

JOINT REPORT

OF THE COMMITTEE CONSTITUTED AS PER ORDER OF HON'BLE NGT IN THE MATTER

ORIGINAL APPLICATION NO.13 OF 2020

Jointly Prepared by:



MAHARASHTRA POLLUTION CONTROL BOARD

AND



MAHARASHTRA INDUSTRIAL DEVELOPMENT CORPORATION

For submission to

HON'BLE NATIONAL GREEN TRIBUNAL, WESTERN ZONE BENCH, PUNE

October 2020

BACKGROUND:

Based on an order dated 28.08.2020 of the Hon'ble National Green Tribunal, Principal Bench, New Delhi in the matter Original Application No.13 of 2020, the Committee constituted with following members: -

- 1) Executive Engineer, Maharashtra Industrial Development Corporation
- 2) Regional Officer, Maharashtra Pollution Control Board, Kalyan

The committee carried out visit to M/s. Bharat Serums & Vaccines Ltd., located at Plot No. K-27, MIDC Additional Ambernath, Anandnagar, Ambernath East-421 506, Dist. Thane, on 7th October 2020. The details are as below:

1. M/s. Bharat Serums and Vaccines Limited (BSVL) is a Limited Company established in 1971 as Gautam Laboratories Pvt. Ltd. It merged into Bharat Serums and Vaccines Private Limited on 2nd February 1983. In 1998, 27th March it is incorporated as Bharat Serums and Vaccines Limited (BSVL). This unit is engaged in manufacturing of life saving vaccines and injectables and supply to hospitals, various Government Agencies etc. Details of the Consent granted by the Board from time to time with their products, water consumption, disposal etc. are as under **(Annexure – I)**.

Sr. No.	Consent to Establish/ Operate/ Expansion	Products with Quantity	Date of issue of Consent & its validity	Water Consumption (Domestic/ Industrial Processing/ Industrial Cooling)	Effluent Generation	Disposal
1.	Operate	Injections & Vaccines (Only Formulations) 5 lakhs/Month	21/07/2004 Valid upto 30.06.2014	Domestic-15CMD Industrial Consumption-50 CMD	Domestic-12 CMD Industrial-35 CMD	Treated effluent shall be reused to the maximum extent and remaining shall be used on land for gardening.
2.	Establish	Injections & Vaccines (Only Formulations) 10 lakhs/Month	06/05/2011 Valid upto Commissioning of the unit	Domestic-5 CMD Industrial Consumption-112 CMD	Domestic-3 CMD Industrial-25 CMD	Treated effluent shall be recycled to the maximum extent and remaining used on land for gardening only till the commissioning of CETP
3.	Operate	Injections & Vaccines	30/01/2015 Valid upto	Domestic-20 CMD	Domestic-15 CMD	Treated effluent shall

		(Only Formulations) 15 lakhs/Month	30/06/2016	Industrial Consumption- 162 CMD	Industrial- 60 CMD	be recycled to the maximum extent and remaining shall be sent to CETP. However domestic effluent shall be used on land for gardening.
4	Operate	Injections & Vaccines (Only Formulations) 15 lakhs/Month	23/01/2017 Valid upto 30/06/2022	Domestic-20 CMD Industrial Consumption- 162 CMD	Domestic- 15 CMD Industrial- 60 CMD	Treated effluent shall be recycled to the maximum extent and remaining shall be sent to CETP. However domestic effluent shall be used on land for gardening.
5	Operate with Expansion for R&D activity	1)Injections & Vaccines (Only Formulations) 15 lakhs/Month 2) Analytical Testing and R & D activity at Plot No.K-27/1.	06/04/2018 Valid upto 30/06/2022	Domestic-20 CMD Industrial Consumption- 162 CMD	Domestic- 15 CMD Industrial- 60 CMD	Treated effluent shall be recycled to the maximum extent and remaining shall be sent to CETP.
6	Operate with Expansion by Capacity Utilization	1)Injections & Vaccines (Only Formulations) 20 lakhs/ Month. 2) Analytical Testing and R & D activity at Plot No.K-27/1. 3)R-FSH (Recombinant-Follicle Stimulating Hormone	03/09/2019 Valid upto 30/06/2022	Domestic- 27 CMD Industrial consumption -216 CMD	Domestic- 26 CMD Industrial - 216 CMD	The treated industrial/ domestic effluent 100% recycled/ reused.

		4)R-HCG (Recombinant- Human Chronic Gonadotropin)				
		5)mAnti-D (Monoclonal Anti Rho-D Immunoglobulin)				

Plot Area Details:

The industry is having total plot area is 29149 sq. mtr., Built up area – 17090.85 Sq. mtr. and obtained necessary permission from MIDC (**Annexure – II copy of MIDC CC / OC**). Green belt developed on 2000.0 sqr. Mtr.

List of Raw Material:

MATERIAL DESCRIPTION	UOM	Quantity per Month
L-Alanyl- L-Glutamine, [200 mM]	L	1.0
Absolute Alcohol	L	46.7
Amphotericin B Lipid Powder	KG	1.5
Amphotericin B USP Micronised	KG	1.3
Benzyl Alcohol IP	L	11.8
Chloroform	L	20.8
Cresol Mixed Isomers	L	20.7
D Mannitol	KG	16.0
Dichloromethane	L	2.5
Dimyristoyl Phosphatidylglycerol DMPG	KG	1.6
Disodium Hydrogen Phosphate Anh. Canton	KG	1.5
Disodium Hydrogen Phosphate Dihydrate	KG	51.8
Enoxaparin Sodium	KG	18.0
Gelofusin	L	289.3
Glycerin	KG	2.4
Glycine	KG	116.0
Histamine Hydrochloride	KG	1.7
L-Histidine	KG	16.5
Human Albumin	L	67.3
Hydrochloric Acid Concentrated (HCL)	L	48.4
Iso Propyl Alcohol	L	479.7
Lipoid HSPC-3-3	KG	1.6
Maltose	KG	2.8
Methanol Extra Pure	L	18.8
Octanic Acid	L	302.3
Pepsin	KG	5.3
Pro-Cho 5 CDM 1 L BE 12-766Q	L	84.1
Resomer R 202 H	KG	1.3
Resomer RG 502.H Leprolide	KG	4.3

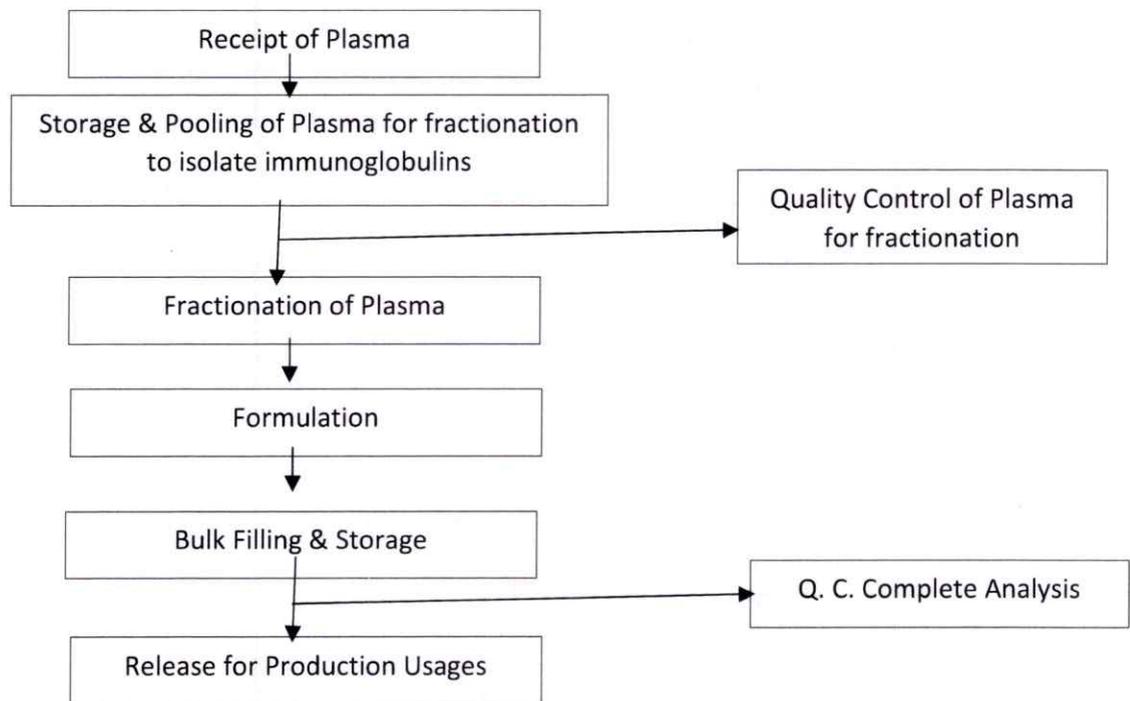
MATERIAL DESCRIPTION	UOM	Quantity per Month
Sodium Acetate Anhydrous	KG	13.9
Sodium Chloride	KG	290.7
Sodium Deoxycholate	KG	737.8
Sodium Dihydrogen Phosphate Dihydrate	KG	345.2
Sodium Hydroxide	KG	83.2
Sodium Hypochlorite	L	11.4
Sodium Thiosulphate	KG	1.3
Soyabean Oil	KG	9.4
Sucrose Ferro	KG	24.5
Tween 80 (Polysorbit 80)	L	1.4
Plasma Snake Venoum Antiserum	L	2235.5
Plasma Rabbies Antiserum	L	640.9
Anti-D Immunoglobulin Monoclonal	L	1.1
Human Chorionic Gonadotropin Bsv Bio	KG	19.4
Normal Immunoglobulin	L	127.3
Streptokinase Bulk	L	1.3
Tetanus Immunoglobulin	KG	13.7
Urokinase Powder	KG	38109.2
Goserelin Acetate	KG	20537.8
Chloroform emprove grade	L	18.3
Uti bulk	KG	6.8
Urea	KG	1.8
Isopropyl alcohol (IPA) Ph, EU	L	3.2
Pearlitol pf mannitol	KG	1.3
Fetal clone 1	L	8.1
Water for injection 10 ml i.p.	NOS	58379.8
Sorbitol	KG	30.5
Albutin 20 %	BT	1.1
Dme medium high glucose	KG	2.2
L-glutamine 200 mm	L	2.3
Soyabean casein digest medium	KG	3.4
Sodium chloride inj 1 ml external	NOS	114092.9
Normal immunoglobulin bulk	L	124.5

Manufacturing process:

1. The manufacturing process is carried out batchwise and originating from Equine biological raw materials used for formulation. This raw material is derived out by separating plasma derivatives from blood components of equines, who are attaining the maximum titres of immunity. This process is lengthy and attained after a certain period of immunization of antigens prepared from venom of Snake, scorpion and Rabies Virus into the bodies of equines. To complete such batch cycle, it takes long period of 2-3 years, since during this period the hyper immune equine are bleed and the venoms characteristic get neutralized phased wise in their bodies hence no fresh batch is charged.

The industry having their own equines (Ponies-small horses) are housed at their unit at Village Khoni, Tal. Kalyan, Dist. Thane. After the direction given by MPC Board on 20/06/2017 they decided to scale down the equine quantities and ultimately stop the plasma manufacturing activity completely. Further industry informed that they have stop bleeding totally from 01/12/2019 and plasma transferred that time to Ambernath unit is now being consumed for completed the remaining batch process by March-2020.

Block diagram of manufacturing process.



2. Once the Raw Material i.e. Plasma is received from Khoni facility, the Plasma is stored in the controlled temperature environment.

Plasma generation Process: The Equines (Pony) are injected with Antigen (Snake Venom, Rabies Virus, Scorpion Venom, etc.), After injecting, at a certain period of immunization of antigens, Antibodies are prepared for venom of snakes, Scorpion and rabies virus into the bodies of equines. The Antibodies are developed slowly to attain a defined level of titre in the bodies of Equine. The process is lengthy, and it takes 2-3 years for completion of cycle. Once, the Equine is ready for process the blood is extracted from body of Equine and plasma derivatives are separated from Blood component of Equines. This Plasma derivatives are major raw material in mfg. of ASVS, ARS. At Ambernath. **(The industry have also submitted a letter dtd. 06/10/2020 alongwith related documents in support of the same) (Annexure – III).**

3. After which pooling of plasma is carried out for fractionation and Immunoglobulins are Isolated.
4. After Isolation quality control of plasma is done for fractionation. Once, Quality confirmed fractionation of Plasma is carried out.
5. After fractionation, formulation process is carried out.
6. Post formulation, Bulk filling is carried out in automated machines and storage. After filling, the samples are sent for Quality control complete analysis of product and post QC analysis the stored formulation is release for production usage i.e. final product in form of vials.

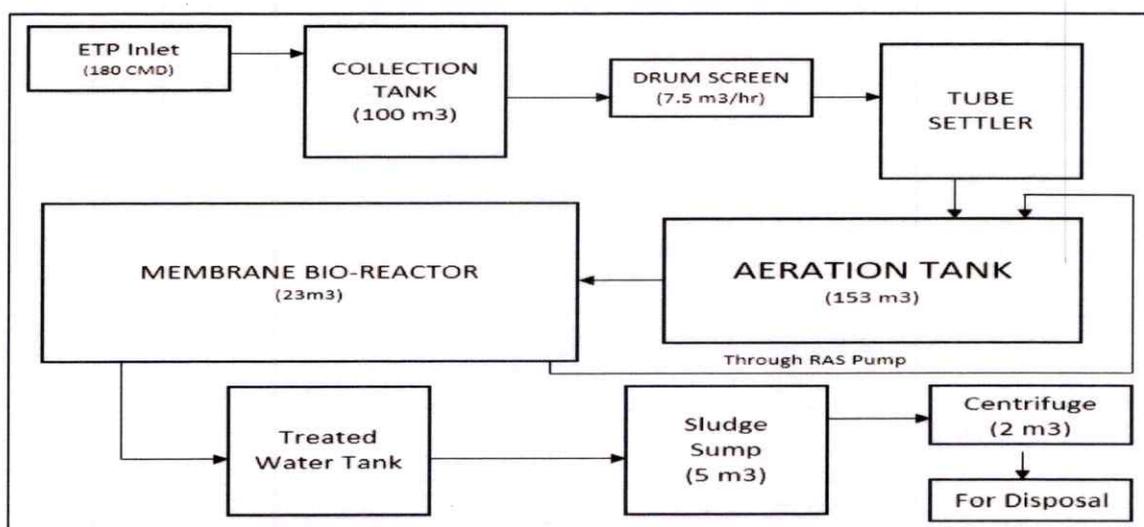
Month Wise Production data:

MONTH	Month wise Production data							
	MPCB Consent Qty.	YEAR 2017-2018	MPCB Consent Qty.	YEAR 2018-2019	MPCB Consent Qty.	YEAR 2019-2020	MPCB Consent Qty.	YEAR 2020-2021
APR	15 Lakhs Unit / M	06,76,195	15 Lakhs Unit / M	07,64,176	15 Lakhs Unit / M	07,07,464	20 Lakhs Unit / M	05,70,159
MAY		09,08,274		09,55,023		09,58,056		07,46,937
JUN		09,85,881		11,25,292		11,40,696		08,26,494
JULY		08,20,386		08,08,350		10,18,319		08,82,876
AUG		11,93,952		09,76,690		12,01,057		10,62,625
SEP		10,50,921		10,09,177	12,55,104	20 Lakhs Unit / M		
OCT		08,82,412		10,69,894	11,56,920			
NOV		09,96,648		09,26,903	09,56,554			
DEC		10,71,004		09,38,413	11,03,330			
JAN		07,37,381		08,89,766	07,86,879			
FEB		08,57,964		09,08,448	10,74,258			
MAR		12,32,675		14,06,603	09,14,494			

Industrial Wastewater Aspects:

The industry generating trade effluent from their manufacturing activity and for that industry has provided effluent treatment plant comprises Bar Screen, Collection Tank, Primary Settling Tank followed by Aeration Tank and Membrane Bio- Reactor (MBR); for sludge de-watering centrifuge has been provided. The plant is operated in SCADA mode.

The block diagram is as below:

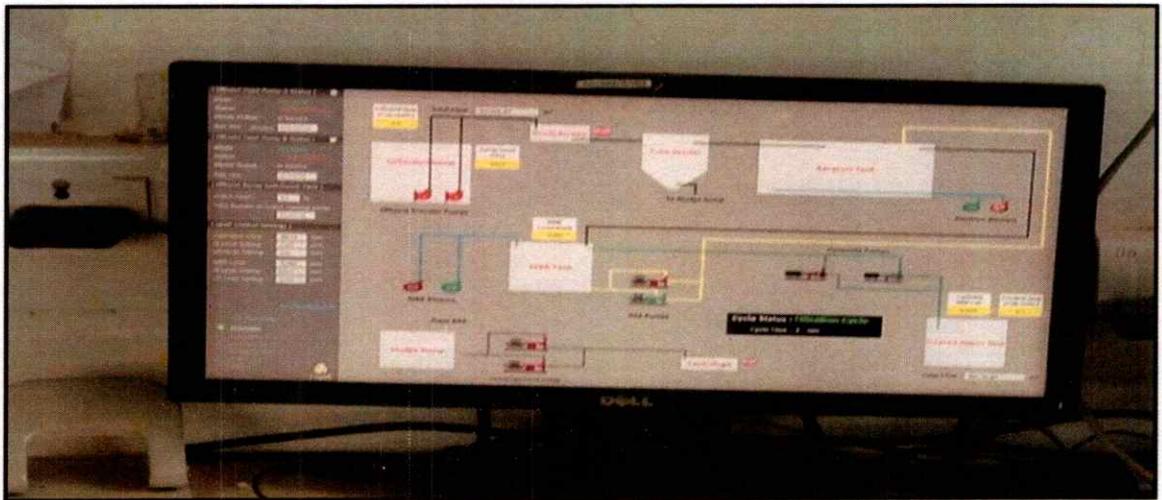


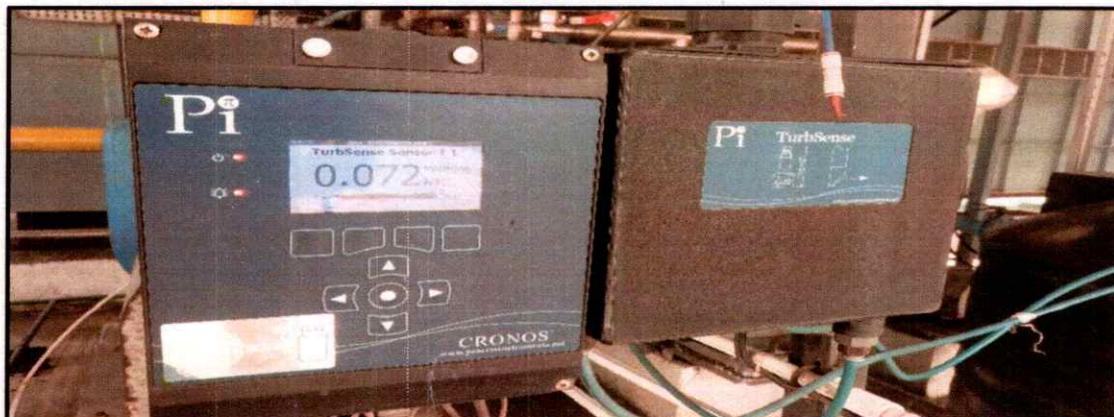
The Board officials collecting the Joint Vigilance samples from time to time and Analysis of results are well within the consented limits. Copies Enclosed as **Annexure XV**

Effluent Treatment Plant (ETP)



Fully Automated ETP - SCADA System





Water Consumption Aspects:

The statement showing the quantity of water supply by the MIDC to the said industry alongwith qty. of effluent generation.

