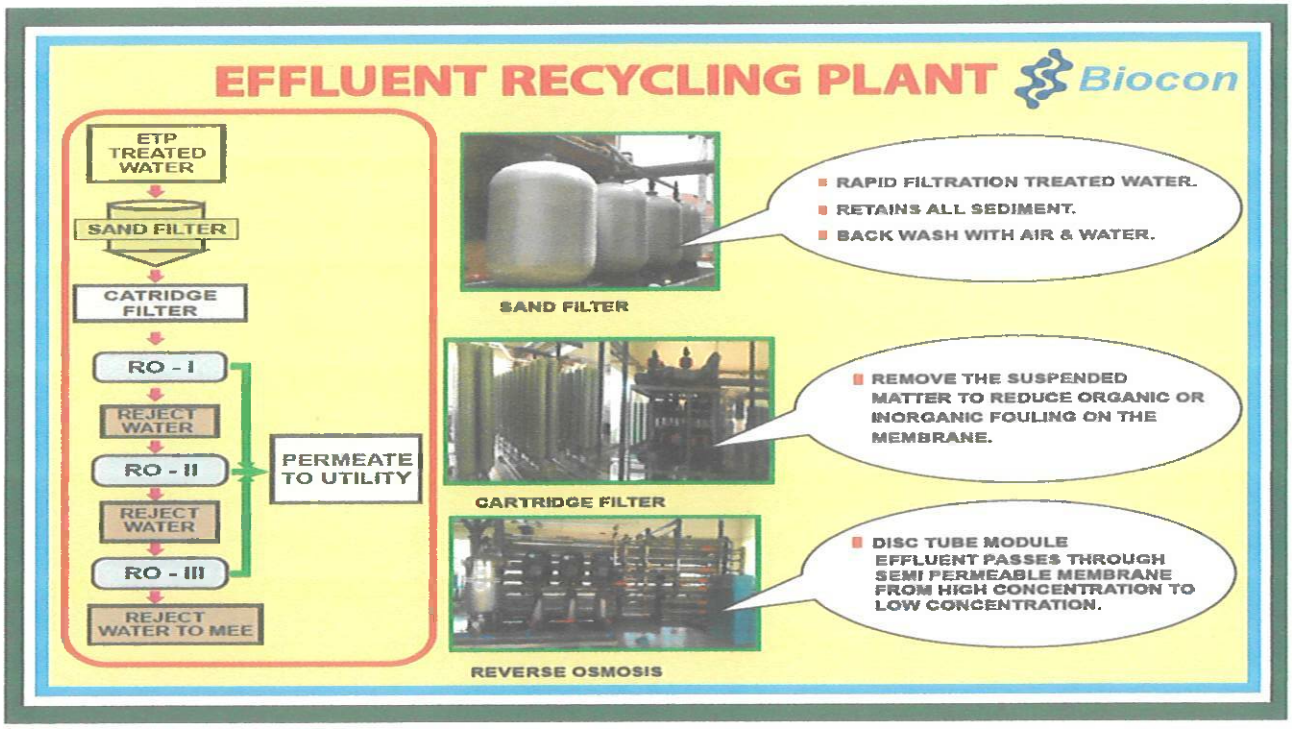
- *The fuel proposed for our existing and proposed boilers is piped natural gas which is devoid of particulate emissions. The emission levels is compiled within prescribed limits of CPCB/KSPCB details are as follows:*

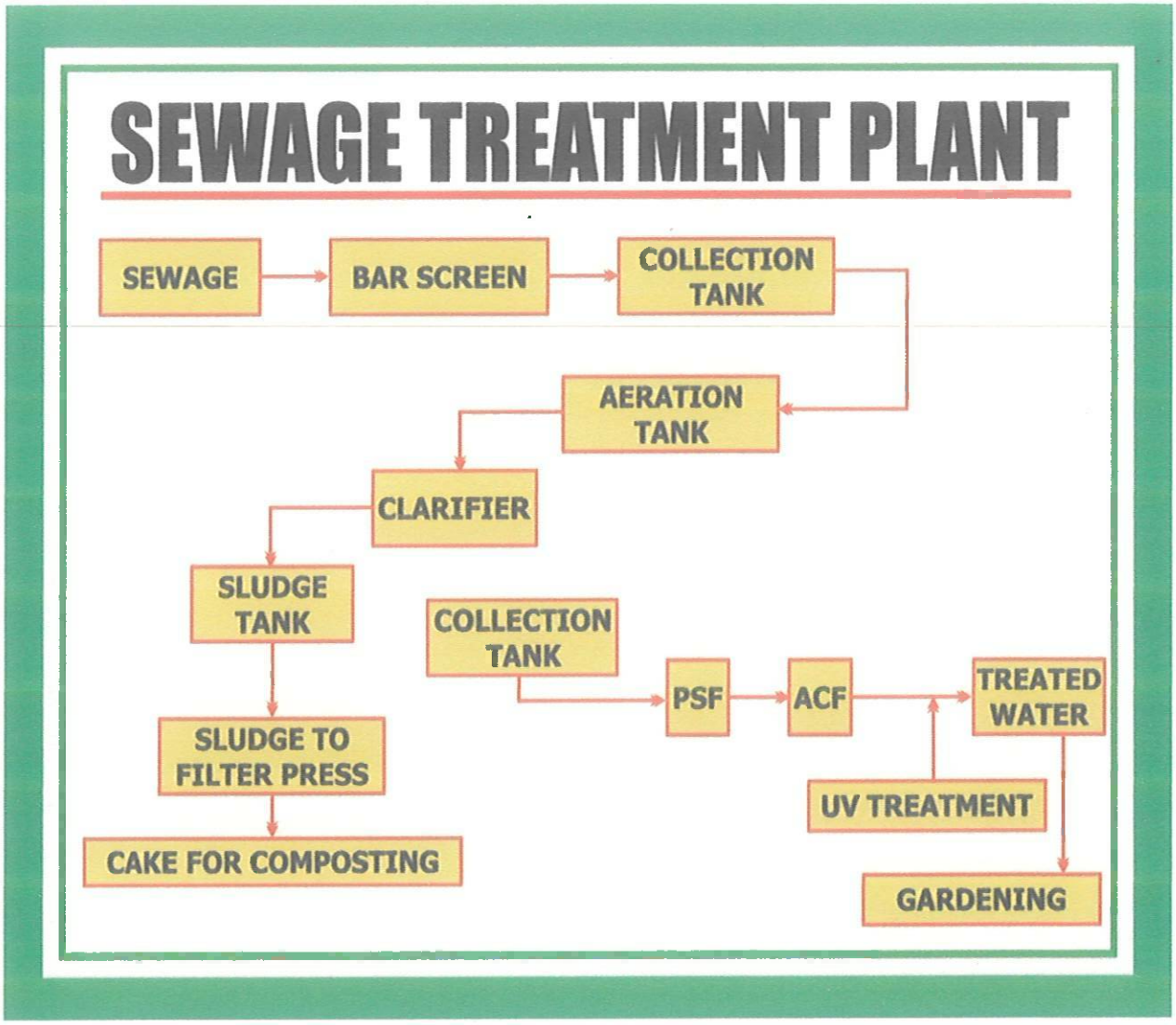
Name of Stack	Std (mg/Nm^3)	Parameters (mg/Nm^3)	April-23	May-23	June-23	Jul-23	Aug-23	Sep-23
Boiler 3	200	SO_2	23.8	20.4	18.1	17.4	14.6	12.8

