

Inspection report of Sri.B.G.Mohan Krishna, Chief Environmental Officer-2, Karnataka State  
Pollution Control Board, Bangalore.

24 DEC 2016

1. Officer's Accompanied : 1) Sri. S Shivappa Naik - EO  
2) Sri. Suneel V - DEO
2. Name & Address of the Industry : M/s. Syngene International Limited,  
(Biocon Special Economic Zone)  
Plot No: 2, 3 & 4, Bommasandra –  
Jigani Link Road Industrial Area, Anekal  
Taluk, Bangalore Urban District - 560 099
3. Date of Inspection : 25/11/2016
4. Persons Contacted : 1) Mr. Vishwajeet – EHS Head  
2) Mr. Krishne Gowda- Manager-EHS &  
3) Mr.Aradya , Manager, EHS
5. Category : Large – Red ( 17 Category)

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**Preamble:**

Keeping in view of the Memo No. 4187, dated: 07.10.2016 with regards to inspection of the M/s. Syngene International Ltd., (Biocon Special Economic Zone) located at Plot No: 2, 3 & 4, Bommasandra – Jigani Link Road Industrial Area, Anekal Taluk, Bangalore Urban District - 560 099, unit was inspected to verify the status of compliance to the Consent conditions. The said industry has obtained consent under the provisions of the Water and Air Act for the period up to 30/06/2016 vide CFO order No. PCB/077/N17/2015-16/H468, dated: 29/07/2015 for Research & Development activities at Bio-safety level-1 only in the following areas:-

- Research & Development in Biotechnology projects for novel compounds for new drugs. Research laboratory facility including research services in the area of *building blocks, process chemistry, analytical research, library synthesis for fine chemicals, food, flavors, cosmetics & health care industries, generation of samples, custom synthesis of chemical compounds and polymer chemistry*. The *Nutraceutical R & D centre* focuses on the development of nutrition products for maternal, child nutrition and diabetes care.
- Conducting in vivo evaluation of small molecules/protein therapeutics on small rodents to address critical pharmacokinetics & toxicity parameters of test molecules and for production of following bulk drugs.

The list of products manufactured are:-

Sl. No.	Product name	Consent Kg/Annum
1	Bmab 100	4
2	Bmab 200	4
3	Bmab 600(Monoclonal antibodies)	4
4	Pimecrolimus	5
5	Everolimus	3

6	<i>Temsirolimus</i>	3
7	<i>Caspofungin</i>	3
8	LYP010	6
9	BMO-1	6
10	BMO-2	6
11	BVX 20	6
12	TH-302	150
13	A3309	1000
14	MK 7655	1000
15	ACH0142684Na	100
16	DOTA	1200
17	595J	1200
18	A1241411	2000
19	Formulations	100000 Tablets

The industry is carrying out the activity in 1000 square feet built up area.

The industry has submitted the CFO application for the period up to 30/06/2021 and the same is forwarded by RO-Anekal to Board Office vide no. 770, dated: 18/04/2016.

#### **WATER POLLUTION CONTROL DETAILS:-**

The source of water to the Biocon park is from BWSSB and is used for domestic and industrial purposes. The unit has employed about 1000 persons.

The details of water consumption are shown below:-

	Water Consumption in KLD	Wastewater generated in KLD	Mode of disposal
<b>Domestic</b>	28	<b>24</b>	Discharge into common STP of M/s Biocon Ltd., Biocon Research Ltd.,
<b>Process</b>	32	<b>29</b>	Discharge into CETP of M/s. Biocon Ltd., Biocon Research treated effluent is being used for boiler feed, cooling tower and gardening.
<b>Washing</b>	8	<b>8</b>	
<b>Boiler Feed</b>	10	--	
	78	61	