Month	Qty. as per MPCB Consent	Qty. as per MIDC Bill 2017-18	Qty. of Effluent gen. 2017-18	Qty. as per MPCB Consent	Qty. as per MIDC Bill 2018-19	Qty. of Effluent gen. 2018-19	Qty. as per MPCB Consent	Qty. as per MIDC Bill 2019-20	Qty. of effluent gen. 2019-20	Qty. as per MPCB Consent	Qty. as per MIDC Bill 2020-21	Qty. of effluent generation. 2020-21
April	182	147.3	70	182	149.4	71	182	151.2	71	243	148.3	99
May	182	157.9	71	182	197.0	73	182	177.5	72	243	155.4	105
June	182	116.0	72	182	175.6	74	182	99.9	60	243	199.4	107
July	182	94.5	67	182	127.4	72	182	201.4	72	243	173.8	104
August	182	159.4	70	182	211.0	71	182	204.5	74	243	148.3	105
September	182	144.9	73	182	218.7	70	243	191.1	79			
October	182	121.7	71	182	215.0	74	243	214.7	85			
November	182	179.6	72	182	155.4	72	243	123.0	90			
December	182	127.0	70	182	144.1	73	243	157.8	95			
January	182	231.4	69	182	142.1	74	243	193.0	100			
February	182	166.2	72	182	140.1	74	243	191.7	102			
March	182	179.0	73	182	140.4	70	243	164.5	95			

(All above quantities are average meter cube per day)

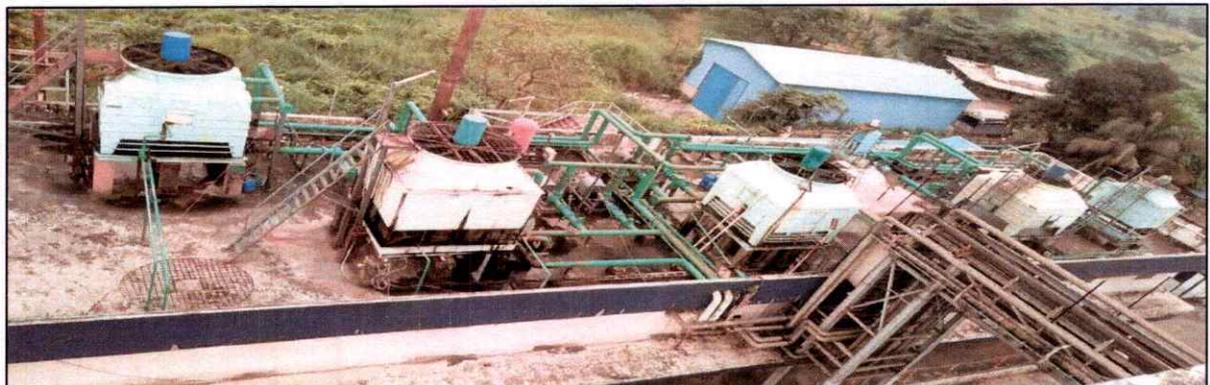
By considering the above the water consumption is well within the consented limit.

The entire treated trade effluent is recycling in cooling tower. Details of Cooling Tower with their Capacity are as under –

Cooling Tower Details									
Cooling Tower No.	Capacity	Design CT in TR	CT Pump Design (m ³ /Hr)	Delta T	Approach	Evaporation loss/hr (0.7%) in KL	Drift loss (0.005%) in KL	Blow down (0.1%) in KL	Total water required/hr (KL)
For Chiller									
1	170 TR	200	180	4	4	1.278	0.009	0.18	1.467
2	190 TR	250	182	4	4	1.2922	0.0091	0.182	1.4833
3	170 TR	200	227	4	4	1.6117	0.01135	0.227	1.85005
4	200 TR	250	190	4	4	1.349	0.0095	0.19	1.5485
For Air compressor 283 cfm									
5	20 TR	20	15	4	4	0.1065	0.00075	0.015	0.12225

Water Requirement for Cooling Tower with their Source:

Cooling Tower Equipment ID.	Capacity	Running Hrs	Total water required for CT (KL)	Potable water	ETP Treated Water	Blowdown	Evaporation
For Chiller							
B/CT/U001	170 TR	14	21	3	18	2.5	18
EN/CT/U0156	190 TR	14	21	3	18	2.5	18
EN/CT/U027	170 TR	14	26	4	22	3.2	23
EN/CT/U180	200 TR	24	37	4.6	33	4.6	33
For Air compressor 283 cfm							
20 TR, EN/CT/U158	20 TR	24	3	0.4	3	0.4	2
Total			107	15	92	13	94



(Photograph of Cooling Tower)

Joint Inspection Report: -

The joint inspection carried out on 07/10/2020. Observations noted during the visit are as under –

- 1) During the visit manufacturing activity was not in operation however plant Cleaning, Validation of manufacturing area & maintenance activities were observed.
- 2) Consented water consumption is 243 CMD, however at present water consumption for the month of Aug. 2020 is 5110 M³/M (170 CMD) as per MIDC water bill.
- 3) Industry has provided Effluent Treatment Plant comprises of bar screen, collection tank, primary secondary tank followed by aeration, Membrane Bio-Reactor (MBR), sludge dewatering centrifuge etc.
- 4) During the inspection provided ETP found in operation and effluent recycle / reusing in cooling tower. The ETP is operated on SCADA system.
- 5) Overflow of cooling tower is taken to ETP through storm water drain.
- 6) Joint vigilance sample of ETP inlet and outlet collected in presence of Industry's representative.
- 7) Industry is having total 5 nos. of cooling towers having capacity 170 TR (2 nos.), 200 TR, 190 TR & 20 TR and total water requirement for these cooling towers is 107 CMD out of this 94 CMD treated effluent water is used and 13 CMD fresh water charged.
- 8) Industry not provided proper leachate collection arrangement at ETP sludge dewatering system.
- 9) At present generated domestic effluent is treated in the existing ETP. The Board has issued Conditional Restart Directions on 21/08/2020 with condition that industry shall provide separate sewage treatment plant on or before 31/12/2020. Accordingly, industry has issued work order for the provision of 50 KLD STP, on 11/09/2020.
- 10) Industry has provided LDO fired boiler having capacity 3 T alongwith stack of height 30 meter. Industry has provided D.G. Set of 750 KVA.
- 11) Industry is regularly monitoring ambient air quality and stack monitoring through NABL approved laboratory.
- 12) There is generation of hazardous waste in the form of 35.3 – ETP sludge, 28.1 – Process Residue & Wastes (generated during ultrafiltration process), 28.5 – Date expired products, 37.2 – Flue gas cleaning residue, which is disposed through CHWTSDF.
- 13) Last disposal of Hazardous waste 28.1 in the tune of 1607 Kg & 35.3 in the tune of 253 kg through MWML on 20/08/2020.
- 14) Industry has obtained Bio-Medical Waste Authorization vide No. SRO Kalyan-II/BMW_AUTH/ 1908000179-2019, dtd. 26/09/2019 valid up to 08/08/2022, for generation and segregation of Bio-medical waste i.e. expired plasma which is disposed through Mumbai Waste Management Ltd.
- 15) Industry has submitted Form- on 10/06/2020 & Form-V on 30/09/2020.

- 16) During joint inspection joint vigilance sample of inlet & outlet of ETP were collected and analysis result are as under –

Table Showing the analysis report of samples collected during the Inspection:

Date of sample collection	Parameters	Consented limit for ETP outlet.	ETP Inlet	ETP Outlet
07/10/2020	pH	5.5 – 9.0	7.2	8.0
	BOD	100	125.0	6.0
	COD	250	272.0	20.0
	Oil & grease	10	1.4	BDL
	Suspended Solids	100	80.0	12.0

All units are in mg/litrs. except pH.

Electricity Consumption details:

Connected Load: 3970 KW Per day

MONTH	KWH			
	YEAR 2017-2018	YEAR 2018-2019	YEAR 2019-2020	YEAR 2020-2021
April	647572	700016	865400	914240
May	820392	682920	944640	1012800
June	797390	690840	953160	970040
July	808925	797320	890800	957320
August	798467	939960	870560	871680
September	851521	943960	854800	-
October	789828	958440	823720	-
November	785039	755600	969680	-
December	811219	845960	968360	-
January	674323	810080	929080	-
February	607080	793280	894920	-
March	733840	858120	648046	-

By considering the above electric consumption is as per the connected load.

Hazardous waste generation details:

Industry has disposed hazardous waste as per chart showing:

Year	Date of Disposal	Haz. Waste Category	Quantity	Disposal to
2017	03/11/2017	34.3 – ETP Sludge	520 Kg	MWML, Taloja
	15/12/2017	34.3 – ETP Sludge	430 kg	MWML, Taloja
2018	03/10/2018	28.1 – Process Residue	212.52 kg	MWML, Taloja
	15/10/2018	34.3 – ETP Sludge	110 kg	MWML, Taloja
2019	26/03/2019	28.5 – Date Expired Products	6.36 kg	MWML, Taloja
	25/09/2019	28.5 – Date Expired Products	115 kg	MWML, Taloja

		35.3 – ETP Sludge	89 kg	MWML, Taloja
	12/12/2019	35.3 – Chemical sludge	85 kg	MWML, Taloja
		28.1 – Process Residue	805 kg	MWML, Taloja
	31/12/2019	35.3 – Chemical sludge	76.4 kg	MWML, Taloja
		28.5 – Date Expired Products	1.03 kg	MWML, Taloja
2020	17/01/2020	28.5 – Date Expired Products	12.4 kg	MWML, Taloja
		35.3 – Chemical sludge	34.7 kg	MWML, Taloja
		28.1 – Process Residue	745.3 kg	MWML, Taloja
	29/02/2020	28.1 – Process Residue	1252 kg	MWML, Taloja
	30/04/2020	28.1 – Process Residue	1111.6 kg	MWML, Taloja
		35.3 – Chemical sludge	126.2 kg	MWML, Taloja
		28.5 – Date Expired Products	4.86 kg	MWML, Taloja
		37.2 – Flue gas cleaning residue	57.3 kg	MWML, Taloja
	01/06/2020	35.3 – Chemical sludge	187 kg	MWML, Taloja
		28.1 – Process Residue	1073 kg	MWML, Taloja
	08/07/2020	4.1 – Oil sludge	1.8 KL	Recycler
	09/07/2020	28.5 – Date Expired Products	4.01 kg	MWML, Taloja
		35.3 – Chemical sludge	247 kg	MWML, Taloja
		28.1 – Process Residue	1419 kg	MWML, Taloja
	20/08/2020	28.1 – Process Residue	1607 kg	MWML, Taloja
35.3 – Chemical sludge		253 kg	MWML, Taloja	

By considering the above the industry has disposed hazardous waste to CHWTSDF as per the Hazardous and Other Waste (M&TM) Rules,2016.

Environment Statement submission details:

The copies of Environmental Statement report since 2017 to 2020 is enclosed.

Environment Statement	Status
2017	Submitted on 28.09.2017
2018	Submitted on 28.09.2018
2019	Submitted on 28.09.2019
2020	Submitted on 30.09.2020

Details of action taken by the Board:

- The Board has issued direction u/s. 33A of Water (P&CP) Act, 1986 to the Additional Ambarnath Manufacturer Association vide letter No. MPCB/JD(WPC)/CD/TB-2647, dtd. 02/07/2016 for not operating and maintaining the CETP located at Plot No. AM-13, Addl. Ambarnath, Dist. Thane and directed to stop receiving the effluent from the member industries. **(Annexure – IV)**

- Based on above direction, Regional Officer, Kalyan vide their dtd. 07/07/2016 issued direction to M/s. Bharat Serum & Vaccines Ltd., Plot No. K-27, Addl. MIDC Ambernath, Dist. Thane, to stop discharge of effluent to CETP immediately **(Annexure – V)**.
- Regional Officer, Kalyan vide their letter No. MPCB/ROK/SCN-P/TB-416, dtd. 07/06/2017 issued show cause notice to the industry as the treated effluent used on land for gardening and thereby violating the Consent condition **(Annexure – VI)**.
- Thereafter based on the reply given by the industry vide their letter dtd. 08/06/2017 assured that they will not use any sort of treated effluent for gardening and to be maintained to use only recycle / reuse in cooling tower **(Annexure – VII)**.
- The Board has issued the Closure direction vide No. MPCB/SROK-II/ROK/CD/443, dtd. 13/06/2017 to M/s. Bharat Serum & Vaccines Ltd., Plot No. K-27 & K-27/1, Addl. MIDC Ambernath, Dist. Thane as the industry using treated effluent on land for gardening thereby violating the consent conditions **(Annexure – VIII)**.
- Thereafter, based on the reply vide letter dtd. 15/06/2017 & undertaking on letter head vide letter dtd. 20/6/2017 stating that till submission of water budget, concrete plan for effluent disposal and your order in this matter they will not manufacturing add on batches which violates terms of consent issued **(Annexure – IX)**.
- Based on the submission and request of the Industry as Unit is manufacturing lifesaving injections and vaccines which are to be preserved and stored below 10°C which require continuous refrigeration and cooling being these products are very sensitive, the Board has considered the request of the industry and issued direction not to disconnect water and electric supply by the concern authorities vide letter dtd. 20/06/2017 subject to condition that industry shall not charge fresh batch of manufacturing till further orders **(Annexure – X)**.

The Board has granted the Consent vide No. MPCB/18/206/1804000316, dtd. 06/04/2018 with condition that industry shall comply with the direction issued by the Board vide letter dtd.20/06/2017. Thereafter, Board has granted Consent for expansion by capacity utilization vide No. MPCB/19/466/1909000025, dtd. 03/09/2019 with stringent condition that industry shall recycle entire treated effluent in utilities and there shall not be any discharge outside the factory premises and also comply Board's direction dtd. 20/06/2017.

Board has extended personal hearing to the industry on 11/03/2020 and decided to forfeit the Bank Guarantee of Rs. 5.0 lacs as industry has not complied the earlier direction **(Annexure – XI copy of minutes of personal hearing)**.

By considering the product manufacturing by the industry the Board has extended the personal hearing on 03/08/2020. **(Annexure – XII copy of minutes of personal hearing)** and decided to issue the conditional Restart direction on 21/08/2020 with following condition - **(Annexure – XIII)**.

1. Industry shall submit concrete proposal of sewage treatment plant along with time bound program, within a period of 15 days and shall complete the same on or before 31/12/2020.
2. Industry shall strictly comply with Consent conditions and directions issued by the Board from time to time.
3. In case of failure of any pollution control system, you shall voluntarily suspend the related manufacturing activity and report to the Board, immediately.

The industry vide letter dtd. 03/09/2020 submitted the proposal and assured to complete the work of STP on or before 31/12/2020. Further industry vide their letter dtd. 11/02/2020 and 15/02/2020 reported that they have not violated Consent condition as well as direction issued by the Board and not charged any new batch. Copy of the same is enclosed for ready reference **(Annexure – XIV)**.

Conclusion:

1. Industry is engaged in manufacturing pharmaceutical products by way of formulation. As per the categorization done by Central Pollution Control Board vide letter dtd. 07/03/2016 said activity comes under Orange category i.e. at sr. no. 74, O – 50. Copy of CPCB Letter is attached as **Annexure XVI**.
2. The Joint Committee has examined the submission made by the industry regarding production, raw material electricity consumption as well as the water supplied by the MIDC. Also, committee inspected the unit on 07/10/2020. Copy of Visit Report is enclosed as **Annexure XVII**.
3. On the basis of submission made by the industry vide letter dtd. 11/02/2020 and 06/10/2020 and record produced during joint inspection regarding production, industry has not charged fresh batch. However, Board has forfeited Bank Guarantee of Rs. 5.0 Lakh due to non-compliance of earlier directions and directed to submit top-up Bank Guarantee of Rs. 10 lakhs towards compliance of Consent conditions.
4. The data regarding water consumption and effluent generation is verified and it is observed that water consumption and effluent generation is within the Consented limits.
5. The industry has provided effluent treatment plant found in operation and adequate by considering the analysis results of treated effluent. However cooling tower blowdown observed connected to ETP through storm water drain which needs to be rectified by providing dedicated arrangement. Industry has not provided proper arrangement for collection of secondary leachates (after De-canting of sludge generated) during dewatering of the sludge.
6. The entire trade effluent and domestic effluent is treated in the existing effluent treatment plant and same is recycled and reused back for top-up purpose of cooling. Discharge of untreated / treated effluent outside the factory premises was not observed.
7. It is observed that the Board has granted the Consent vide on 06/04/2018 with condition that industry shall comply with the direction issued by the Board vide letter dtd.20/06/2017.
8. Thereafter, Board has granted Consent to Operate for expansion by capacity utilization on 03/09/2019 with stringent condition that industry shall 100% recycle the treated effluent in process i.e. utility only. There shall be no discharge of treated effluent outside industry premises and industry shall comply the directions issued by the Board vide letter dtd.20/06/2017.
9. There is no any issue related to air pollution only LDO fired thermopack installed alongwith 30 mtrs. Stack.
10. Industry is regularly disposing generated Hazardous waste through authorized CHWTSDF. The industry disposing process waste having category no. 28.1 – Process Residues & wastes (generated during plasma ultrafiltration process) since beginning till today, however same is not reflected in the Consents till grant of Consent dtd. 03/09/2019.



(R. G. Rathod)

Ex. Engg. MIDC Ambernath



(S. V. Powar)

Deputy. Engg. Addl. MIDC Ambernath



(S. L. Waghmare)

Regional Officer, MPC Board, Kalyan



(Pramod Lone)

Field Officer, MPC Board, Kalyan

ANNEXURE – I

Maharashtra Pollution Control Board

Regional Office Kalyan

Tel 95251-2312432
Fax 95251-2313989



Moolchandani Shopping Centre
1st Floor, 16/18, Oak Baug,
Kalyan (W), Thane - 421301

NO. Ok/Ut has/Thane/R/C-CTC-29
ORANGE/SSI

Date: 21/7/2004

Consent to Operate under Section 26 of the Water (Prevention and Control of Pollution) Act, 1974 under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 and Authorization /Renewal of Authorization under rule 5 of the Hazardous Wastes (Management and Handling) Rules, 1989 and Amendment Rule - 2000.& 2003.