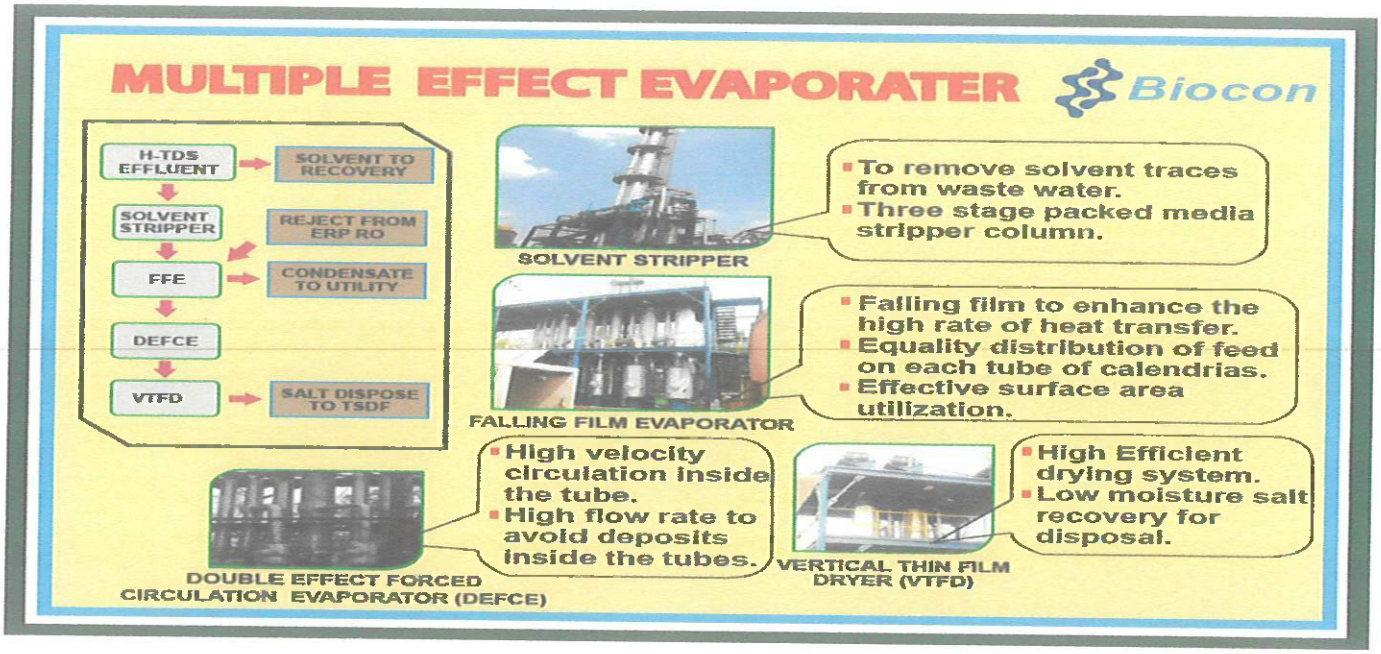
5. **As reflected in the EIA/EMP, 2367 m3/day wastewater will be generated from the project. As the plant is a zero discharge unit the entire quantity of treated trade effluent shall be recycled back to the process and all the rejects shall be evaporated. The process and treatment units description as 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)**

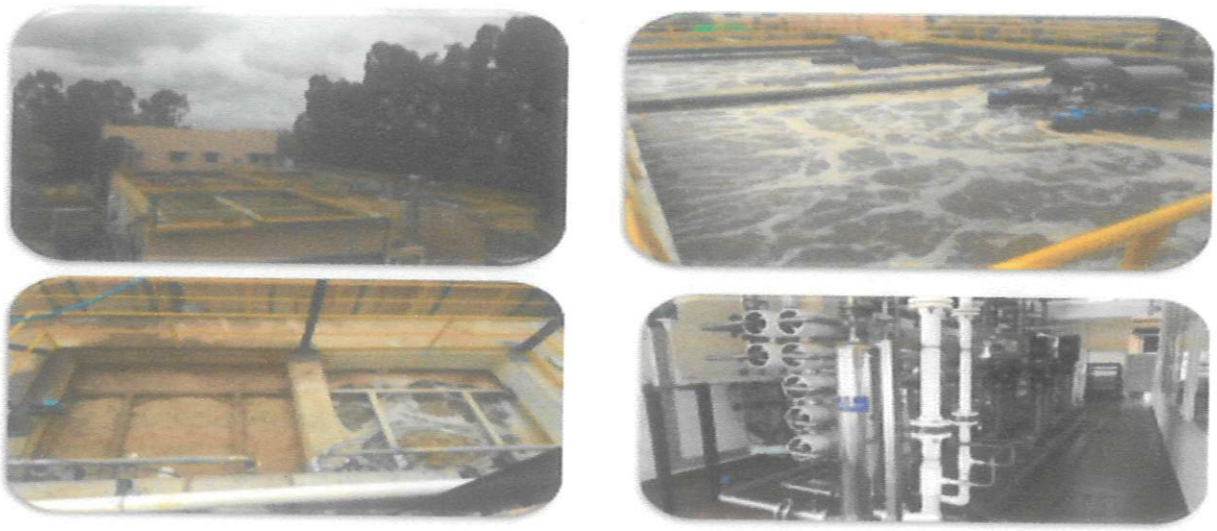
- *All Treatment units as mentioned in EIA have been established and working satisfactorily. Treated water from Effluent Treatment Plant is again recovered in Effluent recycling system. The recycled water is used for Utility consumption like Boiler, cooling towers and chillers and rejects generated are 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.*


SCHEMATIC FLOW DIAGRAM OF EFFLUENT TREATMENT PLANT
Biocon
BIODEGRADABLE STREAM
WASHING FROM PROCESS PLANTS
BIO GAS TO GGPL/ARING
CAKE FOR COMPOSTING
EFFLUENT RECYCLE PLANT


EFFLUENT RECYCLING PLANT
Biocon
ETP TREATED WATER
SAND FILTER
CATRIDGE FILTER
RO - I
REJECT WATER
RO - II
REJECT WATER
RO - III
REJECT WATER TO MEE
PERMEATE TO UTILITY
SAND FILTER
RAPID FILTRATION TREATED WATER.
RETAINS ALL SEDIMENT.
BACK WASH WITH AIR & WATER.
CARTRIDGE FILTER
REMOVE THE SUSPENDED MATTER TO REDUCE ORGANIC OR INORGANIC FOULING ON THE MEMBRANE.
REVERSE OSMOSIS
DISC TUBE MODULE
EFFLUENT PASSES THROUGH SEMI PERMEABLE MEMBRANE FROM HIGH CONCENTRATION TO LOW CONCENTRATION.