The domestic effluents are treated at Common Sewage Treatment Plant of M/s Biocon Limited, of Biocon Park of capacity-300 KLD. The total trade effluent generation at full scale production capacity is estimated as 37 KLD, out of which 29 KLD High TDS effluent are sent to MEE and remaining 8 KLD of effluents are being treated in the Common Effluent Treatment Plant (CETP) provided at M/S. Biocon Limited, and the treated water is being used for common utilities viz., Boiler feed (after passing through RO) and cooling tower makeup etc.,

#### **DETAILS OF 1052 KLD CETP of Biocon Ltd., at Biocon park: -**

The CETP provided at M/s Biocon Limited consists of the following units:-

- 1) Holding Tanks – 4 Numbers
- 2) Flash Mixer – 1 Number
- 3) Clariflocculator – 1 Number

- 4) Equalization Tanks – 2 Numbers
- 5) Flash Mixer – II
- 6) Clariflocculator – II
- 7) UASB Conditioning Tank.
- 8) UASB Reactor.
- 9) Secondary Extended Aeration System.
- 10) Biogas Holder.
- 11) UASB Sludge Storage Tank.
- 12) Secondary settling tank
- 13) Common Sludge Sump and
- 14) Filter Press.
- 15) Reverse Osmosis Plant(two stages)

#### **DETAILS OF STP:-**

The common STP provided at Biocon of capacity 300 KLD consists of the following units:

- Bar screen,
- Grit Chamber
- Equalization tank
- Collection tank
- Aeration tank
- Settling tank
- Filter press
- Pressure sand filter
- Activated carbon filter
- Treated water collection tank
- Additional 30 Cum of Bio Media into the Aeration Tank

To enhance the existing capacity of STP from 150 KLD to 300 KLD capacities, they have added 30 Cumt of Bio Media into the existing Aeration Tank, the Bio media are small plastic media of size 2 cm dia, 1.5 cm height. 1 Cumt of Bio media consists of not less than 68,000 pieces and active Surface area for Bacteria is not less than  $170 \text{ M}^2/\text{M}^3$  and the expected life of media is 20 years. Bio media will provide long contact time between water and biomass due to its large specific surface and effective removal of BOD and COD. The STP was operating at the time of inspection and the treated effluents are being used for on land for gardening in the Biocon Park.

At the time of inspection, it was informed the due to smell generation from ETP. They have taken action to cover the ETP units on the top as if providing a lid. The concentration of ETP is very adjacent to residential area across the compound wall. It was advised to increase the aeration to avoid the unit going anaerobic which would help in reducing over the smell.

At present all the effluents from the manufacturing unit within the park is being treated in the CETP. This has reduced in concentration of effluents & the Combined quantity of ETP has increased. It may be necessary to provide independent ETP at sources at each unit & partially treated effluent from each unit with pollution load could be discharged into Central ETP will be reduce the load on CETP & also the smell problem will come down. F/A informed to examine the same & come up with proposals.

#### AIR POLLUTION CONTROL DETAILS:-

The unit is having the following Air Pollution Sources:-

Sl. no.	Chimney attaché to	Apc measures stipulated	Apc measures provided	Remarks
1	Fume Cup Board R&D Process area-I	3 meter ARL chimney with scrubber	3 meter ARL chimney with scrubber	Adequate
2	Fume Cup Board R&D Process area-II	3 meter ARL chimney with scrubber	3 meter ARL chimney with scrubber	Adequate
3- 9	Fume hoods in R & D process area - 7 Nos.	3 m ARL chimney with individual scrubber	3 m ARL chimney with individual scrubber	Adequate
10- 12	Fume hoods in air handling area – 3 nos	3 m ARL chimney with individual scrubber	3 m ARL chimney with individual scrubber	Adequate
13- 21	Process exhaust – 9 Nos.	3 meter ARL chimney with scrubber	3 meter ARL chimney with scrubber	Adequate

The unit is utilizing power and steam from common utilities provided by M/S. Biocon Limited, Biocon Park.