(To be referred as Water Act, Air Act and HW (M&H) Rules respectively)

CONSENT is granted to M/s. Bharat Serum & Vaccines Ltd, K-27, Addl. MIDC Anandnagar, Ambemath, Dist. Thane located in the area declared under the provision of The Water Act / Air Act subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:-

1. The Consent to Operate is granted for a period upto 30/06/2014.
2. The Consent is valid for the manufacture of -

Sr. No.	Products	Maximum Quantity
1.	Injections & Vaccines (Only Formulation)	5 Lac Units / Month

3. CONDITION UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 35.0 M³.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed 12.0 M³.

(iii) Trade Effluent :

Treatment: The applicant shall provide comprehensive treatment system consisting of Primary/Secondary and/or Tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards :-

(1) pH	Between 5.5 to 9.0
(2) Suspended Solids	Not to exceed 100 mg/l.
(3) BOD 5 days 20. C	Not to exceed 100 mg/l.
(4) C.O.D.	Not to exceed 250 mg/l.
(5) Oil & Grease	Not to exceed 10 mg/l.



(M) Trade Effluent Disposal : ² ~~reated~~ effluent shall reused to the maximum possible extent & remaining shall be used on land for gardening.

(N) Sewage Effluent Treatment - The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards: -

Suspended Solids	Not to exceed	100	mg/L.
B.O.D. days 20 C	Not to exceed	100	mg/L.

(O) Sewage Effluent Disposal : The treated effluent shall be connected to sewerage system provided by M.I.D.C. or used on land for gardening.

(vi) Non-hazardous solid waste:

Type of waste	Quantity	Treatment	Disposal
-----	NIL	-----	-----

(viii) Other Conditions:

--N. A.--

4. The applicant shall comply with the provisions of The Water (Prevention and Control of pollution) Cess Act, 1977 (to be referred as Cess Rules thereunder: The industry falls in the 7th category of the Cess Act and the Rules made thereunder.
The daily water consumption for the following categories is as under:

(i) Domestic	...	15.0	CMD
(ii) Industrial processing	...	40.0	CMD
(iii) Industrial Cooling	...	10.0	CMD
(iv) Agriculture / Gardening	...	-	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the cess as specified under Section 3 of the said Act.



5. **CONDITION UNDER AIR ACT:**

(i) The applicant shall install a comprehensive control system consisting of control equipment as is warranted with reference to generation of emissions and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:-

Control Equipments: ~~—NA—~~

Standards for Emissions of Air Pollution:

(i)	TPM	...	Not to exceed	150 mg/Nm ³
(ii)	SO ₂		Not to exceed	270 Kg/day

(ii) The applicant shall observe the following fuel pattern :

Sr. No.	Type of fuel	Quantity
1)	L.D.O.	7200 Lit./day.

(iii) The applicant shall erect the chimney /(s) of the following specifications:-

Sr.No.	Chimney attached to	Volume Nm ³ /hr	Height In Mtrs.
1)	Boiler (I, II & III) (Common chimney)		30 Mtrs.
2)	D.G. Set (650 KVA)		5.1 Mtrs. above the roof of building.

(iv) The applicant shall provide ports in the chimney /(s) and facility such as ladder, platform, etc., for monitoring the air emissions and the same shall be open for inspection to / and for use of the Board's staff. The chimney /(s) vents attached to various sources of emission shall be painted/ displayed to facilitate identification.

(v) The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 75 dB (A) during day time and 70 dB (A) during night time. Day time is reckoned in between 6 a.m. and 9 a.m. and night time in reckoned between 9 p.m. and 6 a.m.

(vi) Other conditions:

1. The industry should not cause any nuisance in surrounding area.
2. The industry should monitor stack emission & ambient air quality regularly.



4

D. G. Set Conditions:

- 1) Noise from the D.G. set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
- 2) Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/acoustic treatment of the room should be designed for minimum 25 dB(A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB(A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.
- 3) The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m. and night time is reckoned between 10 p.m. to 6 a.m.
- 4) Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirement by proper siting and control measures.
- 5) Installation of DG set must be strictly in compliance with recommendations of DG set manufacturer.
- 6) A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use.
- 7) The DG set shall be operated only in case of power failure.
- 8) The applicant should not cause any nuisance in the surrounding area due to operation of the DG set.

6. CONDITION UNDER HW-(M&H) RULES, 1989 :

(i) The applicant shall handle hazardous wastes as specified below:

Sr. No.	Category	Type of waste	Quantity	Disposal
1.	34.3	ETP Sludge	200 kg / Month	CHWTSDF

28.3, 28.4.
(ii) Treatment :

—N. A.—



7. The applicant shall comply with the Conditions as stipulated under Annexure -I & II enclosed.
8. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be sopped.

For and on behalf of the
Maharashtra Pollution Control Board



V. B. Waghjale 21/7
(V. B. Waghjale)
Regional Officer, Kalyan.

To,

The Applicant,
M/s. Bharat Serum & Vaccines Ltd,
K-27, Addl. MIDC Anandnagar,
Ambernath, Dist. Thane

Copy submitted to:

1. Water Pollution Abatement Engineer, MPCB, Mumbai.
2. Chief Accounts Officer, MPCB, Mumbai.

Copy to:

1. Sub-Regional Officer-Kalyan-II, MPCB, Kalyan.
2. Master file.

Consent fee of Rs . 25,000/-received, vide D.D. No. 053593

Dated 24/06/04 Drawn on IDBI Mumbai.

Add consent fee of Rs 25000/- received vide D.D NO 054274

(visit us on mpcb.mah.nic.in) dt- 19/07/04 Drawn on IDBI Mumbai.



**MAHARASHTRA POLLUTION CONTROL BOARD
REGIONAL OFFICE-KALYAN**

Phone : 0251-2310167/2310212

Fax : 0251-2310192

Email : rokalyan@mpcb.gov.in



Sidhivinayak Sankul 3rd floor, Near Oak
Baug, Station Road,

Kalyan - 421301

Visit At <http://mpcb.gov.in>

Orange/MSI

Consent No. MPCB/ROK/E/KN-391310 CC-65

Date: 06.15.2011

Consent to Establish under Section 25 of the Water (Prevention and Control of Pollution) Act, 1974 under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 and Hazardous Wastes (Management, Handling & Trans Boundary Movement) Rules, 2008.

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively]
CONSENT is hereby granted to

M/s. Bharat Serums and Vaccines Ltd.
Plot No : K-27, MIDC Addl. Ambarnath
Ambarnath, Dist. Thane.

Located in the area declared under the provisions of the Water Act / Air act and Authorization under the provisions of Management Handling & Transboundary Movement) Rules 2008 to subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Establish for expansion is granted for a period valid up to **Commissioning of project or 5 years, whichever is earlier.**
2. The Consent is valid for the manufacture of

Sr. No.	Product	Maximum Quantity	UOM
1	Injections & Vaccines (only Formulation)	10 Lacs	Units/M

3. CONDITIONS UNDER WATER ACT.

- (i) The daily quantity of trade effluent from the factory shall not exceed **25.0 M³**
- (ii) The daily quantity of sewage effluent from the factory shall not exceed **3.0 M³**
- (iii) Trade Effluent

Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0	
2	Suspended Solids	Not to exceed	100	mg/l.
3	BOD 3 days 27 Deg. C	Not to exceed	100	mg/l.
4	COD	Not to exceed	250	mg/l.
5	Oil & Grease	Not to exceed	10	mg/l.

- (iv) **Trade Effluent Disposal:** The treated trade effluent achieving above standards shall be recycled to the maximum extent and remaining shall be used on land for gardening only till the commissioning of CETP.
- (v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

- (1) Suspended Solids Not to exceed 100 mg/l
- (2) BOD 3 days 27o C Not to exceed 100 mg/l

Sewage Effluent Disposal: The effluent shall be connected to a septic tank followed by soak pit which shall be got cleaned periodically. Overflow shall be connected to the sewerage system provided by MIDC.



- vii) Other Conditions: Industry should monitor effluent quality regularly
viii) Non-Hazardous Solid Wastes:

Sr. No.	Type Of Waste	Quantity	UOM	Disposal

The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules 2003 there under

The daily water consumption for the following categories is as under:

(i) Domestic	5.0	CMD
(ii) Industrial Processing	32.0	CMD
(iii) Industrial Cooling	80.0	CMD
(iv) Agriculture / Gardening	—	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

4. CONDITIONS UNDER AIR ACT:

- (i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

Control Equipment:

Standards for Stack Emissions:

1) SPM	Not to exceed	150	mg/Nm ³
2) So ₂	Not to exceed	—	kg/day

- (ii) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
	Shall make use of existing quantity of fuel		

- (iii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
	Shall make use of existing Boilers only	

- (iv) The applicant shall provide ports in the chimney(s) and facilities such as ladder platform etc for monitoring the air emissions and the same shall be open for inspection to and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc and these shall be painted/ displayed to facilitate identification.

- (v) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.

(vi) Other Conditions:

- The industry should not cause any nuisance in surrounding area.
- The industry should monitor stack emissions and ambient air quality Regularly.



5. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDRY MOVEMENT) RULES, 2008:

(i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Category H.W.	Type Of Waste	Quantity	Disposal
1	34.4	Chemical Sludge form waste water treatment	0.6 MT/A	CHWTSDF

- The industry shall comply with the Hazardous Wastes (Management, Handling & Transboundry Movement) Rules 2008.
- It shall be ensured that the Hazardous waste is handled, managed & disposed of strictly in accordance with the Hazardous Wastes (Management, Handling & Transboundry Movement) Rules 2008. And shown & submitted to the Board as & when asked for.
- The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office
- Whenever due to any accident or other unforeseen act or even such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.
- The Capital investment of the industry is Rs.7.80 crores only.
- Board reserves right to revoke, suspend or amend the consent issued
- The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fir necessary
- The applicant shall comply with the Conditions as stipulated under Annexure-I & II enclosed.
- Shall obtain Consent to operate before commencement of production activity.

For and on behalf of the
Maharashtra Pollution Control Board



(S. K. More)
Regional Officer, Kalyan.

To,
M/s. Bharat Serums and Vaccines Ltd.,
Plot No. K-27, MIDC Addl. Ambernath,
Ambernath, Dist. Thane.

Copy submitted to:
Member Secretary MPCB, Mumbai.

Copy to:
1. Sub-Regional Officer, Kalyan.-ii
Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	D.R.No / Date	Drawn On
1	50000/-	000408	28/6/2010	6412601 13/07/2010	IDBI Bank

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 0251-2310167 /2310212

Fax : 0251-2310192

Email : rokalyan@mpcb.gov.in

Visit At : <http://mpcb.gov.in>



Sidhivinayak Sankul,
3rd floor, Near Oak Baug,
Station Road,

Kalyan - 421301

Orange/L.S.I

Date: 30/Jan/2015

Consent No: MPCB/15/ 01267/43

Consent to Operate under Section 26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008. [To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

CONSENT is hereby granted to

M/s. Bharat Serums & Vaccines Ltd.,
Plot No.K-27,MIDC Additional Ambernath,
Anandnagar, Tal-Ambernath, Dist-Thane.

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Operate is granted for a period up to: 30.06.2016.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
1	Injection & Vaccines (Only Formulation)	15.00	Lacs Unit/Month

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 60.0M³.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed 15.0M³.
- (iii) **Trade Effluent Treatment:** The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0	
2	Suspended Solids	Not to exceed	100	mg/l.
3	BOD 3 days 27 Deg. C.	Not to exceed	100	mg/l.
4	COD	Not to exceed	250	mg/l.
5	Oil & Grease	Not to exceed	10	mg/l.

- (iv) **Trade Effluent Disposal:** The treated effluent shall be recycled to the maximum extent and remaining shall be discharge into sewerage provided by MIDC and sent to CETP for further treatment.
- (v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

- (1) Suspended Solids Not to exceed 100 mg/l.
 (2) BOD 3 days 27o C. Not to exceed 100 mg/l.

(vi) **Sewage Effluent Disposal:** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Waste	Quantity	UOM	Treatment	Disposal
---------	------------	----------	-----	-----------	----------

1. Waste card Board Paper 75 Kg/Month --- By Sale

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules, 2003 there under

The daily water consumption for the following categories is as under:

- (i) Domestic purpose ... 20.0 CMD
 (ii) Water gets Polluted & Pollutants are Biodegradable ... 72.00 CMD
 (iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic ... 0.00 CMD
 (iv) Industrial Cooling, spraying in mine pits or boiler feed ... 90.00 CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. **CONDITIONS UNDER AIR ACT :**

- (i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

a. **Control Equipment:** Industry shall provide dust collector followed by wet scrubber of sufficient capacity to control the emissions.

b. **Standards for Stack Emissions:**

- 1) SPM Not to exceed 150 mg/Nm³
 2) SO₂ Not to exceed 270.0 kg/day

6. **Standards for Stack Emissions:**

(i) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
1	LDO	7200.00	Ltrs/Day

(ii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler	30.00
2	DG set(650 KVA)	5.1*

(* Above roof top of the building in which it is installed)

(iii) The applicant shall provide ports in the chimney(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.



- (iv) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.
- (vi) **Other Conditions:**
- 1) The industry should not cause any nuisance in surrounding area.
 - 2) The industry should monitor stack emissions and ambient air quality regularly.

7. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDRY MOVEMENT) RULES, 2008:

(i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	34.3 Chemical sludge from waste water treatment	250	Kg/Month	CHWT/SDF
2	5.1 Used/Spent Oil	5.0	Kg/Month	By sale to registered recycler

- a. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.
- b. The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office.
- c. It shall be ensured that the Hazardous waste is handled, managed & disposed of strictly in accordance with the Hazardous Waste (Management & Handling) Rules, 1989 as amended on 2003 and shown & submitted to the Board as & when asked for.

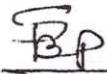
8. Industry shall comply with following additional conditions:

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.
- iii. Solid waste – The non hazardous solid waste arising in the factory premises, sweepings, etc., be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
- iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by he applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms & conditions of this consent regarding pollution levels.
- v. The applicant shall not change or alter quantity, quality, the rate of discharge, temperature or the mode of the effluent / emissions or hazardous wastes or control equipments provided for without previous written permission of the Board.



- vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
 - vii. The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
 - viii. The firm shall submit to this office, the 30th day of September every year, the Environmental Statement Report for the financial year ending 31st March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
 - ix. As inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
 - x. The applicant shall install a separate electric meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
 - xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.
 - xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
9. Applicant shall not carry out any activities which require prior Environmental Clearance as per EIA notification 2006 & as amended.
 10. Board has reserved right to revoke amend or suspend the consent issued.
 11. The Capital investment of the industry is Rs. 4662/-Lacs.




 (B. P. Solunke)
 Regional Officer, Kalyan

To,
 M/s. Bharat Serums & Vaccines Ltd.,
 Plot No. K-27, MIDC Additional Ambernath,
 Anandnagar, Tal-Ambernath, Dist-Thane.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	100	006526	16 sep 2014	IDBI
2	50000	006521	16 sep 2014	IDBI
3	15000	006522	16 sep 2014	IDBI
4	25000	006523	16 sep 2014	IDBI
5	75000	006524	16 sep 2014	IDBI
6	75000	006525	16 sep 2014	IDBI

Copy to: 

1. CAO/ Cess Wing/ Master File.
2. Sub Regional Officer, Kalyan-II, M.P.C.Board, Kalyan

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 0251-2310167 /2310212

Fax : 0251-2310192

Email : rokalyan@mpcb.gov.in

Visit At : <http://mpcb.gov.in>



Sidhivinayak Sankul,
3rd floor, Near Oak Baug,
Station Road,

Kalyan - 421301

Orange/L.S.I

Consent No: MPCB/17/1701001870/32

Date: 23/11/2017

Consent to Operate under Section 26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008. [To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

.....
CONSENT is hereby granted to

M/s. Bharat Serums & Vaccines Ltd.,
Plot No.K-27 & K-27/1, MIDC Additional
Ambernath, Anandnagar,
Tal-Ambernath, Dist-Thane.

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Operate is granted for a period up to: **30.06.2022**.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
1	Injection & Vaccines (Only Formulation)	15.00	Lacs Unit/Month

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed **60.0M3**.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed **15.0M3**.
- (iii) **Trade Effluent Treatment:** The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0	
2	Suspended Solids	Not to exceed	100	mg/l.
3	BOD 3 days 27 Deg. C.	Not to exceed	100	mg/l.
4	COD	Not to exceed	250	mg/l.
5	Oil & Grease	Not to exceed	10	mg/l.

- (iv) **Trade Effluent Disposal:** The treated effluent shall be recycled to the maximum extent and remaining shall be discharge into sewerage provided by MIDC and sent to CETP for further treatment.
- (v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

(1)	Suspended Solids	Not to exceed	100	mg/l.
(2)	BOD 3 days 27o C.	Not to exceed	100	mg/l.

(vi) **Sewage Effluent Disposal:** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Waste	Quantity	UOM	Treatment	Disposal
1.	Waste card Board Paper	75 Kg/Month	---		By Sale

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules, 2003 there under

The daily water consumption for the following categories is as under:

(i)	Domestic purpose	...	20.0	CMD
(ii)	Water gets Polluted & Pollutants are Biodegradable	...	72.00	CMD
(iii)	Water gets Polluted, Pollutants are not Biodegradable & Toxic	...	0.00	CMD
(iv)	Industrial Cooling, spraying in mine pits or boiler feed	...	90.00	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. **CONDITIONS UNDER AIR ACT :**

(i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

a. **Control Equipment:** Industry shall provide dust collector followed by wet scrubber of sufficient capacity to control the emissions.

b. **Standards for Stack Emissions:**

1)	SPM	Not to exceed	150	mg/Nm ³
2)	SO ₂	Not to exceed	270.0	kg/day

(ii) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
1	LDO	7200.00	Ltrs/Day

(iii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler	30.00
2	DG set(650 KVA)	5.1*

(* Above roof top of the building in which it is installed)

(iv) The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.

- (v) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.

(vi) **Other Conditions:**

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality regularly.

6. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDRY MOVEMENT) RULES, 2008:

- (i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	34.3 Chemical sludge from waste water treatment	250	Kg/Month	CHWTSDF
2	5.1 Used/Spent Oil	5.0	Kg/Month	By sale to registered recycler

- a. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.
- b. The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office.