SEWAGE TREATMENT PLANT
SEWAGE
BAR SCREEN
COLLECTION TANK
AERATION TANK
CLARIFIER
SLUDGE TANK
SLUDGE TO FILTER PRESS
CAKE FOR COMPOSTING
COLLECTION TANK
PSF
ACF
TREATED WATER
UV TREATMENT
GARDENING





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

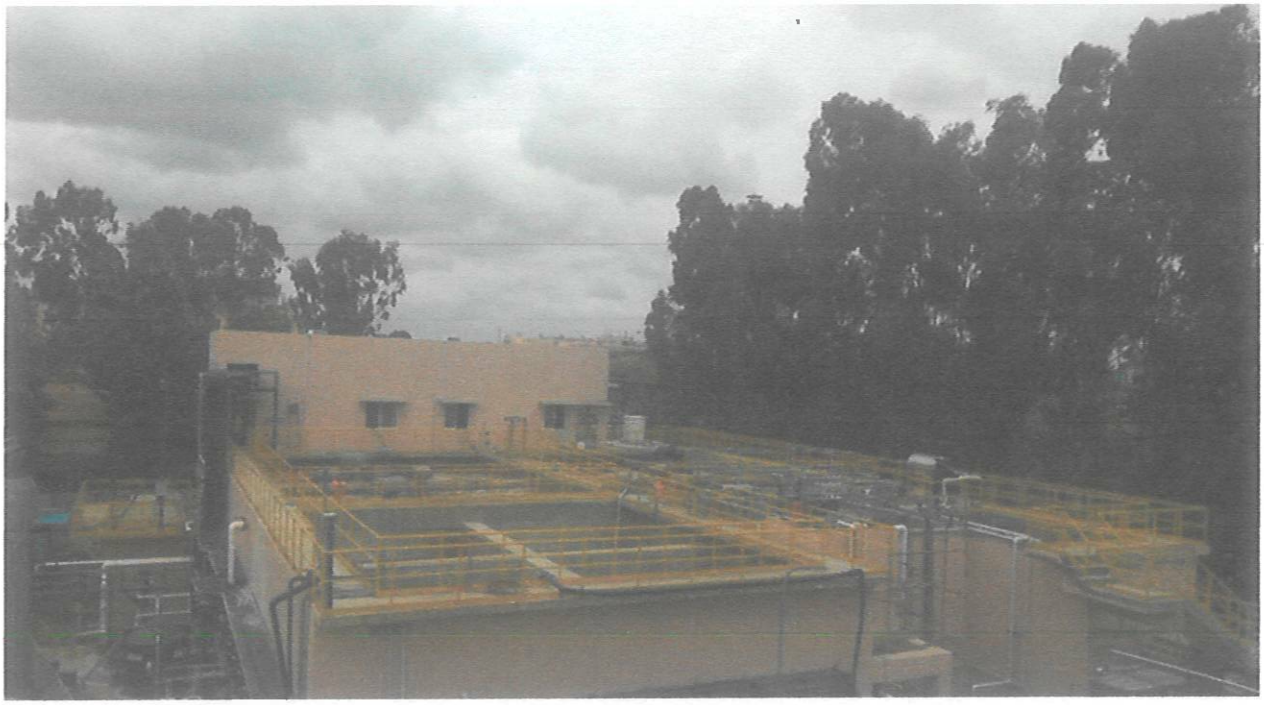
Volute Centrifuge for Sludge Dewatering

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



ZLD Effluent Treatment Plant (MBR followed by RO Systems)

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) with Document No: SOP-000062997 (Procedure for Handling of Solid and Liquid waste)*

- *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 April -2023 to September-2023 is as follows:*

Name of the Solid Waste	***Quantity in MT***	
	Generation	***Disposal***
Wooden Scrap	*17.275 MT*	*12.49 MT*
MS Scrap	*56.04 MT*	*54.47 MT*
GI Scrap	*21.21 MT*	*19.87 MT*
SS Scrap	*7.44 MT*	*5.94 MT*
Aluminium Scrap	*5.39 MT*	*4.76 MT*
Aluminium Filter Scrap	*Nil*	*Nil*
Aluminium Cable Scrap	*Nil*	*Nil*
SS 202 Scrap	*Nil*	*Nil*
Machinery Scrap	*Nil*	*Nil*
Copper Cable	*Nil*	*Nil*
Inert Cell mass – Co-processing	*3055.37 MT*	*1647.8 MT*
Inert Cell Mass- Composting		*1391.5 MT*

Centralized Non-hazardous Waste Collection Area

Departmental Non-hazardous Waste Collection

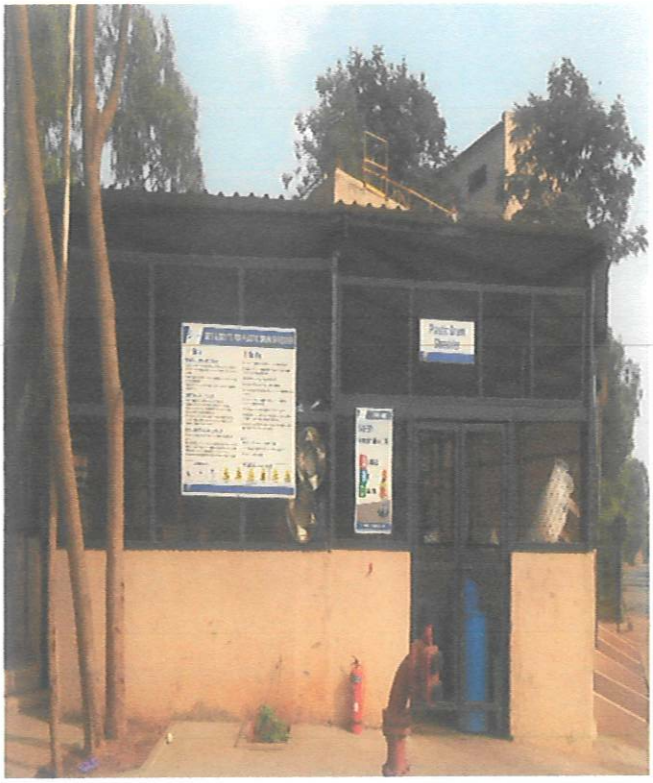
Multi-Purpose Shredder

Multi-Purpose Shredder

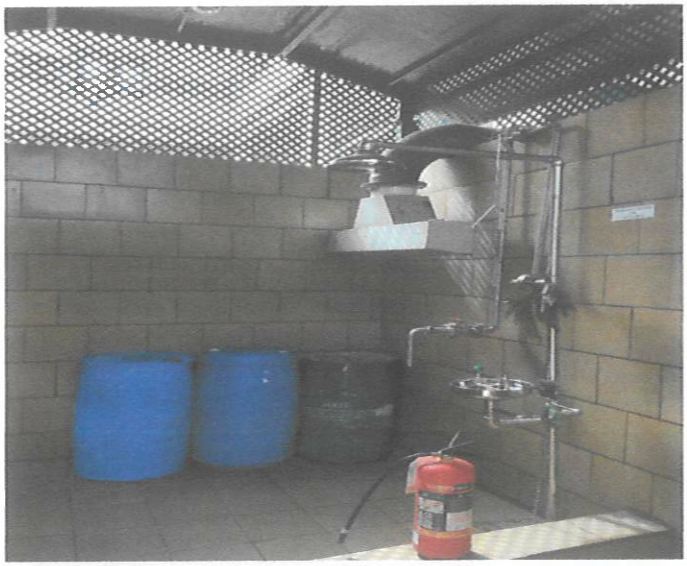
8. As reflected in the EIA/EMP report, the hazardous waste generated from solvent recycling plant as distillation residue, chemical and from ETP and waste oils will be incinerated. Used oils will be sent for recycling to KSPCB/CPCB authorized recyclers. The ash obtained after incineration shall be stored 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.*