Industry has provided intermediate scrubber within the process area in order to reduce emission before the same is let into main scrubber. The F/A was advised to submit entire details of the action to scrubber details, kind of emission submit to the Board.

#### HAZARDOUS WASTE DETAILS:-

Industry is having valid authorization under the Hazardous Waste (Management, Handling & Transboundary ) Rules 2008 for the period up to 30-06-2020.

The details of Hazardous wastes segregation, method of collection and mode of disposal are as follows.

Sl. No	Type of Hazardous Waste	Category no	Authorized Quantity	Disposal mechanism
1	Spent Solvent	20.1/28.4/28.5	576 MT/Annum	Distilled inhouse and disposed through authorized recyclers
2	Distillation residue.	20.3/28.1/36.4	3 MT/Annum	Stored in secured manner and inhouse incineration at Biocon Ltd 20 <sup>th</sup> KM plant or disposed to KSPCB authorized incineration.
3	Spent Carbon	28.2	9 MT/Annum	Disposed to TSDF.

4	Spent catalyst (Containing Ni)	28.2	0.576 MT/Annum	Stored in secured manner & disposed to authorized recycler.
5	Discarded containers/barrels	33.3	240 Nos/Annum	Disposed through authorized recyclers
6	Discarded liners	33.3	12 MT/Annum	Disposed through authorized recyclers
7	Discarded Bottels	33.3	12 MT/Annum	Disposed through authorized recyclers

**SOLID WASTE MANAGEMENT:-**

There is no much solid waste generation other than the Paper waste (waste cartoon boxes), which is being stored and disposed to vendor for recycling.

**ENVIRONMENTAL STATEMENT:-** Submitted for the year 2014-15. They were informed to submit the same for the period 2015-16.

**CESS:-** The industry is filing cess returns and making payment regularly.

**Biomedical Waste(Management & Handling) Rules,1998:-** Industry is having valid authorization under the provisions of the Biomedical Waste(Management and Handling) Rules for the period up to 31/12/2018. The Biomedical waste generated from the industry is disposed through common BMW treatment facility (CBMTF) i.e., with Maridi Eco Industries Pvt Ltd.,

**Other General Observations made during inspection:-**

1. Industry was operating at the time of inspection and engaged in the Research & Development Activity for Molecular Biological & Fine Organic Chemicals and manufacture of Bulk drugs. The vivarium (Testing facility for animals) was housed with imported rodent animals (rats, mice and pigs), pre clinical trials.
2. The different test animals after clinical trials are disposed in accordance with the provisions of the Biomedical Waste (Management and Handling) Rules, 1998 and the authorization is valid upto 31-12-2018.
3. The industry has obtained ISO 14001 certificate and OHSAS 18001 in order to maintain better compliance as well as in maintaining proper records.
4. The domestic and trade effluent generated from M/s Syngene International Limited, (Biocon Special Economic Zone) premises is treated in Common Sewage Treatment Plant and Common Effluent Treatment Plant respectively which was installed inside the premises of M/s Biocon Limited. During inspection they have been informed to provide pretreatment plants before discharging to main plant so as to avoid additional shock load to Common ETP & to avoid smell nuisance. There is a requirement for third party agreement between the unit wherein Biocon park.
5. The industry has been advised to provide continuous monitoring for treated trade effluents.
6. The industry has not maintained register (Form – 3) for solid waste generation separately and the same was informed to maintain and submit at Regional Office Anekal.
7. The records of quantity of Scrubbing for scrubber gases are not maintained and the same has been informed to maintain.

Enclsd : F/A letter submitted after inspection dtd : 29.11.2016.



B.G.MOHAN KRISHNA  
CHIEF ENVIRONMENTAL OFFICER-2,

To,  
Member Secretary for information & necessary action.

**Copy submitted to :**

1. Hon'ble Chairman, KSPCB for information & necessary action.
2. The CEO-1 for information & necessary action.
3. E-Goverance Cell for information & necessary action.
4. The Regional Office - Anekal for information & necessary action.