7. Industry shall comply with following additional conditions:

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.
- iii. Solid waste - The non hazardous solid waste arising in the factory premises, sweepings, etc., be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
- iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by he applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms & conditions of this consent regarding pollution levels.
- v. The applicant shall not change or alter quantity, quality, the rate of discharge, temperature or the mode of the effluent / emissions or hazardous wastes or control equipments provided for without previous written permission of the Board.
- vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.

- vii. The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
- viii. The firm shall submit to this office, the 30th day of September every year, the Environmental Statement Report for the financial year ending 31st March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- ix. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- x. The applicant shall install a separate electric meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
- xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection System.
- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
8. Applicant shall not carry out any activities which require prior Environmental Clearance as per EIA notification 2006 & as amended.
9. This Board reserves the right to amend, to revoke, suspend the consent issued or add any conditions in this consent and the same shall be binding on the Applicant.
10. The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.
11. The Public Liability Insurance (PLI) Act 1991 referred to PLI Act 1981 provides a mandatory Public Liability Insurance for an owner, industry or Installation handling its liability arising out of accident involving Hazardous Chemicals.
12. Industry has submitted the MIDC Plot Amalgamation letter dated 3.5.2016. Industry vide letter dated 23.01.2017 committed that they will not carry out any production process activity at Plot No.K-27/1 & they proposed to store the finished goods at the plot No.K-27/1.
13. The Capital investment of the industry is Rs. 4848/-Lacs.

(D.B.Patil)

Regional Officer, Kalyan

To,
M/s. Bharat Serums & Vaccines Ltd.,
Plot No.K-27 & K-27/1, MIDC Additional Ambarnath,
Anandnagar, Tal-Ambarnath, Dist-Thane.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	75,000/-	SBIB0005350	01.09.2016	IDBI
2	1,65,000/-	483838	07.12.2016	IDBI

Copy to:

1. CAO/ Cess Wing/ Master File.
2. Sub Regional Officer, Kalyan-II, M.P.C.Board, Kalyan

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 0251-2310167 /2310212

Fax : 0251-2310192

Email : rokalyan@mpcb.gov.in

Visit At : <http://mpcb.gov.in>



Sidhivinayak Sankul,
3rd floor, Near Oak Baug,
Station Road,

Kalyan - 421301

ORANGE/L.S.I.

Date: 06 / 04 / 2018

Consent No: MPCB/18/ 206 / 1804000316

Consent to Operate under Section 26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2016

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

.....
CONSENT is hereby granted to,

M/s. Bharat Serums & Vaccines Ltd.,
Plot No. K-27 & K-27/1, MIDC,
Addl. Ambernath, Dist. Thane

Located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW (M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Operate is granted for a period up to:- 30/06/2022.

2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Max. Qty	UOM
1	Injection & Vaccines (Only Formulation) at Plot No. K-27	15.0 Lakhs	Unit/M
2	Analytical Testing and R & D Activity at Plot No. K-27/1	-	-

3. CONDITIONS UNDER WATER ACT:

(i) The daily quantity of trade effluent from the factory shall not exceed 60.0 M3.

(ii) The daily quantity of sewage effluent from the factory shall not exceed 15.0 M3.

(iii) **Trade Effluent Treatment:** The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0	
2	Suspended Solids	Not to exceed	100	mg/l.
3	BOD 3 days 27 Deg. C.	Not to exceed	100	mg/l.
4	COD	Not to exceed	250	mg/l.
5	Oil & Grease	Not to exceed	10	mg/l.

(iv) **Trade Effluent Disposal:** The treated trade effluent shall be recycled in maximum extent and remaining shall be discharge into sewerage provided in MIDC and sent to CETP for further treatment. There shall be no discharge of effluent outside industry premises.



(v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

- | | | | |
|-----------------------|---------------|-----|-------|
| (1) Suspended Solids | Not to exceed | 100 | mg/l. |
| (2) BOD 3 days 27o C. | Not to exceed | 100 | mg/l. |

(vi) **Sewage Effluent Disposal:** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Of Waste	Qty	UOM	Treatment	Disposal
1	Waste Cardboard Papers	75.0	Kg/M	-	Sale

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. **The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules, 2003 there under**

The daily water consumption for the following categories is as under:

- | | | |
|---|-----|----------|
| (i) Domestic purpose | ... | 20.0 CMD |
| (ii) Water gets Polluted & Pollutants are Biodegradable | ... | 72.0 CMD |
| (iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic | ... | 0.00 CMD |
| (iv) Industrial Cooling, spraying in mine pits or boiler feed | ... | 90.0 CMD |

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. **CONDITIONS UNDER AIR ACT:**

- (i) The applicant shall install a comprehensive control system consisting of control equipment's as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

Control Equipment: Industry shall provide adequate capacity of Air pollution control System to sufficient capacity to control the emissions.

Conditions for D.G. Set :

- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
- Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.
- The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.

- d. Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use
- g. D.G. Set shall be operated only in case of power failure
- h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.

Standards for Stack Emissions:

- | | | | |
|--------------------|---------------|-----|--------------------|
| 1) TPM | Not to exceed | 150 | mg/Nm ³ |
| 2) SO ₂ | Not to exceed | 270 | Kg/day |

file
06/04/18

(ii) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
1	LDO	7200.0	Ltr/Day

(iii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler	30.0
2	D.G. Set (750 KVA)	5.1

(iv) The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.

(v) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.

(vi) **Other Conditions:**

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality Regularly.

6. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDRY MOVEMENT) RULES, 2016:

(i) The Industry shall handle hazardous wastes as specified below.

S. No.	Type Of Waste	Qty	UOM	Disposal
1	34.3- Chemical Sludge from Waste Water treatment	250.0	Kg/M	CHWTSDF
2	5.1 - Used / Spent Oil	5.0	Kg/M	By Sale to Authorized Recycler/CHWTSDF

(ii) Treatment: - NIL

1. The authorization is hereby granted to operate a facility for collection, storage, transport & disposal of hazardous waste.
2. The industry should comply with the Hazardous Waste (M&H) Rules, 2016.



- a. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipment's, the production process connected to it shall be stopped.
- b. The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office.
- c. It shall be ensured that the Hazardous waste is handled, managed & disposed of strictly in accordance with the Hazardous Waste (Management & Handling) Rules, 1989 as amended on 2016 and shown & submitted to the Board as & when asked for.

7. Industry shall comply with following additional conditions:

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.
- iii. Solid waste – The nonhazardous solid waste arising in the factory premises, sweepings, etc., be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
- iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by the applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms & conditions of this consent regarding pollution levels.
- v. The applicant shall not change or alter quantity, quality, the rate of discharge, temperature or the mode of the effluent / emissions or hazardous wastes or control equipment's provided for without previous written permission of the Board.
- vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- vii. **The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.**
- viii. The firm shall submit to this office, the 30th day of September every year, the Environmental Statement Report for the financial year ending 31st March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- ix. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- x. The applicant shall install a separate electric meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
- xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection System.
- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

8. Applicant shall not carry out any activities which require prior Environmental Clearance as per EIA notification 2006 & as amended.
9. This Board reserves the right to amend, to revoke, suspend the consent issued or add any conditions in this consent and the same shall be binding on the Applicant.
10. The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.
11. The Public Liability Insurance (PLI) Act 1991 referred to PLI Act 1981 provides a mandatory Public Liability Insurance for an owner, industry or Installation handling its liability arising out of accident involving Hazardous Chemicals.
12. If CETP does not work for achieving standards & problem of pollution occurs, industry shall voluntarily stop the production or total effluent shall be reused.
13. This amendment in consent for addition of Analytical Testing and R & D Activity at Plot No. K-27/1 is issued overriding effect to the earlier consent granted vide no. MPCB/17/1701001870/32, dtd. 23/01/2017.
14. This consent is issued considering your submission regarding allotment of NOC by MPC Board dtd. 27/04/2006 and allotment of plot by MIDC vide letter dtd. 31/05/2006.
15. Industry shall restrict the production to the consented quantities only. The expansion of production is hereby refused. You shall recycle the treated effluent back in process till CETP is not operational.
16. Industry shall comply with the directions issued by MPC Board dtd.20/06/2017.
17. The Capital investment of the industry is Rs. 4749.37 Lakh.



(D. B. Patil)
Regional Officer, Kalyan

To,
M/s. Bharat Serums & Vaccines Ltd.,
Plot No. K-27 & K-27/1, MIDC,
Addl. Ambernath, Dist. Thane

Received Consent fee of -

Sr. No.	Amount(Rs.)	Transaction No.	Date
1	375000	7602926 (NEFT)	12/12/2017

Copy to:

1. CAO/ Cess Wing/ Master File.
2. Sub Regional Officer, M.P.C. Board, Kalyan-II

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 0251-2310167 /2310212

Fax : 0251-2310192

Email : rokalyan@mpcb.gov.in

Visit At : <http://mpcb.gov.in>



Sidhivinayak Sankul,
3rd floor, Near Oak Baug,
Station Road,

Kalyan - 421301

ORANGE/S.S.I.

Date: 03/09/2019

Consent No: MPCB/19/466 / 1909000025

Consent to Operate under Section 26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management & Transboundary Movement) Rules 2016

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

Consent to Operate for expansion by capacity utilization is hereby granted to,

M/s. Bharat Serums & Vaccines Ltd.,
Plot No. K-27 & K-27/1, MIDC,
Addl. Ambernath, Dist. Thane

Located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW (M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Operate is granted for a period up to:- 30/06/2022.

2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Max. Qty	UOM
1	Injection & Vaccines (Only Formulation) at Plot No. K-27	20.0 Lakh	Unit/M
2	Analytical Testing and R & D Activity at Plot No. K-27/1	-	-
3	r-FSH (Recombinant - Follicle Stimulating Hormone)	0.009	Kg/A
4	r-HCG (Recombinant - Human Chronic Gonadotropin)	0.105	Kg/A
5	mAnti- D (Monoclonal Anti Rho-D Immunoglobulin)	0.3	Kg/A

3. CONDITIONS UNDER WATER ACT:

(i) The daily quantity of trade effluent from the factory shall not exceed 216.0 M3.
(100% recycle / Reuse)

(ii) The daily quantity of sewage effluent from the factory shall not exceed 26.0 M3.

(iii) Trade Effluent Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0	
2	Suspended Solids	Not to exceed	100	mg/l
3	BOD 3 days 27 Deg. C.	Not to exceed	100	mg/l
4	COD	Not to exceed	250	mg/l
5	Oil & Grease	Not to exceed	10	mg/l

(iv) **Trade Effluent Disposal:** The treated effluent shall be 100% recycled in process i.e. utility only. There shall be no discharge of treated / untreated effluent outside industry premises.

(v) **Sewage Effluent Treatment:** As per your Consent application you have provided septic tanks and soak pit for treatment of domestic effluent and overflow of the same is treated in ETP.

(vi) **Sewage Effluent Disposal:** In case treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at Sr. No. iii & iv shall be applicable.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Of Waste	Qty	UOM	Disposal
1	Waste Cardboard Papers/ Boxes	200.0	Kg/M	Sale
2	Scrap material such as Plastic/ Metal scrap / glass ware	65.0	Ton/Y	Sale to authorized recycler

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Act, 1974

The daily water consumption for the following categories is as under:

- | | | |
|---|-----|-----------|
| (i) Domestic purpose | ... | 27.0 CMD |
| (ii) Water gets Polluted & Pollutants are Biodegradable | ... | 96.0 CMD |
| (iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic | ... | 0.00 CMD |
| (iv) Industrial Cooling, spraying in mine pits or boiler feed | ... | 120.0 CMD |

5. CONDITIONS UNDER AIR ACT:

- (i) The applicant shall install a comprehensive control system consisting of control equipment's as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

Control Equipment: Industry shall provide adequate capacity of Air pollution control System to sufficient capacity to control the emissions.

Conditions for D.G. Set :

- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
- Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.
- The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.
- Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.



Signature
2/ 87919

- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use
- g. D.G. Set shall be operated only in case of power failure
- h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.

Standards for Stack Emissions:

1) TPM	Not to exceed	150	mg/Nm ³
2) SO ₂	Not to exceed	270	Kg/day

(ii) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
1	Diesel	100.0	Ltr/Day
2	LDO	7200.0	Ltr/Day

(iii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler	30.0
2	D.G. Set (750 KVA)	5.0
3	Fume Hood	6.0

(iv) The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.

(v) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.

(vi) Other Conditions:

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality Regularly.

6. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT & TRANSBOUNDARY MOVEMENT) RULES, 2016:

(i) The Industry shall handle hazardous wastes as specified below.

S. No.	Type Of Waste	Qty	UOM	Disposal
1	4.1 - Oil Sludge Emulsion	2500.0	Ltr/A	By Sale to Authorized Recycler/CHWTSDF
2	5.1 - Used / Spent Oil	200.0	Ltr/A	
3	28.1 - Process Residue & Wastes	5.8	Ton/M	CHWTSDF
4	28.5 - Date Expired Products	100.0	Kg/A	CHWTSDF
5	33.1 - Empty Barrels /container / liner contaminated with hazardous chemicals / wastes	350.0	Nos/M	By Sale to Authorized Recycler/CHWTSDF

6	35.3- Chemical Sludge from Waste Water treatment	500.0	Kg/M	CHWTSDF
7	28.6 - Spent solvent	200.0	Ltr/M	By Sale to Authorized Recycler/CHWTSDF
8	28.5 - Date Expired Products	35.0	Ltr/M	CHWTSDF
9	37.2 - Flue Gas Cleaning Residue	130.0	Kg/M	CHWTSDF
10	29.5 - Spent Catalyst	10.0	Nos./Y	CHWTSDF
11	28.4 -Off specification products	50.0	Kg/M	CHWTSDF
12	Other hazardous Waste	10.0	Kg/M	By Sale to Authorized Recycler/CHWTSDF

(ii) Treatment: - NIL

1. The authorization is hereby granted to operate a facility for collection, storage, transport & disposal of hazardous waste.
2. The industry should comply with the Hazardous Waste (M&H) Rules, 2016.

a. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipment's, the production process connected to it shall be stopped.

b. The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office.

c. It shall be ensured that the Hazardous waste is handled, managed & disposed of strictly in accordance with the Hazardous Waste (Management & Handling) Rules, 1989 as amended on 2016 and shown & submitted to the Board as & when asked for.

7. Industry shall comply with following additional conditions:

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.
- iii. Solid waste - The nonhazardous solid waste arising in the factory premises, sweepings, etc., be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
- iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by the applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms & conditions of this consent regarding pollution levels.



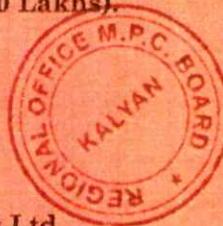
[Handwritten signature]
4

- v. The applicant shall not change or alter quantity, quality, the rate of discharge, temperature or the mode of the effluent / emissions or hazardous wastes or control equipment's provided for without previous written permission of the Board.
- vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- vii. **The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.**
- viii. The firm shall submit to this office, the 30th day of September every year, the Environmental Statement Report for the financial year ending 31st March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- ix. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- x. The applicant shall install a separate electric meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
- xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection System.
- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
8. **Applicant shall not carry out any activities which require prior Environmental Clearance as per EIA notification 2006 & as amended.**
9. **This Board reserves the right to amend, to revoke, suspend the consent issued or add any conditions in this consent and the same shall be binding on the Applicant.**
10. **The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may be deemed fit necessary.**
11. **The Public Liability Insurance (PLI) Act 1991 referred to PLI Act 1981 provides a mandatory Public Liability Insurance for an owner, industry or Installation handling its liability arising out of accident involving Hazardous Chemicals.**
12. **If CETP does not work for achieving standards & problem of pollution occurs, industry shall voluntarily stop the production or total effluent shall be reused.**
13. **This consent is issued with overriding effect to earlier Consent to Operate granted by Board vide No. MPCB/18/206/1804000316, dtd.06/04/2018.**



[Handwritten Signature]
5

14. PP shall strictly comply the Directions issued by the Board vide No.MPCB/PSO/Restart/B-2469, dtd. 20/06/2017.
15. PP shall recycle entire treated effluent in utility as per letter submitted by PP vide dtd. 30/08/2019.
16. Total capital investment of the industry is Rs. 4848.0 Lakhs (Existing Rs.4749.0 Lakhs + Rs. 099.0 Lakhs).



(S. L. Waghmare)
31/9/19
Regional Officer, Kalyan

To,
M/s. Bharat Serums & Vaccines Ltd.,
Plot No. K-27 & K-27/1, MIDC,
Addl. Ambernath, Dist. Thane

Received Consent fee of -

Sr. No.	Amount(Rs.)	Transaction No.	Date
1	4500	TXN1906000529	07/06/2019
2	4500	TXN1908000664	12/08/2019
3	9000	TXN1909000058	03-09-2019

Copy to:

1. CAO/ Cess Wing/ Master File.
2. Sub Regional Officer, M.P.C. Board, Kalyan-II

ANNEXURE – II



MAHARASHTRA INDUSTRIAL DEVELOPMENT CORPORATION
(A Government of Maharashtra Undertaking)

Office :- Executive Engineer (Civil) Division Ambernath.

e-mail : eeambarnath@midcindia.org

Phone No. 0251-2610377.

No. MIDC/SPA/EE/AMB/A-99044/2020

Date:16/03/2020

OCCUPANCY CERTIFICATE

To,
M/s. Bharat Serums and Vaccines Ltd.,
Plot No. K-27, K-27 PART & K-27/1, MIDC, Industrial Area.
Additional Ambernath.
Pin-421506.

Sub:- Issue of Occupancy certificate for factory Buildings
on Plot No. K-27, K-27 PART & K-27/1, MIDC, Industrial Area, Addl.
Ambernath.

- Ref:** 1. Online application vide No. SWC/7/19/20200309/689382 dt. 09/03/2020.
2. Plans approval vide letter No.EE/AMB/K-27K-27Pt/K-27/1/B-33243/of 2019
dt.12.04.2019.
3. Building Completion Certificate By Architect/Mrs. Monali Patankar dt.05.03.2020.
4. Site Inspection Report of DE(AAIA) dt. 14/03/2020.
5. Final Fire NOC issued vide No. MIDC/Fire/A-84826 dtd. 04/03/2020.

Dear Sir,

This is to certify that, the development work of (Factory building) having fresh built up area 3260.54 sq.m. and total upto date built up area- 17090.85 sq.m on Plot No. K-27, K-27 PART & K-27/1, situated at Addl. Ambernath Industrial Area, MIDC, Additional Ambernath, is completed as per details mentioned in Annexure A. Fresh built up area 3260.54 sq.m. is completed under the supervision of Architect Mrs. Monali Patankar (License No. CA/96/20310).