Waste Oil
E- Waste
(Electronic Waste)



Hazardous waste collection area



Decontamination Facility

Hazardous waste Generation and Disposal for the period April-2023 to September- 2023 is as follows

Sl. No	Category Number	Types of hazardous waste as per authorization	Authorization per Annum	Quantity in KL or MT (June - 2023 to November - 2023)			
				Previous Stock	Generated	Dispose	Stock
1	5.1	Used or Spent Oil	80 MT	Nil	10.86 MT	10.86 MT	Nil
2	5.2	Waste or Residue containing oil	25 KL	Nil	Nil	Nil	Nil
3	20.3/28.1	Distillation residue /Process residue and waste	2200 MT	7.314 MT	96.485 MT	103.309 MT	0.49 MT
4	28.2	Spent catalyst	150 MT	Nil	Nil	Nil	Nil
5	28.3	Spent carbon	90 MT	0.709 MT	36.454 MT	23.77 MT	13.393 MT
6	28.4	Off specification products	100 MT	Nil	Nil	Nil	Nil
7	28.5	Date expired, discarded Products	100 MT	Nil	Nil	Nil	Nil
8	20.2/28.6	Spent Solvent	70,000 MT (10,000 KL/A Disposal)	Nil	*6222.153 MT	2704.59 MT	Nil
9	33.1	Empty barrels /containers	25,000 No's (1500 MT)	Nil	114.065 MT	106.253 MT	7.812 MT
10	37.3	Concentration or Evaporation residue	3800 MT	56.84 MT	1840.6 MT	1799.07 MT	98.37 MT
11	33.1	Liners contaminated with hazardous chemicals and wastes	80 MT	0.013 MT	37.387 MT	36.51 MT	0.89 MT
12	33.2	Contaminated Cotton rags or other cleaning materials	5.0 MT	Nil	Nil	Nil	Nil
13	20.2	Spent Solvent (From Stripper)	2500 MT	17.9 MT	720.61 MT	714.44 MT	24.07 MT
14	35.3	Chemical Sludge from ETP	2500 MT	1.08 MT	477.58 MT	462.3 MT	16.36 MT

*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*

**** Hazardous waste Authorization renewal obtained on 12th September 2022 with No. 333195 PCB ID:10305 dated 12/09/2022*

- *Biological Sludge generated from ETP is disposed for Compost Manufacturer*

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/ Composting 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	*3055.37 MT*	*1647.8 MT*
Inert Cell Mass- Composting		*1391.5 MT*
Biological Sludge- Composting	*796.88 MT*	*766.5 MT*

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*
- *Coproculative 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.*

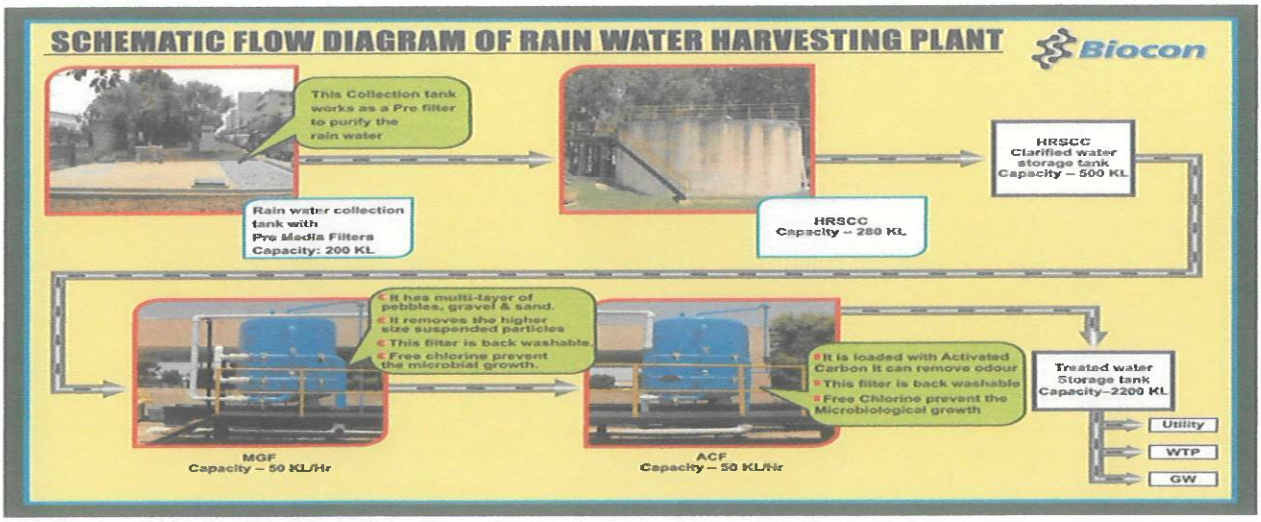
AHC at Biocon

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)