As requested vide ref. no. 1 & as per site inspection report vide ref no. 4 , you are permitted to occupy this building having total built up area- 17090.85 sq.m. (FSI-0.65).

If any discrepancies observed on site in future with respect to site inspection report vide ref no. 4, then legal action as per MR&TP Act 1966 as deemed fit shall be taken, please note.

Thanking you,

Yours faithfully,

**Rajaram
G Rathod**

**Executive Engineer &
Special Planning Authority,
M.I.D.C., Division (c)
Ambernath**

Digitally signed by Rajaram G Rathod
DN: cn=Rajaram G Rathod, o=Maharashtra Industrial Development Corporation,
email=rajaram.g.rathod@midc.gov.in, c=IN, ou=Maharashtra,
serial=1617, version=1.0
Date: 2020.03.16 11:42:15 +05'30'

Encl : Annexure A



MAHARASHTRA INDUSTRIAL DEVELOPMENT CORPORATION

(A Government of Maharashtra Undertaking)

No. **EE/AMB/K-27, K-27 PART & K-27/1/B-33243**/of 2019,
Office of the Executive Engineer,
MIDC, (Civil) Division Ambernath.
Date: - 12/04/2019

To,
M/s. Bharat Serums and Vaccines Ltd.,
Plot No. **K-27, K-27 PART & K-27/1**
MIDC Industrial Area,
Addl. Ambernath.

Sub :- 1] Building Plan Approval for Plot No. No. K-27,K-27 Part and K-27/1,
Addl. Ambernath Indl. Area.
2] Drainage Plan Approval.

Ref :- Online application vide **SWC/7/521/20170511/485416 dt.11/05/2017.**

Dear Sir,

You have submitted application for approval to Building Plan for new structures on K-27/1 and additions to existing structures on K-27 and K-27 Part in Addl. Ambernath Indl. Area.

Your application is examined and following approvals are hereby granted...

Building Plan Approval

Since you have paid following Charges.....

- I) Development charges, amounting to **Rs. 2,85,508.96** vide Receipt No. **1073/CH/7174/2017 dt. 27/11/2017 & 1073/CH/9546/2017 dt. 05/04/2019.**
- II) Scrutiny fees, amounting to **Rs. 26,084.32** vide receipt No. **1073/CH/7174/2017 dt. 27/11/2017.**
- III) Compounding charges, amounting to **Rs. 4,15,800** vide Receipt No. **1073/CH/9546/2017 dt. 05/04/2019.**
- IV) Compounding offence for marginal deficiency, amounting to **Rs. 87,500** vide R. No. **DV034180Q000299 dt. 08/04/2019.**

- 1) The set of fresh plans, received from you vide your letter cited above, is hereby approved subject to acceptance and follow up of following conditions by you.
- 2) You had submitted plans and drawings for **7005.19 Sqm** of plinth area for the plot area of **29149.00 Sqm**, at present this office has approved plans for total upto date **17090.85 Sqm**. of built up area. This office has now approved **09 Nos.** of drawings details of which are mentioned on the accompanying statement.

A. In case of approval to the modified plans, the earlier approval to the building plans granted vide letter No. **Nil dtd. Nil** by this office is treated as cancelled. The drawings approved now supercede previously approved drawings. You are requested to return the cancelled plans to this office for cancellation and record.

B. The drawings submitted now includes existing structures/proposed structures, which were not approved previously. Present approval along with the previously approved plans vide letter No. **EE/AMB/B-43232/2014 dtd. 16/05/2014** & OC vide letter No.**EE/AMB/D-73174/of 2017 dtd. 17/10/2017** from the office of the Executive Engineer is to be treated as combined approval.

- 3) This building plan approval is with respect to planning point of view and in accordance to MIDC's Development Control Rules, since MIDC is Special Planning Authority (SPA) for this Area. In addition, to this approval the plot holder shall obtain approval for plans from other requisite authorities as per necessity, such as from :-
 - i) Industrial Safety and Health Department, Govt of Maharashtra.**
 - ii) Explosive Department, Govt. of India.**
 - iii) Food & Drugs Department, Govt. of Maharashtra.**
- 4) The plot holder shall obtain prior Environment Clearance Certificate before Commencement of any construction activities, if applicable to their project as per the notification issued by MoEF, Govt. of India vide Notification issued by MoEF, New Delhi dtd.14. 09. 2006 and its subsequent amendments'.
- 5) You are requested to submit certified copies of above approvals from the concerned authorities to this office, in triplicate before any work is started OR within three months from the date of issue of this letter whichever is earlier.
- 6) For the sanitary block, overhead water storage tank shall be provided at the rate of 500 liter per W.C. or Urinal.
- 7) For necessary approach road to the plot from the edges of MIDC. Road, 900 mm dia CD works or a slab drain, as may be approved by the Executive Engineer, shall be provided.
- 8) Temporary structures shall not be allowed except to during construction period (after obtaining prior approval from Executive Engineer.) and the same shall be demolished immediately after building work is completed.
- 9) During the period of construction, stacking of materials shall be done only in the area of plot allotted. In no case, material be stacked along MIDC, road land width/open plot area.
- 10) The marks demarcating boundary of the plot shall be preserved properly and kept in good condition and shown to department staff as and when required.
- 11) No tube well, bore well or open well shall be dug.
- 12) Plans for any future additions, alterations or extensions will have to be get approved from this office, as well as from concerned competent authority.
- 13) The present approval to the plans does not pertain to approval to the structural design, RCC members, foundations etc. It is only locational approval to the layout of various structures & floors with reference to the plot, in accordance to MIDC DCR.

- 14) In case any power line is passing through the plot, the plot holder should approach MSEDCL and obtain their letter specifying the vertical and horizontal clearance to be left and plan his structures accordingly.
- 15) The compound wall gate should open inside the plot and if the plot is facing on two or more sides of the road then gate shall be located at least 15 m. away from the corner of junction or roads.
- 16) Plot holders shall make his own arrangement for 24 hours of storage of water, as uninterrupted water supply cannot be guaranteed.
- 17) In case, water stream/ nallah is flowing through the allotted plot, the plot holder has to ensure that the maximum quantity of rain water that flows at the point of entry of stream is allowed to flow uninterruptedly through the plot and upto the point of out flow of the original stream. The points of entry and exit of the natural stream shall not be changed. The detailed plans section and design for allowing maximum expected discharge of rain water through the plot have to be furnished to this office and no filling of plot and diversion of nalla is allowed unless a written permission is obtained from the Executive Engineer/SPA.
- 18) This permission stands cancelled, if no construction work is started within 12 (Twelve) months from the date of issue of this letter or the date given in the agreement to lease to start construction work whichever is earlier. The date of starting construction work and date of completion shall be informed to the Executive Engineer in charge immediately. The construction shall be completed within the given stipulated time limit as per the lease agreement.
- 19) Breach of any rules stipulated will render the plot –holder liable for action as provided in MIDC., Act 1961 (II of 1962 and regulations made there under) and also terms of lease agreement and schedule of penalties prescribed by the Corporation for this purpose.
- 20) This office is empowered to add, amend, vary or rescind any provisions of Building Rules & regulations from time to time as it may deem fit, and the plot-holder has to be abide by these rules and regulations.
- 21) As soon as the building work is completed, the plot-holder shall approach to the concerned Deputy Engineer/Executive Engineer, to get the work verified and building shall not be occupied unless building completion certificate and occupancy certificate is obtained from this office.
- 22) **This approval is subject to permission of competent authority under Urban Land (Ceiling & Regulations) Act. 1976.**
- 23) The plot-holder within a period of one year from the date of agreement to lease, shall plant at least one tree per 100 Sq. m. of plot area along the periphery of the plot. In addition, he shall also plant one tree per 15 m. on the frontage of road or part thereof

inside the plot and maintain the trees so planted in good condition throughout the period of agreement to lease.

- 24) The basement if provided is to be used only for storage purpose. No. manufacturing activities are allowed, similarly toilet is not allowed at the basements.
- 25) The Name and plot number shall be displayed at main entrance of plot.
- 26) The plot holder shall construct ETP as per consent of MPCB & treat & dispose effluent as per MPCB Consent to establish & operate, if applicable with prior approval of MIDC SPA.
- 27) The plot holder shall ensure that, the foundation of the building / structure shall rest on the firm strata and not on made up / filled ground. The Architect and structural consultant appointed by the owner will be solely responsible for this condition.
- 28) MIDC issues permission for development of plots which are situated on river banks, adhering to the contents of the River Policy dt. 13th July 2009 and as per category of Industries. PIL No. 17 of 2011 is filed against this policy at the Hon'ble High Court Bombay. It is clarified that, grant of any permission by the MIDC to any new industry in industrial estate situated on river banks will be subject to any further orders which may be passed by Hon'ble High Court, Bombay under PIL No. 17 of 2011.
- 29) ~~As per the Chief Fire Officer, MIDC's circular vide No. A-04499 dt. 05.01.2015, you have to provide 4 Nos of 5 Kg capacity of DCP fire extinguishers (ABC Type) following IS:15683 within the proposed factory building at prominent locations and the same shall be always maintained in good operating condition as per the IS code.~~
- 30) Since you have consumed 65 % of FSI as per the approved plan, you are requested to utilize remaining FSI as per agreement to lease.

B] Drainage

i) Drainage Plan Approval (Internal Works)

The set of plans in triplicate received along with the letter under reference for the above work is scrutinized the proposal is approved subject to condition as follows:

The work of internal and external water supply and sanitary fittings etc for the above building shall be carried out through the licensed plumber registered at local authority or of Environmental Engineering Department, or Govt. of Maharashtra.

- 1) The work should be carried out as per specifications confirming to I.S.S. In case they are not covered under I.S.S. then standard practice allowed by Municipal Corporation of Grater Bombay shall be followed.
- 2) The wastewater from water closets and urinals shall be passed through a septic tank of standard design.
- 3) The outlet of septic tank will ultimately have to connect to MIDC's sewerage system when provided, as per approved plans.

- 4) The present approval to the plans does not pertain to the design of septic tank, effluent treatment plant etc. It is only locational approval to these structures with reference to the plot.
- 5) You will be allowed to join your effluent to MIDC's common effluent collection system only after obtaining of necessary N.O.C. from M.P.C. Board and actual commissioning of pretreatment activity the factory effluent will be allowed to connect to MIDC system.
- 6) Overhead water tank shall be provided at the rate of 500 Liters per W.C./ Urinal provided.
- 7) The waste water from the closets and Urinals shall be passed through the septic tanks, which is to be adequate to meet the requirements of the persons working in the factory and process waste if any, prior to septic tank in series with suitable size of 100 mm dia sewer trap, inspection chamber with 80 mm dia vent pipe shall be provided.
- 8) All vent pipes shall be minimum 80 mm dia size.
- 9) All rain water down take pipes shall be minimum 100 mm dia and should be provided at the rate of 1 Nos. Per 25 Sq. m. of roof area.
- 10) All S.W. pipes shall be minimum of 150 mm dia size.
- 11) It should be seen that no overflow of water from the soak pit or any process waste enters in to adjoining property or road.
- 12) Rain water pipes are not to be connected to underground effluent collection system. Separate drainage system shall be provided for collection of Industrial and Domestic wastes. Manholes shall be provided at the end of collection system with arrangements for measurement of the flow.
- 13) In case any of the requirements, stated as above is violated by the plot holder then he is liable for disconnection of water supply and is liable for action provided under MIDC., Act and various regulations and as per provision in the lease agreement.
- 14) The completion of work as per above requirements, it shall be jointly, inspected by the concerned Deputy. Engineer, of MIDC and your representative who has designed and executed work, without which drainage completion certificate will not be issued.
- 15) The waste water after treatment shall be soaked in a soak pit, if sewer line is not available for the plot; whereas if effluent collection system, of MIDC is functioning, then effluent shall be connected to the same after getting drainage plans approved from this office. The effluent shall be outletted only after pretreatment confirming to the standards stipulated by Maharashtra Pollution Control Board of Govt. of Maharashtra and after obtaining their consent under water Act 1974, Air Act 1981, & Hazardous waste Rules 2008 and subsequent amendments.

Undersigned reserves right to amend any additional recommendations deemed fit during the final inspection due to the statutory provision amended from time to time and in the interest of the protection of the company.

You are hereby requested to go through above approvals carefully with the above conditions, and take necessary actions accordingly.

Thanking you,

Your's faithfully,

Rajaram
G Rathod

Digitally signed by Rajaram G Rathod
DN: cn=Rajaram G Rathod, o=Special Planning Authority, ou=Special Planning Authority, email=Rajaram.G.Rathod@spacivil.mah.nic.in, c=IN

Executive Engineer
Special Planning Authority
M.I.D.C., Civil Division
Ambarnath.

- DA:-** 1. One Statement showing details of drawings and built up area approved.
2. Copy of approved drawings/plans.

PLAN APPROVAL

EE/AMB/B-33243 / of 2019, dated:- 12/04/2019 issued by the Office of the Executive Engineer,
MIDC, (Civil) Division, Ambarnath. (W)
Name of Industrial Area :- **Additional Ambarnath Indl. Area.**
Addressed to :- **M/s. Bharat Serums and Vaccines Ltd., Plot No. K-27, K-27 PART & K-27/1.**

Sr. No.	Drg No.	Name of Architect	Particulars		Built up Area							
			BCC	Plan Appl.	Ground Floor m ²	Mezz. Floor	First Floor in m ²	2 nd Floor in m ²	Extra height in m ²	Terrace Floor in m ²	Total area In m ²	
1.	01	M/s. Arnita Sez Consultants Pvt. Ltd Reg. Lic. No. CA/85/8879	BCC		4962.30	-----	4386.12	-----	937.19	48.16	10333.77	
					Plan Approval vide EE/AMB/1214/of 2009 dtd. 04/06/2009 & BCC issued vide EE/AMB/3189/of 2011 dt. 12/05/2011.							
2.	04	Mrs. Sonali A. Kadam Reg. Lic. No. CA/2004/34917	BCC		709.48	-----	-----	-----	354.74	-----	1064.22	
					Plan Approval vide EE/AMB/54207/of 2013 dtd. 18/02/2013 & BCC issued vide EE/AMB/B-85778/of 2013 dt. 20/06/2013.							
3.	08	Mrs. Sunita Waikar Reg. Lic. No. CA/88/8879	BCC		73.40	576.98	58.59	1261.12	462.23	-----	2432.32	
					Plan Approval vide EE/AMB/B-43232/of 2014 dtd. 16/05/2014 & OC issued vide No. EE/AMB/D- 73174/of 2017 dtd. 17/10/2017							
4.	09	Mrs. Monali R. Patankar Reg. Lic. No. CA/96/20310	Present Approval		1222.49	-----	1160.04	861.89	16.12	-----	3260.54	
					Total						6967.67	576.98

REMARKS:-	1. Area under demolition.	-:-	Nil m ²
	2. Plot Area	-:-	29149.00 m ² .
	3. 10% R. G.	-:-	(-) 2914.90 m ² .
	4. Net Plot Area	-:-	26234.10 m ² .
	5. Upto date ground coverage in m ²	-:-	7005.19 m ² .
	6. F.S.I. in Ground coverage	-:-	0.26 < 0.50
	7. Total Built up area in m ²	-:-	17090.85 m ² .
	8. Total F.S.I consumed.	-:-	0.65 < 1.00

**Rajaram
G Rathod**

Executive Engineer & SPA
MIDC., (Civil) Division
Ambarnath

ANNEXURE -III



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

Ref: BSVL/MPCB/2020-21/002

Date: 06/10/2020

To,
 The Regional Officer - MPCB,
 Kalyan.

Sub: Manufacturing Process Clarification

KA: Mr. Conc.

Dear Sir,

With respect to the above-mentioned subject matter we wish to submit the clarification regarding the manufacturing

The process starts from our location at Khoni and thereafter, it concludes at Ambernath facility.

Following are the Steps of the process:

I. **Khoni Equine Raw Material Generation Process:**

1. The Equines (Pony) are injected with Antigen (Snake Venom, Rabies Virus, etc.).
2. After injecting, after a certain period of immunization of antigens, Antibodies are prepared against venom of Snakes and Rabies virus into the bodies of equines.
3. The Antibodies are developed slowly to attain a defined level of titre in the bodies of Equine. The process is lengthy and cyclic and last for period of years across the life span of the equines as per statutory norms with respect to concerned guidelines.
4. Once, the Equine is ready for process the blood is extracted from body of Equine and plasma derivatives are separated from Blood component of Equines. This Plasma derivatives are major raw material in mfg. of ASVS, ARS. At Ambemath plant.

II. **Ambemath Equine Mfg. Process:**

1. Once the Raw Material Plasma is received from Khoni facility, the Plasma is stored in the controlled temperature environment (2 deg. to 8 deg. C).
2. After which pooling of plasma is carried out for fractionation and Immunoglobulins are Isolated.
3. After Isolation quality control of plasma is done for fractionation. Once, Quality confirmed fractionation of Plasma is carried out.
4. After fractionation, formulation process is carried out.
5. Post formulation, Bulk filling is carried out in automated machines and storage.
6. After filling, the samples are sent for Quality control complete analysis of product and post QC analysis the stored formulation is release for production usage i.e. final product in form of vials.

Page 1 of 2



Corporate Office
 17th Floor, Liberty Tower,
 Hoechst Reliable Plaza,
 Nariman Point, Mumbai.
 Pin - 400 021
 Tel. +91-22-4504 3456
 Fax +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708
 Tel. +91-22-4504 3000
 Fax +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604
 Tel. +91-22-2582 2181, 2582 1389
 +91-22-6797 7696
 Fax +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambemath Factory
 Plot No. K-27, Anand Nagar
 Additional MIDC.,
 Ambemath (East), Pin - 421 501
 Tel. 0251-262 7000
 Fax 0251-262 7008
 E-mail : ambemath@bharatserums.com

Warehouse
 Building No. H-4, Premise No. 1
 Survey No. 15, Sonare Village
 Mumbai - Nashik Highway
 Taluka - Bhamburda,
 Dist Thane Pin - 421 302
 Tel +91-22-2663 026 2



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021 India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

The process is basically the cycle of the product which begins at from the First Injection of Venom (Antigen) injected into the body of the Equine, continuous booster doses, series of bleedings, plasma extraction in lots, plasma pheresis, lot testing, dispatch to Ambernath. This above process is cyclic and continuous as per Equine Antibody generation for life Saving Drugs in conjunction with Statutory bodies w.r.t animal welfare

The process of Antibody generation is continued as per statutory guidelines to ensure health status of Equines and drug availability (Life Saving) as per government requirements.

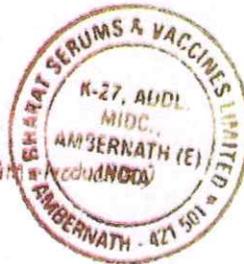
The raw plasma dispatched for Ambernath are processed based on equipment capacities and traceability is maintained for the same. Hence, appropriate nomenclature for a particular processing cycle is provided.

We hereby confirm that, MSEB Connected load is 3970 KW and Average consumed load is 1500 KW. Also, MIDC Water Consumption as per MPCB Consent is 243 CMD and Average water Consumed is 173 CMD.

Thanking You.

For Bharat Serums and Vaccines Ltd.


 (Mr. Manoj Nerurkar - GM)
 (Technical Signatory)



Encl:

1. Immunization, Bleeding and Plasma Extraction Record - 2017 Onwards
2. Sample of Plasma Pooling Record
3. Equine Manufacturing Process Flow Chart

Page 2 of 2

Corporate Office
 17th Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai.
 Pin - 400 708
 Tel : +91 22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower
 Behind Reliable Plaza,
 Airoli, Navi Mumbai.
 Pin - 400 708
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372 Road No. 27,
 Wagle Industrial Estate
 Thane (West), Pin - 400 604
 Tel : +91-22-2582 2181, 2582 1399
 +91-22-6797 7696
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambernath Factory
 Plot No. K-27, Anand Nagar,
 Additional MIDC
 Ambernath (East), Pin - 421 501
 Tel : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambemath@bharatserums.com

Warehouse
 Building No. H-4 Premise No.1
 Survey No. 15, Sonale Village
 Mumbai - Nasik Highway,
 Taluka Bhiwandi,
 Dist Thane Pin 421 302
 Tel : +91 22-2663 026 / 27

ANNEXURE – IV

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 24010437/24020781
/24037124/24035273
Fax : 24044632/24024068
/24023516
Email : jdwater@mpcb.gov.in
Visit At : <http://mpcb.gov.in>



Kalpataru Point, 3rd & 4th floor, Sion-
Matunga Scheme Road No. 8, Opp Cine
Planet Cinema Near Sion Circle, Sion (E),
Mumbai - 400 022

MPCB/JD(WPC)/CD/TB- 2647

Date: 2/7/2016

To
M/s. Addl. Ambernath Manufacturers' Association,
Addl. Ambernath CETP,
Plot no. AM13, MIDC Addl. Ambernath, Tal-Ambernath,
Dist - Thane.

Sub: Directions u/s 33A of the Water (Prevention & Control of
Pollution) Act, 1974 and u/s 31A of the Air (Prevention &
Control of Pollution) Act, 1981.

- Ref: 1. Proposed Directions issued dtd: 20/05/2016
2. Show cause notice for closure issued by the Board vide
Letter MPCB/ROK/TB/SCN/384 dtd: 24/05/2016.
3. Minutes of the Meeting extended to you on 02/06/2016
4. Your Reply dtd: 03/06/2016
5. Personal hearing extended to you on 29/06/2016

WHEREAS, the Maharashtra Pollution Control Board has granted you conditional consent to operate Common Effluent Treatment Plant (CETP) at Plot no. AM-13, MIDC Addl. Ambernath, Tal-Ambernath subject to the certain terms and conditions including important condition to maintain and operate it properly so as to achieve the standards prescribed in the consent order dated 15/01/2014 which was expired on 31/12/2014.

WHEREAS, an application for Renewal of Consent was submitted in the name of Division of Bharat Udyog Ltd., being Operator of CETP. AND WHEREAS, the MIDC has removed the Division of Bharat Udyog Ltd., for not operating and maintaining the CETP on account of its being Operator of said CETP, which has been involved in the litigation as per information gathered by the Board. AND WHEREAS, existing management is also not operating and maintaining AAMA ETP.

AND WHEREAS, on account of not operating and maintaining your CETP and non-operation and maintenance of ETPs of Members of your CETP, you are discharging highly polluted effluent into local nalla, which further leads to Waldhuni River, which further meets to

2 :

Ulhas Creek and thereby causing serious pollution thereof. AND WHEREAS, the capacity of your CETP is 7.5 MLD, whereas you are collecting and treating only 3.5 MLD industrial effluent, thereby the CETP is being operated under capacity, which further is responsible for discharging polluted effluent.

AND WHEREAS, on account of above non-compliances, Show Cause Notice issued by the Board dated 11/12/2013, followed by the Proposed Directions dated 17/04/2015 with further Show Cause Notice dated 14/12/2016 for making improvement in your O & M. AND WHEREAS, inspite of above actions, you have not taken effective steps to comply with those notices, the Board has issued directions dated 20/02/2016, 09/05/2016, directing you to take effective steps to improve and upgrade CETP to collect, treat and dispose of 3.5 MLD industrial effluent. AND WHEREAS, you have not complied with those directions, and therefore, the Regional Officer, MPCB, Kalyan had issued Proposed Directions dated 20/05/2016 as to why further stringent action shall not be initiated against you including closure of CETP.

AND WHEREAS, a personal hearing was extended to you before Chairman of the Board on 02/06/2016. During the course of personal hearing, you have informed that Additional Ambernath CETP has been handed over to AAMA by MIDC for proper O & M and repairs, so as to put it into full operation on account of non-operation thereof by the earlier Operator. You were directed to submit an Action Plan within two days to comply with the Operation, Maintenance and Repairs, so as to make operational CETP to achieve standards by 15th June, 2016. You are also directed to get an Action Plan ratified by the MIDC. MIDC was directed to remove accumulated sludge in the sump within five days. The instructions were agreed to be followed by you and MIDC.

AND WHEREAS, further opportunity of hearing was extended to you on 28/06/2016 by the Member Secretary. During the course of hearing, your representative was not present. Though sludge removing was in process, as per information obtained from you, it was decided to call concrete Action Plan at micro level (individual unitwise) by 29/06/2016 and improvement within three days, failing which to consider closure of CETP. It was also decided to call names of defaulters contributing high COD.

AND WHEREAS, no specific Action Plan was being received to secure the compliance to the discharge standards and thereby, you are causing serious pollution in the local nalla, leading to Waldhuni river, which further meets to Ulhas Creek. Therefore, it was decided to

: 3 :

issue Final Directions against your CETP and all defaulting members, which are not meeting consented standards with directions to achieve zero discharge

AND WHEREAS, you have been issued with the show cause notice for closure under section 33 A of the Water (Prevention & Control of Pollution) Act, 1974, pointing out the non compliances on the part of member industries and thereby causing pollution in the surrounding areas vide show cause notice dated 24/05/2016. AND WHEREAS, the MPCB is monitoring your CETP regularly and also placing the JVS analysis results on the Website of MPCB for bringing more transparency in respect of operation and maintenance of CETPs in the State of Maharashtra in compliance of the order passed by Hon'ble High Court at Judicature at Bombay in the group of Writ Petitions filed by before it in the Public Interest Litigation no. 17/2011.

AND WHEREAS, the above monitoring reports and non compliances on your part were brought to your notice from time to time by the MPCB. AND WHEREAS, you have been directed to take corrective measures to improve the performance of CETP by way of proposed directions dated 09/05/2016 with reference to short term and long term measures to be taken by you, prosecution notice dated 02/04/2016, directions dated 22/04/2016 for installation of SCADA and directions dated 20/05/2016. AND WHEREAS, in spite of above notices and directions, you have failed to comply with those directions and thereby continue to cause serious pollution at a discharge point in sea

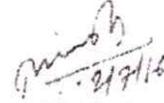
AND WHEREAS, after going through the results of your CETP at your outlet, for more than last one year, it has been observed that your management is totally negligent towards pollution prevention and causing continuous pollution in the surrounding area even after giving a number of opportunities to improve the performance of CETP.

NOW THEREFORE, I, P. K. Mirashe, the Member Secretary of the Maharashtra Pollution Control Board in exercise of powers conferred upon me by the Board has come to the conclusion that your previous management was not only negligent towards pollution prevention, but also has no intention to improve the operation and maintenance of CETP, thereby discharging highly polluted effluent from the final outlet of CETP into the local nalla leading to Waldhuni river, which further meets to Ulhas Creek and causing serious pollution in saline zone. I, therefore, hereby direct you to stop receiving effluent from member industries within 72 Hours or till AAMA CETP submits concrete time bound proposal for upgradation, maintenance and operation of existing CETP, so as to achieve standards prescribed in the

: 4 :

Consent dated 15/01/2014. The directions of closure hereby makes it clear that you should not receive any effluent from your member industry or any other industries into CETP for further treatment and disposal. You are further directed to bring these directions to the notice of your Members, informing them not to discharge any under treated or untreated effluent into the inlet of CETP or in the nearby area, which will cause further damage to the environment.

This is issued with the approval of Chairman of the Board.



(P. K. Mirashe)
Member Secretary

Copy submitted to:

1. Hon'ble Chairman, MPC Board, Mumbai
2. CEO, MIDC, Udyog Sarathi, Mahakali Caves Road, Andheri East, Mumbai - 400093

Copy to:

1. Joint Director (WPC)/Principal Scientific Officer/Law Officer (P&L Divn), MPCB, Mumbai - for information and necessary action.
2. Regional Officer, MPCB, Kalyan/Sub-Regional Officer, MPCB, Kalyan II - for information and necessary follow up action.

ANNEXURE – V

**MAHARASHTRA POLLUTION CONTROL BOARD
REGIONAL OFFICE-KALYAN**

Tel. No. (0251) 2310167/2310212
Fax No. (0251) 2310192
Visit us on: <http://mpcb.gov.in>
E.mail: rokalyan@mpcb.gov.in



Siddhivinayak Sankul,
3rd Floor, Near Oak Baug,
Station Road,
Kalyan (West) – 421 301.

NO. MPCB/ROK/TB/MIDC Addl. Ambernath CETP Member/ Closure/ 500 Date: 07/07/2016

To,
M/s. Bharat Serum & Vaccines Ltd
Plot NO. K-27 Addl. MIDC Anand Nagar Ambernath,
Dist Thane.

Sub: Directions under section 33 A of Water (Prevention and Control of Pollution) Act, 1974.

Ref: Directions issued to Ambernath MIDC CETP Company Pvt. Ltd., vide no. MPCB/JD(WPC)/CD/TB-2647 dated 02/07/2016.

AND WHEREAS, being a member of CETP you are jointly and severely responsible for not only to operate and maintain your ETP so as to achieve discharged standards prescribed in your consent, but also at the same time to ensure that CETP is operated and maintained so as to achieve the standards prescribed for discharge from final outlet of CETP.

AND WHEREAS, substandard effluent is being received from member industries, which affects the performance of CETP and becoming non complied CETP.

AND WHEREAS, the MPCB also directed earlier to Ambernath MIDC CETP Company Ltd., MIDC Additional Ambernath, to submit an undertaking to comply with the standards prescribed in their consent. AND WHEREAS, an undertaking has not submitted to achieve standards within stipulated time period by CETP and continued negligence towards improvement in operation and maintenance of CETP thereby discharging highly polluted effluent from the final outlet of CETP into the Creek and causing serious pollution thereof.

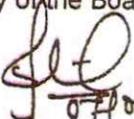
AND WHEREAS, the Maharashtra Pollution Control Board (MPCB) has issued directions vide letter dated 02/07/2016 to Ambernath MIDC CETP Company Ltd., MIDC Additional Ambernath, to stop receiving effluent from the member industries within 72 hours or till Ambernath MIDC CETP Company Ltd., MIDC Additional Ambernath, submits concrete time bound proposal for up-gradation, maintenance and operation of existing CETP so as to achieve the standards prescribed in the Consent dated 15.01.2014.

AND WHEREAS, the CETP has not submitted any concrete proposal to take improvement measures so as to achieve standards within stipulated time period, thereby CETP is falls under non performing category.

AND WHEREAS, it has been observed that due to discharge of sub-standard effluent including toxic contents by some of member industries, effective performance of CETP is being hampered. AND WHEREAS, the CETP Authorities were directed to inform you the facts and circumstances under which directions of closure of CETP has been issued by the Board and not to receive any effluent from the member industries within 72 hours to the CETP. WHEREAS, you have not stopped discharging pretreated/substandard effluent to CETP and thereby non complying with the directions issued by the Board dt. 02/07/2016 to CETP.

NOW THEREFORE, you are directed to take immediate steps to stop your discharge of effluent into CETP immediately, failing which the Board will have no option than direct the Competent Authority to disconnect electricity/water supply of your unit with further direction to MIDC to regulate your activity to ensure closure of generating and discharging effluent to CETP, please be noted.

This is issued with the approval of the Member Secretary of the Board.


07/07/16
(D.B.Patil)

Regional Officer, Kalyan

Copy submitted for information to:

- 1) The Member Secretary, MPC Board, Mumbai.
- 2) The Joint Director (WPC), MPC Board, Mumbai.
- 3) The Principal Scientific Officer, MPC Board, Mumbai

Copy to:

The Sub-Regional Officer, Kalyan-II, MPC Board for serving the directions to industries generating effluent and discharging effluent to CETP immediately by special messenger and ensuring compliance of directions within 48 hours .

ANNEXURE – VI

MAHARASHTRA POLLUTION CONTROL BOARD REGIONAL OFFICE-KALYAN

Tel. No. (0251) 2310167/2310212
 Fax No. (0251) 2310192
 Visit us on: <http://mpcb.gov.in>
 E.mail: rokalyan@mpcb.gov.in



Siddhivinayak Sankul,
 3rd Floor, Near Oak Baug,
 Station Road,
 Kalyan (West) – 421 301.

No. : MPCB/ROK/SCN-P/TB- 416

Date:- 07/06/2017

To,
 M/s. Bharat Serums & Vaccines Ltd.,
 Plot no. K-27 & K-27/1, MIDC,
 Addl.Ambernath, Anandnagar,
 Tal. Ambernath, Dist Thane.

Sub: - Show Cause Notice under the provision of Water (Prevention and Control of Pollution) Act 1974 and Air (Prevention and Control of Pollution) Act 1981.

Ref: - 1) Consent Granted by Board by vide letter 23.01.2017, valid up to 30.06.2022
 2) Visit of Board officials to your unit on 06/06/2017.
 3) Proposal for Action Submitted by Sub-Regional Office MPCB Kalyan-II vide letter dtd-06/06/2017.

WHEREAS, it is mandatory to obtain Consent to operate under the provisions of the Water (P&CP) Act, 1974 and the Air (P&CP) Act, 1981 and the Hazardous Waste (Management Handling & Transboundary Movement) Rules, 2016 and it is obligatory on your part to provide adequate and suitable treatment & disposal arrangements as well as air pollution control devices, so as to achieve the standards prescribed in the consent order and to dispose off it in accordance with the condition laid down for disposal in the consent and comply the consent conditions.

AND WHEREAS, the Officer of MPC Board visited your unit on 06/06/2017 for verification of consent condition compliance and different directions issued by Board from time to time. This office has received proposal from Sub-Regional Office MPCB, Kalyan-II vide letter dtd-06/06/2017 reporting following Non-Compliances:-

- 1) During the visit industry was in operation engaged in manufacturing of Injections.
- 2) You have provided ETP comprising collection tank, equalization tank, aeration, filtration for treatment of effluent. As per consent conditions treated effluent is to be recycled to maximum extent & remaining is to be discharge to CETP.
- 3) You are using treated effluent for gardening, thus violating consent conditions.

: 2:

NOW THEREFORE, in the exercise of the power conferred upon me by Board under section 33(A) of the Water (P & CP) Act, 1974 and under Section 31 of the Air (P & CP) Act, 1981, the following directions are proposed to be issued:

- 1) Why your consent shall be revoked / refused?
- 2) Why your activity shall not be directed to close down forthwith?
- 3) Why the competent authority shall not be directed to disconnect water/electricity supply to your unit?

You are hereby directed to file your substantive reply / objections to these directions within 48 hours time, failing which, the Board will have no option than to confirm above directions against you, which may please be noted.


07/06/17
(D.B. Patil)
Regional Officer, Kalyan

Copy submitted for information to:

1. Member Secretary, M.P.C. Board, Mumbai.
2. Principal Scientific Officer, M.P.C. Board, Mumbai..
3. Law Officer M.P.C. Board, Mumbai

Copy to:

- 1) Sub- Regional Officer, MPC Board, Kalyan-II-He is directed to serve the directions to the above industry and submit the report.
- 2) Master file.

ANNEXURE – VII



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1071PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

Ref. : BSVL/MPCB/SCN-Reply/CO-001/17-18.

Date: 08/06/2017

To,
 The Regional Officer,
 Maharashtra Pollution Control Board,
 Kalyan, Dist : Thane

Sub : Show Cause Notice under Section 33 A of Water (P & CP) – Compliance thereof

Ref. : 1) Your Visit at our Factory dated 6/6/2017

2) Your letter for Show Cause Notice vide No: MPCB/ROK/SCN-P/TB-416 dated 7/6/2017

Dear Sir,

With reference to the above subject, We would like to Clarify as Follows,

We are engaged in the Formulation Activity and the Effluent mainly Comprising of Bottle washing and Floor washing. We have provided our Own In-house Full-fledged Effluent treatment System consisting of Physico chemical Treatment with Secondary - Biological Treatment (ASP) Followed by Tertiary Treatment – Pressure Sand Filtration and Activated Carbon Filtration.

Details are as Follows,

Sr.	Unit of Treatment	Nos off
1.	Oil and Grease Trap	01
2.	Equalization cum Neutralization Tank	02
3.	Flash Mixing Tank	01
4.	Chemical Dosing System	01 Lot
5.	Primary Clarifier Tank with Tube Settler Media	01
6.	Aeration Tank No- 1	01
7.	Extended Aeration Tank No - 2	01
8.	Secondary Clarifier Tank with Tube Settler Media	01
9.	Clarified Water Tank	01
10.	Pressure Sand Filter	01
11.	Activated Carbon Filter	01
12.	Treated Water Tank	01
13.	Sludge Drying Beds	02

We are operating the entire System on Round the clock basis.

8/6/2017
 प्रादेशिक कार्यालय, कल्याण.
 म.प्र.नि. मंडळ,
 सिध्दी विनायक संकूल,
 ब्रा व पथा मजला, ओक बाग
 स्टेशन रोड, कल्याण (प.)
 जिल्हा.ठाणे.

Corporate Office
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax. : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax. : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2161, 2582 1399,
 +91-22-579 77996
 Fax. : +91-22-2582 3540
 E-mail: factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-252 1645 / 262 1643 / 262 1083,
 358 4623 / 659 7257
 Fax. : 0251- 252 1059
 E-mail: ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No. 1
 Survey No. 15, Sonale Village
 Mumbai - Naxik Highway,
 Taluka - Shirwadi,
 Dist - Thane, Pin - 421 302.
 Tel. : 0252 - 2853 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0930 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

After Treatment, the Entire Treated Effluent is Recycled/Reused for Cooling Tower. From Inception stage Only, We are Recycling/Reusing the Treated Effluent to Cooling Tower. As the Treated Effluent is having the good Quality, in case of summer season, we suppose to use excess of Treated Effluent (If any) to Gardening and more ever, we are Recycling/Reusing it to Cooling Tower.