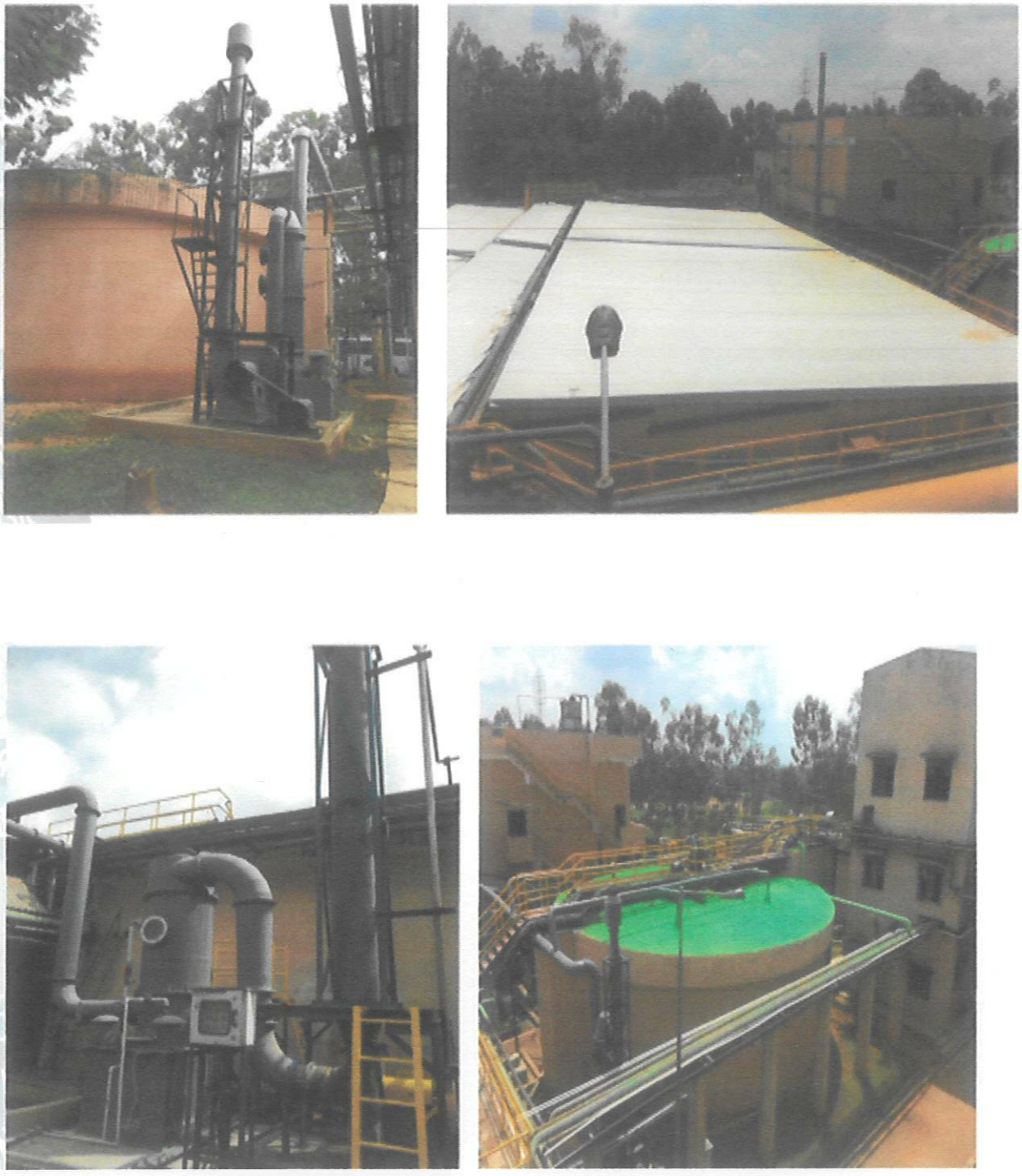
- *All the Environmental protection measures and safeguards as recommended in EIA/EMP/ Risk Analysis reports as well as recommendations of the public hearing panel were taken in to due consideration and all the efforts are made for effective Environmental management. Flow chart of Effluent treatment 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

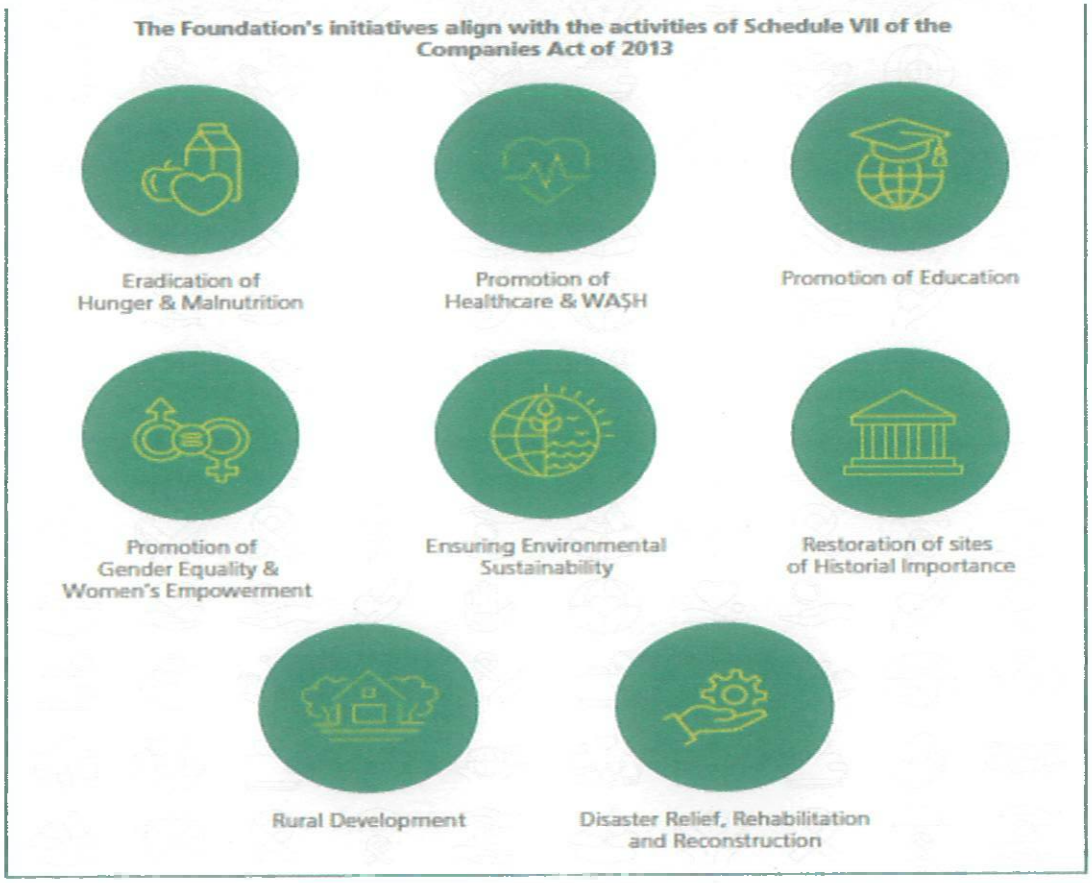
Scrubbing System in ETP and Odour Control Measures for Aeration Tanks



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)


10 Reduced Inequalities
Women's Health
Child's Health
Geriatric Health
Mental Health
WASH
COVID 19 Relief
Women's Safety
Rural Development
WASH
16 Peace, Justice and Strong Institutions
Women's Safety
Domestic Violence Counselling
Women and Child Helplines
Rehabilitation of Women Victims
Legal Aid to Women Victims
Rescue of Woman Victims
11 Sustainable Cities and Communities
Mass Rapid Transit
Miyawaki Afforestation
Urban Landscaping
Revival of Urban Water Bodies
17 Partnership for the Goals
Government
Tertiary Hospitals
Research Institutions
Oral Cancer Task Force
Capacity Building
Data Sharing
Joint implementation
Collaborative Research
Grant in Aid
Employee Volunteerism
12 Responsible Consumption and Production
Revival of Water Bodies
Miyawaki Afforestation
Mass Transit System
13 Climate Action
Mass Transit System
Miyawaki Afforestation
Revival of waterbodies


The Foundation's initiatives align with the activities of Schedule VII of the Companies Act of 2013
Eradication of Hunger & Malnutrition
Promotion of Healthcare & WASH
Promotion of Education
Promotion of Gender Equality & Women's Empowerment
Ensuring Environmental Sustainability
Restoration of sites of Historial Importance
Rural Development
Disaster Relief, Rehabilitation and Reconstruction

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. As per the EC -2020 dated 03/09/2020 with No. SEIAA 45 IND 2020 general conditions point no. 4 The total water requirement for the proposed project is 6556 KLD and it will be met from the KIADB water supply. The waste water generation will be 3098 KLD, out of which 434 KLD will be the domestic sewage shall be treated in two sewage Treatment systems with total capacity of 550 KLD. The industrial effluent of 2664 KLD shall be treated in ETP with stripper MEE and ATFD after proposed expansion.*