In view of your kind Suggestion and as per Consent condition, we will not use any sort of Treated Effluent for Gardening and will maintain to use only for Recycle/Reuse to Cooling Tower as per our regular use.

So, with respect to your Show Cause Notice issued, we have taken immediate action and stopped using the Treated Effluent to Gardening and henceforth, we assure you that We will take utmost care so as to maintain our disposal of Treated Effluent as per the direction issued.

This is for your information and Kind perusal please.

Thanking you,

Yours faithfully,
 For Bharat Serums and Vaccines Ltd.

(Authorized Signatory)

- Cc to: 1) The Member Secretary, M.P.C.Board, MUMBAI
 2) The Principal Scientific Officer, M.P.C.Board, MUMBAI
 3) The Law Officer, M.P.C.Board, MUMBAI
 4) The Sub Regional Officer, MPCB, Kalyan

Corporate Office
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagla Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2181, 2582 1399,
 +91-22-279 77096
 Fax : +91-22-2582 3640
 E-mail: factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-262 1645 / 262 1648 / 262 1093,
 656 4623 / 656 7057
 Fax : 0251- 262 1089
 E-mail: ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonab Village
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist - Thane, Pin - 421 302.
 Tel. : 0252 - 2663 023 / 27

ANNEXURE – VIII

MAHARASHTRA POLLUTION CONTROL BOARD REGIONAL OFFICE-KALYAN

Tel. No. (0251) 2310167/2310212
 Fax No. (0251) 2310192
 Visit us on: <http://mpcb.gov.in>
 E.mail: rokalyan@mpcb.gov.in



Siddhivinayak Sankul,
 3rd Floor, Near Oak Baug,
 Station Road,
 Kalyan (West) – 421 301.

No. : MPCB/SROK-II/ROK/CD/ 443

Date: - 13/6/17

To,
 ✓ M/s. Bharat Serums & Vaccines Ltd.,
 Plot no. K-27 & K-27/1, MIDC,
 Addl. Ambarnath, Anandnagar,
 Tal. Ambarnath, Dist Thane.

Sub: Closure directions u/s 33A of the Water (P&CP) Act, 1974 and u/s 31 of the Air (P&CP) Act, 1981.

- Ref:**
- 1) Consent Granted by Board by vide letter 23.01.2017, valid up to 30.06.2022
 - 2) Visit of Board officials to your unit on 06/06/2017.
 - 3) Proposal for Action Submitted by Sub-Regional Office MPCB Kalyan-II vide letter dtd-06/06/2017.
 - 4) Show Cause Notice under the provision of Water (Prevention and Control of Pollution) Act 1974 and Air (Prevention and Control of Pollution) Act 1981 vide letter dtd-07/06/2017.
 - 5) Reply submitted by you vide letter dtd-08/06/2017.
 - 6) Report received from Sub-Regional Office MPCB Kalyan-II vide office note dtd-13/06/2017

WHEREAS, you are operating the industry in the pollution prevention area declared under the Provisions of the Water (P&CP) Act, 1974 and the Air (P&CP) Act, 1981 and the Hazardous Waste (Management Handling & Tran boundary Movement) Rules, 2008.

AND WHEREAS, this office had issued you different directions from time to time for compliance of consent conditions as given in references above.

AND WHEREAS, As per consent conditions treated effluent is to be recycled to maximum extent & remaining is to be discharge to CETP. This office has received proposal from Sub-Regional Office MPCB, Kalyan-II vide letter dtd-13/06/2017 submitted that you, you have agreed, that the trade effluent is being used on land for gardening, thus violating the consent conditions.

AND WHEREAS, after examining all the reports and records available with this office I have come to the conclusion that you are knowingly and willfully violating the provisions of the Water (P&CP) Act, 1974 and Air (P&CP) Act, 1981.

..2

Lead
[Signature]
 14/06/17

: 2:

NOW THEREFORE, in exercise of powers conferred upon me by the Board u/s 33A of the Water (P&CP) Act, 1974 and u/s 31 of the Air (P&CP) Act, 1981. I, the Regional Officer, Kalyan hereby direct you to stop your manufacturing activity taking all precautionary measures for safe closure of the unit within 72 hours from receipt of this direction,. It may also be noted that, the competent authorities are being directed to disconnect the electricity and water supply to your unit.



(D.B.Patil)

Regional Officer, Kalyan

Copy submitted for information to:

1. Member Secretary, M.P.C.Board, Mumbai.
2. Law Officer M.P.C.Board, Mumbai.
3. Principal Scientific Officer, M.P.C.Board, Mumbai.

Copy f.w.cs to:

1. Executive Engineer, Maharashtra State Electricity Distribution Co.Ltd. Addl.Ambernath Division, Dist- Thane- He is directed to disconnect electricity supply to the aforesaid unit after completion of 72 hours for safe closure of the unit & inform this office accordingly.
2. Executive Engineer, Addl. Ambernath MIDC Dist-Thane- He is directed to disconnect electricity supply to the aforesaid unit after completion of 72 hours for safe closure of the unit & inform this office accordingly.

Copy to:

Sub-Regional Officer, M.P.C.Board, Kalyan-II:-He is directed to serve the directions to above industry and keep follow up and report the compliance thereof.

ANNEXURE – IX



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India

Tel. : +91-22-6656 0900 / 6656 0980

Fax : +91-22-6656 0933

E-mail : corporate@bharatserums.com

Website : www.bharatserums.com

Ref. : BSVL/MPCB/CD-Reply/CO-002/17/16

Date : 15/06/2017

To,
The Member Secretary,
Maharashtra Pollution Control Board,
Mumbai

26/6/2017
16/6/2017
प्रादेशिक कार्यालय, कल्याण.
ग.प्र.नि. मंडळ,
शिंदी विनायक संकूल,
ब्रा ब ४था मजला, ओक बाग,
स्टेशन रोड, कल्याण (प.)
जिल्हा ठाणे.

3 प्रती
आयुक्त धारा 33A (पुणेकरिता)
महाराष्ट्र प्रदूषण नियंत्रण मंडळ,
कल्याण पॉइंट, २/३/४ था मजला, साबण सर्कल जवळ,
सिने पॉलिटेक्नॉलॉजी, साबण (पूर्व),
मुंबई - ४०० ०२२.
२२/०६/२०१७

Sub : Closure Direction under Section 33 A of Water (P & CP) - Compliance thereof

Ref. :

- 1) Your Visit at our Factory dated 6/6/2017
- 2) Your letter for Show Cause Notice vide No: MPCB/ROK/SCN-P/TB-416 dated 7/6/2017
- 3) Our reply vide our letter date 8/6/2017 submitted to your office
- 4) Closure Direction vide ref. MPCB/SROK-II/ROK/CD/443 dated 13/06/2017 received from your side on 14/6/2017 at 4 pm

Dear Sir,

With reference to the above subject, we would like to Clarify as Follows,

About Our Manufacturing Activity :

This is in reference of the hard copy of the letter No. MPCB/SROK-II/ROK/CD/443 dated 13th June, 2017 received by us on 14th June 2017.

Bharat Serums & Vaccines Ltd. (BSVL) has been in the business of making life saving injectable products since 1971.

We, as an Indian Pharma company have improved the quality of life of millions of people through our diverse range of "Life-saving Pharmaceutical products". At BSVL, we have focused on developing products utilizing our in-house research & development capabilities and continue to manufacture world class products which is evident from our publications and patents.

We, have the unique role and responsibility to produce medicines which are affordable to poor and marginalized sections of the society. We have successfully bridged this gap by providing these products to the needy Indian population, thereby focusing on saving the lives of millions of Indians. This role is a delicate balance between manufacturing as per the market needs and adhering to the laws governed under the NPPA Act. Thereby ensuring continuous production of these essential life-saving medicines.

Corporate Office
3rd Floor, Liberty Tower,
Plot No. K-10,
Behind Reliable Plaza,
Kaiwa Industrial Estate,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3456
Fax : +91-22-4504 3200

R & D Centre
3rd Floor, Liberty Tower,
Plot No. K-10,
Behind Reliable Plaza,
Kaiwa Industrial Estate,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3000
Fax. : +91-22-4504 3200

Thane Factory
Plot No. A-371/372, Road No. 27,
Wagle Industrial Estate,
Thane (West), Pin - 400 604.
Tel. : +91-22-2582 2181, 2582 1393,
+91-22-679 77696
Fax. : +91-22-2582 3640
E-mail: factory@bharatserums.com

Ambarnath Factory
Plot No. K-27, Anand Nagar,
Additional M.I.D.C.,
Ambarnath (East), Pin -421 501.
Tel.: 0251-262 1645 / 262 1648 / 262 1083,
656 4623 / 656 7857
Fax.: 0251- 262 1009
E-mail: ambarnath@bharatserums.com

(Contd. Pge-2
Warehouse
Building No. H-4, Premise No.1
Survey No. 15, Sonale Village
Mumbai - Nasik Highway,
Taluka - Bhiwandi,
Dist - Thane, Pin - 421 302.
Tel.: 0252 - 2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

(Page-2)

Majority of BSVLs' medicine sales are directed towards fulfilling the goal of the Indian government in eradication of various diseases. And the supply is made to various government hospitals and Institutions of various states and the Indian Armed forces.

In this connection, we have all the necessary statutory licenses from various governmental agencies, to ensure uninterrupted manufacturing and supply of life saving medicines.

Stringent environmental conditions are maintained as per the Environmental Policy employed by BSVL. The current plant manufacturing the above medicines is situated at Ambernath MIDC East and is equipped with a *well designed ETP*.

About Effluent Treatment System :

The Effluent mainly Comprising of Bottle washing and Floor washing. We have provided our own In-house Full-fledged Effluent treatment System consisting of Physico chemical Treatment with Secondary - Biological Treatment (ASP) Followed by Tertiary Treatment - Pressure Sand Filtration and Activated Carbon Filtration.

Details are as Follows,

Sr.	Unit of Treatment	Nos off
1.	Oil and Grease Trap	01
2.	Equalization cum Neutralization Tank	02
3.	Flash Mixing Tank	01
4.	Chemical Dosing System	01 Lot
5.	Primary Clarifier Tank with Tube Settler Media	01
6.	Aeration Tank No- 1	01
7.	Extended Aeration Tank No - 2	01
8.	Secondary Clarifier Tank with Tube Settler Media	01
9.	Clarified Water Tank	01
10.	Pressure Sand Filter	01
11.	Activated Carbon Filter	01
12.	Treated Water Tank	01
13.	Sludge Drying Beds	02

(Contd. Page-3)

Corporate Office
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax. : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax. : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 804.
 Tel.: +91-22-2582 2181, 2582 1399,
 +91-22-679 77696
 Fax.: +91-22-2582 3640
 E-mail: factory@bharatserums.com

Ambernath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambernath (East), Pin -421 501.
 Tel.: 0251-262 1645 / 262 1648 / 262 1083,
 656 4623 / 656 7857
 Fax.: 0251- 262 1089
 E-mail: ambernath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist - Thane, Pin - 421 302.
 Tel.: 0252 - 2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

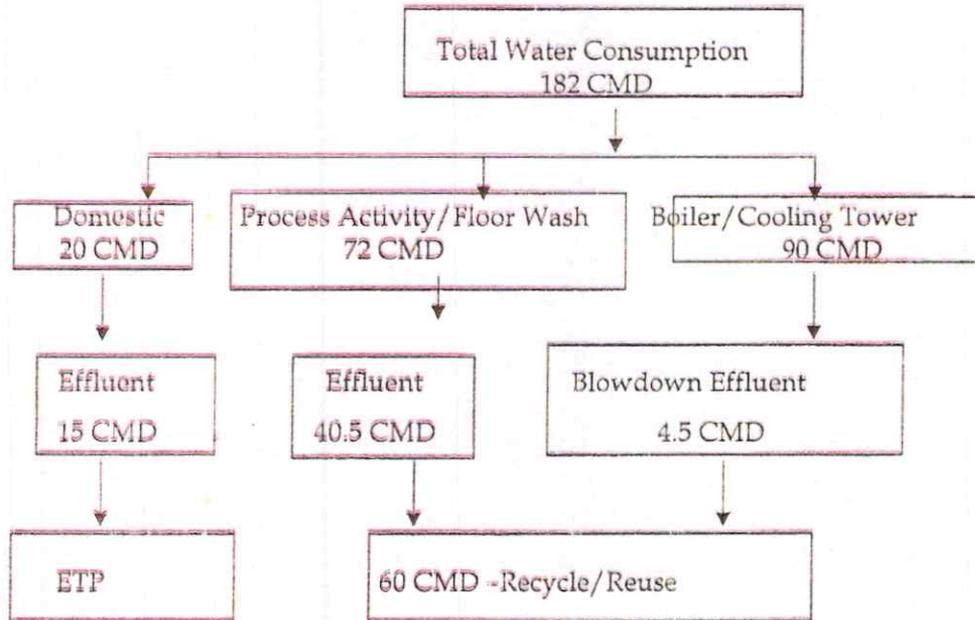
(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

(Page-3)

We are operating the entire System on Round the clock basis.

After Treatment, the Entire Treated Effluent is Recycled/Reused for Cooling Tower from Inception stage Only, We are Recycling/Reusing the Treated Effluent to Cooling Tower, Floor washing, internal cleaning and washing in the Process area.



We were issued Consent to Operate, in Orange category, from your office dated 21/07/2004 valid till 30/06/2014, mentioning therein that we have to use Treated Effluent to maximum extent for reusing and remaining water on land for gardening. Later on the renewed consent dtd.06/05/2015, the condition of usage of effluent water for gardening was maintained till the time of commissioning of CETP and on 30/05/2015 another renewed consent to discharge the remaining Trade effluent to CETP for further treatment. Again on 23/01/2017 the renewed consent is issued with above condition of CETP in Orange category.

Kindly note that your office have given Closure directions u/s 33A TO Addl. Ambernath Manufacturing Association who are the CETP operators vide letter dtd.02/07/2016, at the same time we were also issued letter dtd.07/07/2016 from your office directing us not to discharge any effluent to CETP and no other alternative was suggested. Thereafter on we have confirmed and communicated to your office vide our letter 11/07/2016 that we are

Corporate Office
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax. : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel.: +91-22-2582 2181, 2582 1399,
 +91-22-679 77696
 Fax.: +91-22-2582 3640
 E-mail: factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin -421 501.
 Tel.: 0251-262 1645 / 262 1648 / 262 1083,
 656 4623 / 656 7857
 Fax.: 0251- 262 1089
 E-mail: ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonate Village
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist - Thane, Pin - 421 302.
 Tel.: 0252 - 2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

(Page-4)

using the treated water which is highly purified, for reusing purposes like cooling tower, floor cleaning & gardening purpose and as directed we are not discharging any effluent to CETP. Your officials had visited our plant to inspect and confirmed our say.

The water quality of Effluent discharge reports is attached herewith from your and external Laboratory, please refer the JVS result which implies that we have complied to the Parameters as specified by MPCB and not deviating the standards, in-fact even they are matching to the norms of drinking water as given by WHO and other regulatory bodies.

PH = 6.9, B.O.D = 8, C.O.D = 24, Oil & Grease = BDL, Suspended solids = 8.

So In view of all above compliance, with respect to the Closure direction, we are pained to see the same. As intimated as above, we are engaged in the Formulation Activity with manufacturing of Injections and Vaccines which are the Life-saving injections and vaccines used in the Governmental Hospitals and health care centers and are used in case of emergencies and directly associated with the Human health care. These medicines are to be manufactured, preserved and stored in cold conditions below 10 degree which require continuous refrigeration and cooling, also these are very sensitive products requiring continuous water looping. We have pre booked orders in hand from Govt. institutions & Hospitals for such injectable medicines and required to be fulfilled within this fortnight and it is not at all possible to stop the production activity as directed since it will not only affect our business but will affect the health of the needy patients at their time of life and death situation. Which may also result in shortage of life saving medicine supply to the Human society.

We were/are committed to discharge our effluent to the CETP as per our consent condition, even we are paying the CETP charges through MIDC, though we have stopped the usage of drainage and CETP as per your directions (copy of the bill attached).

We assure that we will come up very soon with a concrete plan for reuse of entire treated effluent water, if CETP is not functional in next few days.

(Contd. Page-5)

Corporate Office

3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708,
 Tel. : +91-22-4504 5456
 Fax : +91-22-4504 5200

R & D Centre

3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kalwa Industrial Estate,
 Airoli, Navi Mumbai,
 Pin - 400 708,
 Tel. : +91-22-4504 3000
 Fax. : +91-22-4504 3200

Thane Factory

Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel.: +91-22-2562 2181, 2562 1399,
 +91-22-679 77696
 Fax.: +91-22-2562 3640
 E-mail: factory@bharatserums.com

Ambernath Factory

Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambernath (East), Pin -421 501.
 Tel.: 0251-262 1645 / 262 1648 / 262 1083,
 656 4623 / 656 7857
 Fax.: 0251- 262 1089
 E-mail: ambarnath@bharatserums.com

Warehouse

Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist - Thane, Pin - 421 302.
 Tel.: 0252 - 2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

(Page-5)

We also assure you that We will comply with the directions given by time to time, and being our activity a Life-saving activity, with a principal of Natural Justice, we request you to withdraw the Closure Direction immediately.

Thanking you,

Yours faithfully,
 For Bharat Serums and Vaccines Ltd .

(Handwritten Signature)
 (Authorized Signatory)

- Cc to : 1) The Regional Officer, MPCB, Kalyan
 2) The Principal Scientific Officer, M.P.C.Board, Mumbai
 3) The Law Officer, M.P.C.Board, Mumbai
 4) The Sub Regional Officer, MPCB, Kalyan

Encl: A/A

imp note:- Having shortfall of the Antisnake venom injection (ASVS) in the market especially now during monsoon will endanger the human lives who come across snake bites and since we are GOY. Supplier of the same current in the Indian Market, we should ^{not} be hold responsible for any casualties happening due to our closure. In the past- there were critical Parliamentary questions to us on ASVS shortfall issue through we were small suppliers of ASVS that time.