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 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 (June 2023 to November - 2023)*			
				Previous Stock	*Generated*	*Dispose*	*Stock*
1	*28.1*	*Process residues and waste*	*6 MT*	*Nil*	*0.12 MT*	*0.12 MT*	*Nil*
2	*20.2/28.6*	*Spent Solvent*	*50 KL*	*Nil*	*Nil*	*Nil*	*Nil*
3	*33.1*	*Discarded Containers, Used barrels (MS Drums, HDPE barrels/ Carbouys)*	*60 MT*	*Nil*	*Nil*	*Nil*	*Nil*
4	*33.1*	*Discarded Liners*	*30 MT*	*Nil*	*Nil*	*Nil*	*Nil*
5	*28.4*	*Off Specification Products*	*75 MT*	*Nil*	*3.06 MT*	*3.06 MT*	*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*	*Nil*	*Nil*	*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*	*0.5997 MT*	*0.5997 MT*	*Nil*

11	*Schedule III-B 3050*	*Wood Scrap*	*400 MT*	*0.72 MT*	*11.88 MT*	*11.88 MT*	*Nil*
12	*Schedule III-DB 1010*	*MS Scrap*	*48 MT*	*Nil*	*3.66 MT*	*3.66 MT*	*Nil*
13	*Schedule III-DB3020*	*Carton Boxes/Paper Board*	*10 MT*	*Nil*	*Nil*	*Nil*	*Nil*

Hazardous waste Generation and Disposal for the period April-2023 to September 2023 is as follows

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

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 joinees 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 and the 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. Apart from the existing green belt area we are exploring additional development with Karnataka State Forest department.*

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.*

- *Prevention*	*1. Introduction of vent gas system* *2. Liquid – Liquid extraction column for Mother liquor treatment* *3. To install new Economizer to improve the thermal efficiency of the boiler For reduction of $C0_2$*
- *Less Hazard chemical*	*1. Introduction of new filtration methodology by elimination of vacuum filtration.* *2. Replacement of hazardous chemical (acetic anhydride vs propanic anhydride at the R& D stage itself.* *3. Introduction of butane troch instead of LPG for strille operation*
- *Designing of safety chemical*	*1. Elimination of PET ether usage by introduction of agitated thin film evaporator.* *2. overflow protection interlock for day tank* *3. Ammonia leak detection system in process area.*

- *Energy efficiency*	*1. Replacement of 160 W to 36 W LED light in manufacturing unit (550 Nos)* *2 Pilot trail for Power generation from cyclone separator exhaust – Achieved single phase power* *3. Installed the Economizer of capacity 16 TPH boiler 3 no's to save the fuel and reduced the emission*

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.

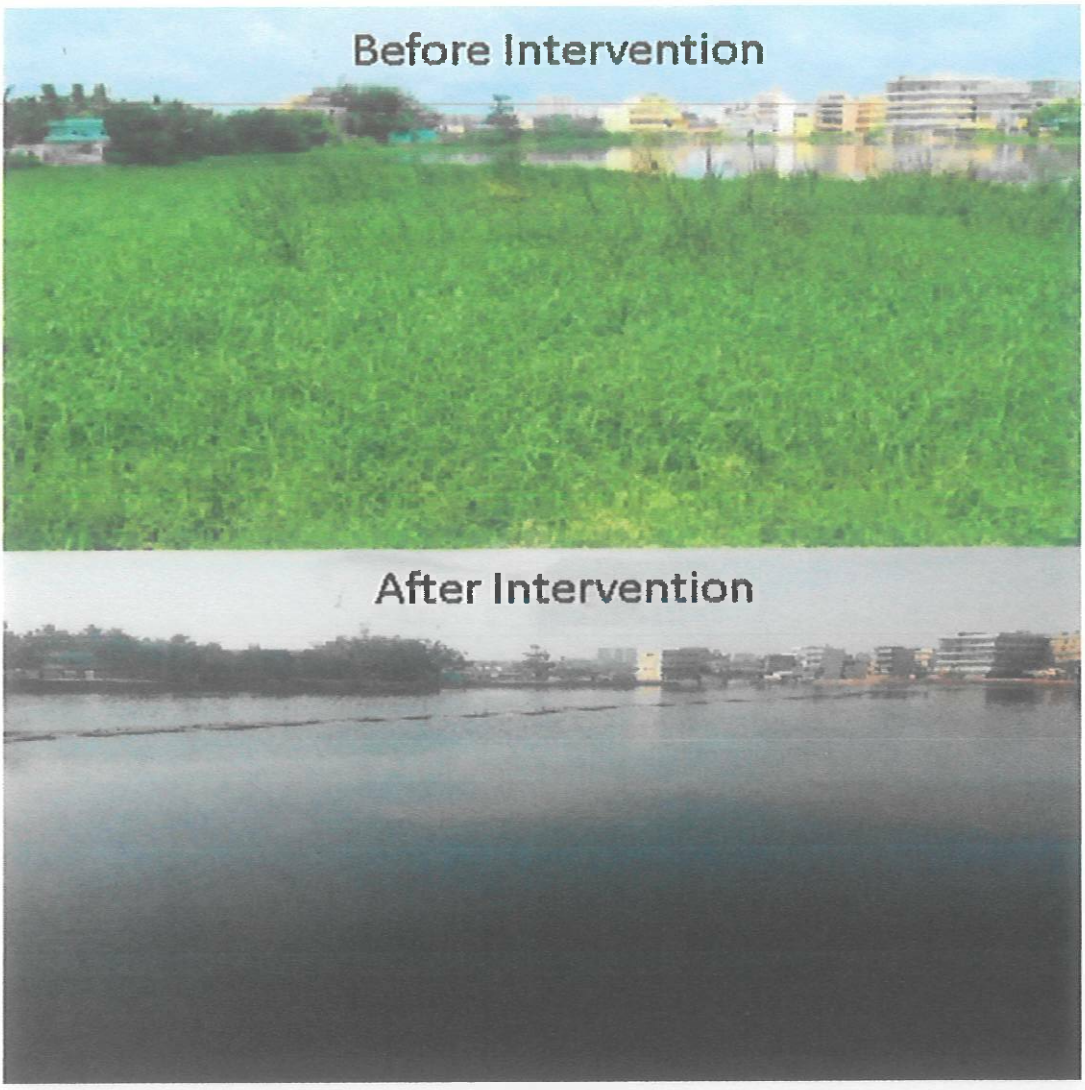
- *Dedicated Fuel storage facility available at site which is approved by PESO. Onsite emergency preparedness and response plan already in place.*
- *Onsite Emergency Plan available at site which is prepared as per the requirement of Department of Factories.*
- *Since the site does not come under MAHU 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.*
- *Agro Fuel (Biomass) based Boiler of 35 TPH capacity is installed and under commissioning as per EC 2020 general conditions point no. 4.*

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. The rejuvenation of Hebbagodi Lake project has taken up in April-2023 and is under progress by Biocon Foundation. As a part of World Environment Day celebration plantation drive has been conducted at Yarendahalli Lake by Biocon group of companies, Hennagara and Tirupalya government school students..*



Hebbagodi Lake Development

B. General conditions

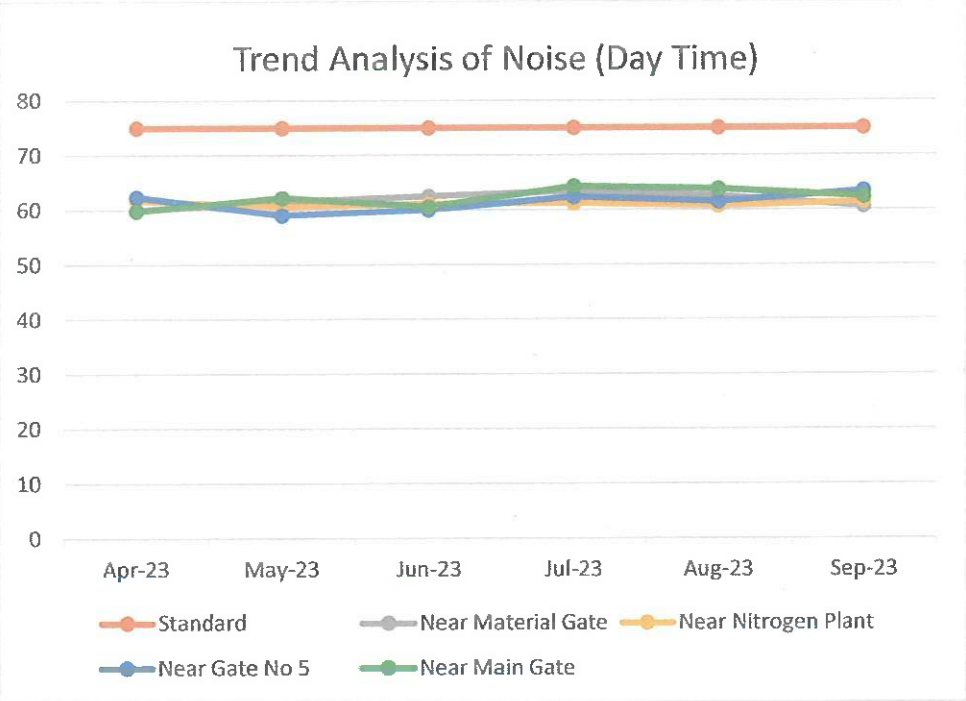
1. **The project authorities must strictly adhere to the stipulations made by the Karnataka State Pollution Control Board. (EC-2005, EC-2017)**
   - *Biocon has adhered to all the guidelines prescribed by the KSPCB.*

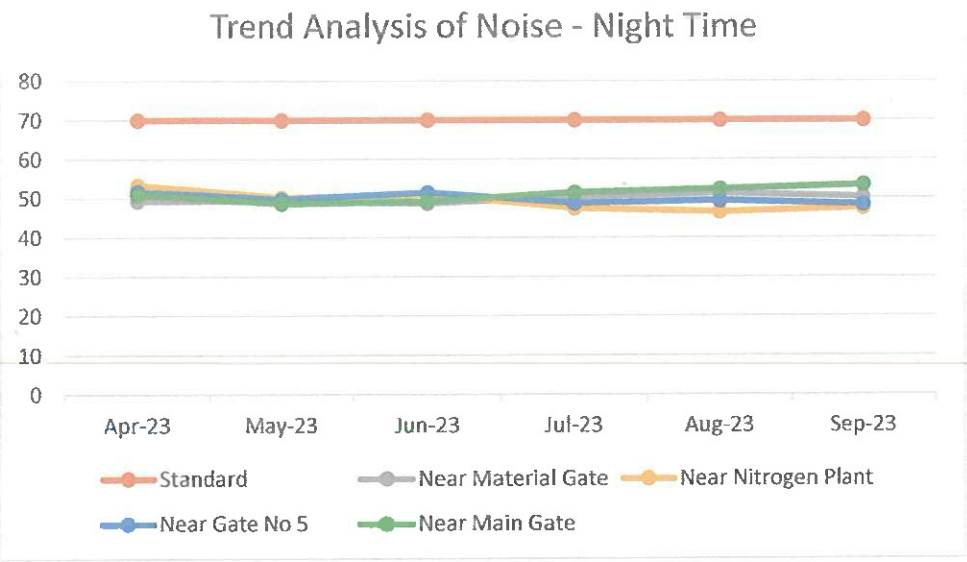
2. **At no time, the emissions should go beyond the prescribed standards. In the event of failure of any pollution control system adopted by the units, the respective unit should be immediately put out of operation and should not be restarted until the desired efficiency has been achieved. (EC-2005,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

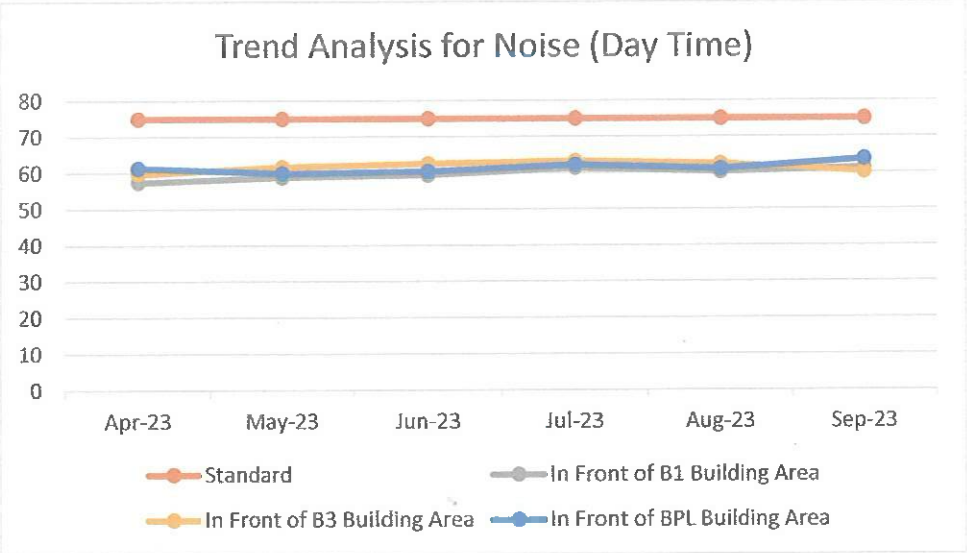
operation and will be restarted after achieving the desired efficiency.

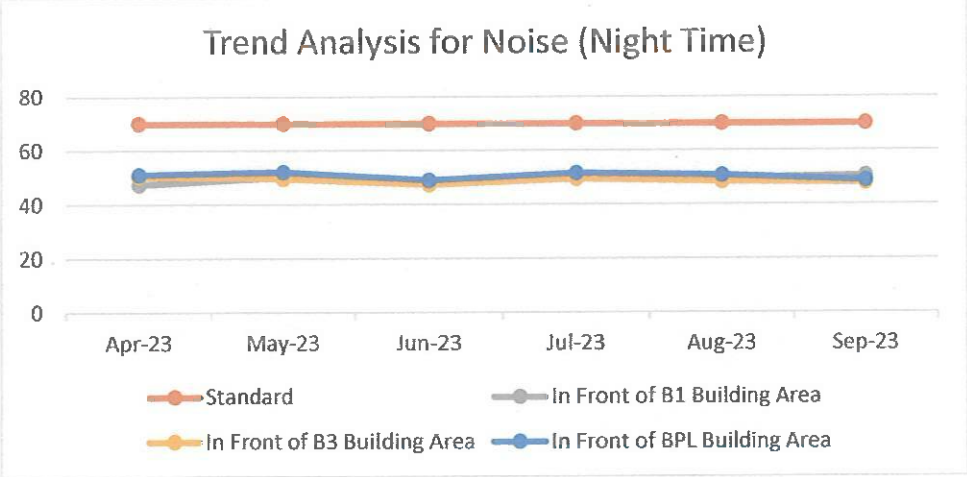
3. **The overall noise levels in and around the plant area should be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures etc,. on all sources of noise generation. The ambient noise levels should conform to the standards prescribed 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 April 2023 to September 2023 is as follows.*




Trend Analysis of Noise - Night Time
80
70
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
Near Material Gate
Near Nitrogen Plant
Near Gate No 5
Near Main Gate


Trend Analysis for Noise (Day Time)
80
70
60
50
40
30
20
10
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area


Trend Analysis for Noise (Night Time)
80
60
40
20
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Standard
In Front of B1 Building Area
In Front of B3 Building Area
In Front of BPL Building Area

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 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 on 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*

<u>EC-2017 General Conditions</u>

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 of 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.**

- *NA, there is no forest diversion in vicinity of the site, the land is a converted to industrial utilizations from the relevant government agencies. 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.**

- *The site is an industrial converted land hence this is not applicable.*

iii. **The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan/ Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with six monthly compliance report. (In case of the presence of schedule -1 species in the study area).**

- *NA, there is no forest diversion is in vicinity of the site, as such no clearance is required.*

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. Hazardous Waste Authorization obtained.*

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. The storage of chemicals does not exceed the prescribed limit mentioned in the MSIHC (Manufacture, Storage and Import of Hazardous Chemicals) guidelines under Rule 10.*

II .AIR QUALITY MONITORING AND PRESERVATION

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. CNG (Compressed Natural Gas) is used for boiler & high-speed diesel is used for DG-Sets as fuel. So according to KSPCB Memo no; KSPCB/DGS/OFB/ MON/CC/2001/5269 dt 24.02.2001 Online Continuous Stack Emission Monitoring Systems is not applicable.*

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. The emission values are meeting the National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July 2010 and same has been followed.*

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)**

- *As per the regulatory norms industry has provided the web camera with night vision capability and flow meters for continuous monitoring of effluent and same is maintained.*

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, all hazardous chemicals will be stored in a designated area with limited personnel access and hazardous chemicals stored in tanks, tank farms, drums, carboys etc. will be provided with flame arresters on tank farm to the solvent transfer through pumps.

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.**

- Currently the process residue and spent carbon wastes are disposing at in-house incinerator facility as per the existing H&OW authorization and same shall be disposed off to cement plants once all necessary approvals & consents are received. ETP sludge, process inorganic & evaporation salt are disposed off to the TSDF.

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.**

The rejuvenation of Hebbagodi Lake project has taken up in April-2023 and is under progress by Biocon Foundation. As a part of World Environment Day celebration plantation drive has been conducted at Yarendahalli Lake by Biocon group of companies, Hennagara and Tirupalya government school students.

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.

Biocon Biologics Biocon Syngene

ENVIRONMENT, OCCUPATIONAL HEALTH, SAFETY & SUSTAINABILITY POLICY

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

We shall strive to achieve this by :

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

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

Kiran Mazumdar Shaw
Chairperson & Managing Director

Date: 21-08-2019
V: 007

Emergency Contact No. 2000

Biocon Biologics Biocon Syngene

ಪರಿಸರ, ಔದ್ಯೋಗಿಕ ಆರೋಗ್ಯ, ಸುರಕ್ಷತೆ ಮತ್ತು ಸುಸ್ಥಿರ ನೀತಿ

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

ಈ ಮೂಲಕ ನಾವು ಈ ಸಾಧನೆಗಳನ್ನು ಮಾಡಲು ಯತ್ನಿಸುತ್ತಿದ್ದೇವೆ,

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

ಇಎಚ್ಎಸ್ಎಸ್ ನೀತಿಯ ಅನುಷ್ಠಾನಕ್ಕೆ ಬಯೋಕಾನ್ ಗ್ರೂಪ್ ಆಡಳಿತವು ಬದ್ಧವಾಗಿದೆ. ಈ ನೀತಿಯು ಬಯೋಕಾನ್ ಗ್ರೂಪ್ನ ಎಲ್ಲಾ ಸಂಸ್ಥೆಗಳ ಎಲ್ಲಾ ವಹಿವಾಟುಗಳು, ಉದ್ಯೋಗಿಗಳು ಮತ್ತು ಒಪ್ಪಂದದ ಕೆಲಸಗಾರರಿಗೆ ಅನ್ವಯಿಸುತ್ತದೆ.

ಕಿರಣ್ ಮಜುಂದಾರ್ ಷಾ
ಚೇರ್ಪರ್ಸನ್ ಮತ್ತು ವ್ಯವಸ್ಥಾಪಕ ನಿರ್ದೇಶಕರು

ದಿನಾಂಕ: 21-08-2019
ಆವೃತ್ತಿ: 007

ತುರ್ತು ಸಂಪರ್ಕ ಸಂಖ್ಯೆ. 2000

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. Year wise progress of implementation of action plan will be reported to the Ministry of Environment, Forest and Climate Change/Regional Office.

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

- The internal and external audits on EHS management system is conducted internally every six months and once in a year by third-party vendor TUV Nord authority, find below ISO certificate.

TÜV NORD

CERTIFICATE

Management system as per

ISO 14001 : 2015

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

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

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

Scope -

Development, Manufacture and Distribution of Biopharmaceuticals

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

Valid from **30,11,2022**
Valid until **29,11,2025**
Initial certification **22.12.2004**

Certification Body
at TÜV NORD CERT GmbH

Mumbai, **28.11.2022**

TÜV NORD CERT GmbH Am TÜV 1 45307 Essen www.tuev-nord-cert.com

TUV India Pvt. Ltd., 801, Raheja Plaza – 1, L.B.S. Marg, Ghatkopar (W), Mumbai - 400 086, India www.tuv-nord.com/in

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-01-00

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 hard copy of HYCRs shall not be acceptable.**

- *Noted and complied. The Half Yearly Compliance Reports (HYCRs) with its contents of a covering letter, compliance reports, and environmental monitoring data in PDF format merged into a single document and e-mailed to Regional Office of MOEF&CC for email ID rosz.bng-mefcc@gov.in every six months.*

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 22/09/2023.

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, we shall extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/ monitoring reports.

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 INFORMATIONS

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 1192.78 Crores
4.	Year of Commencement of project	- 2005

For Biocon Limited-SEZ

30/12/2023

Authorized Signatory

Date: 29.12.2023
Place: Bangalore