Corporate Office
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kailwa Industrial Estate,
 Airoli, Navi Mumbai.
 Pin - 400 708
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Plot No. K-10,
 Behind Reliable Plaza,
 Kailwa Industrial Estate,
 Airoli, Navi Mumbai.
 Pin - 400 708
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel.: +91-22-2582 2181, 2582 1399,
 +91-22-679 77696
 Fax.: +91-22-2582 3640
 E-mail: factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin -421 501.
 Tel.: 0251-262 1645 / 262 1648 / 262 1083,
 656 4623 / 656 7057
 Fax.: 0251- 262 1089
 E-mail: ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist - Thane, Pin - 421 302.
 Tel.: 0252 - 2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN: U24230MH1971PLC013134)
Registered Office : 17th Floor, Honecker House, Nariman Point, Mumbai - 400021, India
Tel : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
E-mail : corporates@bharatserums.com Website : www.bharatserums.com

Ref: BSVL/MPCB/CD-Reply/CD/445/17/17
Dated: 20th June, 2017

To,
The Member Secretary,
Maharashtra Pollution Control Board,
Kalpataru, Bion, Mumbai

Subject: Undertaking

Ref: Closure Direction vide tel. MPCB/SROK-II/ROE/CD/445 dated 13/06/2017

Dear Sir,

With reference to your closure notice Ref. No. MPCB/SROK-II/ROE/CD/445 dated 13/06/2017, we hereby inform you that being our company manufacturing life-saving medicines, which requires continuous Electricity and Water supply for cooling temperature and hence electricity power and water supply are essential for the existing online products.

We further hereby undertake that till submission of our revised budget, concrete plan for effluent disposal and your order in this matter, we would not be manufacturing additional batches, which violate the terms of Consent issued.

Thanking you,

For Bharat Serums and Vaccines Ltd

Authorized Signatory

For CD
20/6/17



Corporate Office
2nd Floor, Liberty Tower,
17th Flr. 17th,
Honecker Building Plaza,
Kalpataru Industrial Estate,
Kalpataru, Bion, Mumbai
Pin - 400 021
Tel : +91-22-6656 0900
Fax : +91-22-6656 0933

R & D Centre
2nd Floor, Liberty Tower,
17th Flr. 17th,
Honecker Building Plaza,
Kalpataru Industrial Estate,
Kalpataru, Bion, Mumbai
Pin - 400 021
Tel : +91-22-6656 0900
Fax : +91-22-6656 0933

Thane Factory
Plot No. A-37/1972, Road No. 27,
Tangle Industrial Estate,
Thane (West), Pin - 400 024
Tel : +91-22-6656 0900 / 6656 0980
+91-22-679 77880
Fax : +91-22-6656 0933
E-mail : thane@bharatserums.com

Ambarnath Factory
Plot No. A-27, Ambarnath Road,
Ambarnath (D.D.),
Ambarnath (West), Pin - 421 001
Tel : 0201-260 1045 / 260 1046 / 260 1052
And 2621 / 262 7987
Fax : 2621-262 1055
E-mail : ambarnath@bharatserums.com

Chorebhat
Building No. 11-4, Thane Road, 11-4,
Chorebhat No. 15, Goregaon Village,
Mumbai - North, Maharashtra,
India - 400046
Pin - Thane, Pin - 421 302
Tel : 022-2661 376 / 377

ANNEXURE – X

MAHARASHTRA POLLUTION CONTROL BOARD

Tel: 24010437/24020781/24014701

Fax: 24024068 / 24023516

Website: <http://mpcb.gov.in>

E-mail: psa@mpcb.gov.in



Kalpataru Point, 2nd - 4th Floor

Opp. Cine Planet Cinema,

Near Sion Circle, Sion (E)

Mumbai-400 022.

No. MPCB/PSO/Restart/B- 2469

Date: 20.06.2017.

To,
M/s Bharat Serums and Vaccines Ltd,
Plot No- K27 and K27/1,
MIDC Addl Ambernath
Dist- Thane

Sub: Temporary Re-connection of the Water and Electricity supply of M/s Bharat Serums and Vaccines Ltd, Plot No- K27 and K27/1, MIDC Addl Ambernath.

Ref: 1. Closure Directions issued by RO Kalyan dated 13.06.2017
2. Industry letter dated 15.06.2017
3. Office Note approved by MS, MPCB on 15.06.2017

With reference to above referred letter at Sr. No.1, Regional Officer, Kalyan issued Closure Directions for non-compliance observed and not obeying the directions of the Board time to time.

Vide your letter dated 15.06.2017, it is requested to not to disconnect the electric supply, as the industry is manufacturing Life Saving injections and vaccines which are to be preserved and stored below 10° C which require continuous refrigeration and cooling being these products are very sensitive.

It is to inform you that Board has considered your request and decided to grant temporary permission for not to disconnect the electricity and water supply, subject to condition that, you shall not charge fresh batch of manufacturing till further orders.

This is issued with approval of the Member Secretary of the Board.

21/06/17
Clerk to Deputy Engineer

M.I.D.C. Sub Division,

Addl. Ambernath

Copy submitted for information to:

Member Secretary, MPCB, Sion, Mumbai-22

Copy to:

1. Regional Officer, MPCB, Kalyan - for information and n.a.

2. Sub-Regional Officer, MPCB, Kalyan-II- for further necessary follow up and report

compliance to Regional Officer.

Copy to:

1. Executive Engineer, MIDC, Division Ambernath- He is directed to restore the water supply of the said unit, immediately.

2. Executive Engineer, MSEDCL, Ambernath- He is directed to restore the Electric supply of the said unit, immediately.



(Dr. A.R. Supate)

Principal Scientific Officer

प्रादेशिक कार्यालय, कल्याण,
म.प्र.नि. मंडळ,
शिवाजी विज्ञान संकुल,
रुसा व प्रथम मजला, ओक बाज,
वैशाल रोड, कल्याण (प.)

21/06/17
Clerk to Deputy Engineer
Executive Engineer
M.I.D.C. Ambernath Div. (Civil)

ANNEXURE – XI

Minutes of Personal Hearing of M/s Bharat Serum & Vaccines Limited, Plot no-K-27, K-27/1, MIDC Addl Ambarnath, Dist- Thane before MS, MPCB

Date: 11.03.2020

Time: 3.00 PM

Venue: MS Chamber

Following were present for the personal hearing:

Industry Representatives:

1. Mr. Venkatesh Chindarkar , Manager
2. Mr. Ajit Khandeshi, Consultant

MPCB Representatives:

1. Shri. E.Ravendiran, Member Secretary
2. Dr. A.R. Supate, Principal Scientific Officer
3. Dr. Y.B.Sontakke, Joint Director (WPC)
4. Shri. S.L.Waghmare, Regional Officer, Kalyan
5. Shri. Sanjay Bhosale, SRO, Kalyan-II
6. Shri. Gopal Kadam, JSA, PSO Division

It is Orange/LSI type of industry engaged in manufacturing of injection and vaccines. C to O valid upto 30.06.2022, I.E is 216 CMD and D.E is 26 CMD. Board has issued closure directions on dtd. 13.06.2017.

RO Kalyan informed that earlier Board has issued temporary permission for not to disconnect water & electricity supply of the unit subject to condition that industry shall not charge fresh batch on 20.06.2017. Thereafter industry has submitted their report on 19.08.2019 that their existing batch will be finished on or before Dec. 2019. Board has extended personal hearing to the said industry on 06.01.2020 wherein it was decided that industry shall not load fresh batch till further orders, to comply with the directions of 20.06.2017, submit BG of Rs. 5 Lakh and SRO K - II to verify the water budget, JVS reports and land availability for the disposal of treated effluent and also submit report alongwith ECC for operating in violation of temporary restart and disposal of treated / untreated effluent on the land in violation to the Consent conditions.

FO of SROK-II visited the unit on 13.02.2020 for verification of the compliance of Consent conditions and temporary restart direction wherein it is observed that industry has loaded anti rabies injection product fresh batch on 11.2.2020. ETP outlet JVS reports collected on 10.1.2018 ,13.8.2018 ,27.8.2018 ,24.7.2019 ,31.8.2019 are within consented limit. Total plot area 29149 Sq.m2 , total built area 17090.85 sq. mtr as per plan approval letter issued by MIDC Executive engineer on 12.4.2019. This land is

:2:

adequate for disposal of treated effluent in the tune of 50 CMD. However we may not allow the industry for disposal of treated effluent on land for gardening.

Industry representative mentioned that existing batch will be completed in March 2020. Also Further mentioned that they have not loaded fresh batch. They have submitted BG of Rs. 5 Lakh. Further informed that they have installed fully automated effluent treatment plant consisting primary, secondary and tertiary treatment system and is 100% reused. Industry has requested to allow them to use the treated effluent water on land for gardening purpose as they have sufficient land available for gardening. Further, requested to grant permanent restart order as they have provided full-fledged pollution control devices for effluent treatment and Air Pollution Control and achieving the standards less than consented standards.

PSO and Joint Director (WPC) informed that as per the policy of Board, permission for discharge of treated effluent on land for gardening is not permitted. Hence, we may not allow industry to discharge treated effluent on land, but industry shall use treated sewage for gardening purpose.

After due deliberation it is decided that:

1. Industry shall provide separate treatment system for industrial effluent and domestic effluent.
2. Industry shall provide separate STP for domestic wastewater within two months and its treated sewage shall be used for gardening. No treated / untreated sewage will be released outside the premises of industry.
3. Industry shall operate the maintain the ETP properly to achieve consented standards and 100% reuse the treated effluent for industrial purpose viz. Cooling Tower, Vacuum Pump, Chillers etc.
4. Industry shall not discharge treated effluent on land for gardening or any other purposes.
5. Existing BG of Rs. 5,00,000/- stands forfeited for violation of earlier directions. Industry shall submit BG of Rs.10,00,000/- towards compliance of consent Conditions
6. Industry shall apply for amendment in the consent for condition of discharge of treated effluent.
7. SRO, Kalyan-II shall monitor the compliance monthly and report the non-compliance if any to RO, Kalyan for further necessary action.

(E. Ravendran)
Member Secretary

ANNEXURE = XII

Minutes of Personal hearing extended to M/s. Bharat Serums & Vaccines Ltd., Plot No. K - 27, K - 27/1, MIDC Addl. Ambernath, Dist. Thane w.r.t. Closure Directions issued

Date: 03.02.2020 :

Time: 2.45 pm through video conferencing.

Industry Representatives:

1. Shri. Venkatesh Chindarkar, Manager.
2. Shri. A. Khandeshi, Consultant.

MPCB Representatives:

1. Shri. E. Ravendiran, MS, MPCB.
2. Shri. A. R. Supate, Principal Scientific Officer, MPCB.
3. Shri. P. K. Mirashe, AS (T), MPCB.
4. Shri. Shankar Waghmare, Regional Officer, Thane.
5. Shri. Sanjay Bhosale, SRO-Kalyan - II.
6. Shri. Ajit R. Suryawanshi, FO, RO Kalyan.

It is ORANGE/LSI unit engaged in manufacturing of injections and vaccines. Consent to Operate is valid up to 30.06.2022, I.E. is 216 CMD & D. E. : 26 CMD. Board has issued Closure Direction on 13/06/2017. Further Board has issued temporary permission on 20/06/2017 for not to disconnect water & electricity supply of the unit subject to condition that industry shall not charge fresh batch.

PSO informed that in the last personal hearing which was extended on 11/03/2020 industry has directed to provide separate treatment i.e. sewage treatment plant for treatment of domestic effluent.

Shri. Venkatesh Chindarkar, Manager, informed that due to COVID 19 pandemic situation industry is unable to provide separate treatment for sewage generated from the industry and ready to provide the same and requested to extend the time for the same. He also informed that presently industry is in operation on 30% production capacity, also obtained licence for development of vaccines of COVID.

After the discussion it was decided to allow industry to continue their production activity with following terms and conditions.

1. Industry shall submit concrete proposal of sewage treatment plant along with time bound program, within a period of 15 days and shall complete the same on or before 31/12/2020.
2. Industry shall strictly comply with Consent conditions and directions issued by the Board from time to time.

...xxx...



ANNEXURE - XIII

MAHARASHTRA POLLUTION CONTROL BOARD

Tel: (0251) 2310167/2310212
 Fax: (0251) 2310192
 Website: <http://mpcb.mah.nic.in>
 E-mail: rokalvan@mpcb.gov.in



Siddhivinayak Sankul,
 3rd Floor, Near Oak Baug,
 Station Road,
 Kalyan (West) - 421 301.

No. MPCB/RESTART/2008210001

Date: 21/08/2020

To, Bharat Serums & Vaccines Ltd.,
 M/s. Bharat Serums & Vaccines Ltd.,
 Plot No. K - 27, K - 27/1, MIDC Addl. Ambernath,
 Dist. Thane.

- Sub: - Conditional Restart Direction u/s 33A of the Water (Prevention & Control of Pollution) Act, 1974 and/or u/s 31A of the Air (Prevention & Control of Pollution) Act, 1981.
- Ref: - 1. Consent to Operate granted by the Board vide no. MPCB/19/466/1909000025 dtd. 03/09/2019.
 2. Closure Direction issued by the Board vide dtd. 13/06/2017.
 3. Temporary permission issued by the Board for not to disconnect water & electricity supply on 20/06/2017.
 4. Request letter to restart the unit submitted by you vide dtd. 19/08/2019.
 5. Personal hearing extended on 03/08/2020.
 6. Minutes of the personal hearing approved on 21/08/2020.

This refers to the Closure Direction issued by the Board vide under ref. no. 2 to your unit due to using treated effluent on land for gardening and causing environmental pollution problems. This also refers to the temporary permission issued by the Board for not to disconnect water & electricity supply on 20/06/2017.

Considering your request letter submitted by you vide under ref. no. 4, minutes of the personal hearing received from authorities it was decided to allow industry to continue their production activity with following terms and conditions -

1. Industry shall submit concrete proposal of sewage treatment plant along with time bound program, within a period of 15 days and shall complete the same on or before 31/12/2020.
2. Industry shall strictly comply with Consent conditions and directions issued by the Board from time to time.
3. In case of failure of any pollution control system, you shall voluntarily suspend the related manufacturing activity and report to the Board, immediately.

These Directions are issued under the power conferred upon me by Board under section 33 A of the Water (Prevention & Control of Pollution) Act, 1974 and under Section 31 A of the Air (Prevention & Control of Pollution) Act, 1981. These Directions shall followed scrupulously, in case of any non-compliance the Board is constrained to take stringent legal action including forfeiture of bank guarantee and closure of unit, which may please be noted.

This is issued with the approval of competent authority.


 Regional Officer, Kalyan.

Copy Submitted to:

- 1) Member Secretary, MPC Board, Sion, Mumbai.
- 2) Principal Scientific Officer, MPCB, Sion, Mumbai.
- 3) Law officer, MPCB Sion, Mumbai;-for information.

..2..

:2:

Copy f. w. cs to:
Copy f. w. cs to:

- 1) The Executive Engineer, MIDC Badlapur area, Badlapur, Dist. Thane - for Information.
- 2) The Executive Engineer/ Addl. Engineer, MSEDCL, Badlapur, Dist. Thane - for Information.

Copy to:
Copy to:

- 1) Sub Regional Officer, MPC Board, Kalyan-II- He is directed to monitor the compliance made by the industry and submit report of the same.
- 2) Master File.

[Handwritten Signature]
21/09/2023

ANNEXURE – XIV

Copros Submitted Online to MPCB



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India

Tel. : +91-22-6656 0900 / 6656 0980

Fax : +91-22-6656 0933

E-mail : corporate@bharatserums.com

Website : www.bharatserums.com

Ref: BSVL/MPCB/2020-21/Reply-002

Date: 03/09/2020

To,
The Regional Officer,
MPCB Kalyan.

Sub: Submission of time bound programme of Erection and Commissioning of STP.

Ref: Personal Hearing dated dated 03/08/2020 via video conferencing and approved minutes of personal hearing dated 21/08/2020.

Dear Sir,

This is with reference to the Personal Hearing dated. 03/08/2020 done via Video Conferencing, as directed by the Board vide Approved Minutes dated 21/08/2020 of the same, as the submission we hereby enclose the following details of the time bound programme as required for building and commissioning of STP

- 1) STP Plant Layout
- 2) STP Plant Process Flow Layout
- 3) STP schedule with Bar Chart
- 4) Approximate Completion date – Before 31/12/2020

In case of any changes / development in the above process we will approach and inform you in advance accordingly.

Trust this is in order.

Thanking You,
For Bharat Serums and Vaccines Ltd.

(Authorized Signatory)

C.C:

1. The Member Secretary, MPCB HQ, Sion.
2. The Principal Scientific Officer, MPCB HQ, Sion.

Corporate Office
3rd Floor, Liberty Tower,
Behind Reliable Plaza,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3456
Fax : +91-22-4504 3200

R & D Centre
3rd Floor, Liberty Tower,
Behind Reliable Plaza,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3000
Fax : +91-22-4504 3200

Thane Factory
Plot No. A-371/372, Road No. 27,
Wagle Industrial Estate,
Thane (West), Pin - 400 604.
Tel. : +91-22-2582 2181, 2582 1399
+91-22-6797 7896
Fax : +91-22-2582 3640
E-mail : factory@bharatserums.com

Ambarnath Factory
Plot No. K-27, Anand Nagar,
Additional M.I.D.C.,
Ambarnath (East), Pin - 421 501.
Tel. : 0251-262 7000
Fax : 0251-262 7008
E-mail : ambarnath@bharatserums.com

Warehouse
Building No. H-4, Premise No.1
Survey No. 15, Sonale Village,
Mumbai - Nasik Highway,
Taluka - Bhiwandi,
Dist. Thane. Pin - 421 302.
Tel. : +91-22-2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24238MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

o/c.

Ref: BSVL/MPCB/2019-20/Reply-002

Date: 11/02/2020

To,
Regional Officer,
Maharashtra Pollution Control Board,
Kalyan – II.

Sub: Compliance to your letter dtd. /02/2020

Dear Sir,

We are in receipt of your letter No: ROK/TB/40/200206-PSO/22 dtd. _/02/2020. Accordingly, we put forth our following reply in compliance there to:

1. We are into manufacturing of life saving injectable medicines. Our outlet water effluent was / is good which after treatment attains very good parameters / quality. Hence for many years were having MPCB Consent to operate, permitting us to discharge the treated water from ETP for gardening till the year 2015.

On dated 30/06/2015 we received Consent To Operate with revised discharge condition of treated water for disposing the same to CETP, since the CETP was installed and commissioned to that effect by MIDC.

(Attached Annexure 01 (a) & 01 (b))

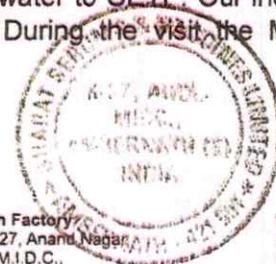
2. On 02/07/2016 MPCB gave closure direction to Add. Ambernath CETP vide letter MPCB/JD(WPC)/CD/TB-2647 for violating effluent treatment and discharge condition.
(Attached Annexure 02)

3. On 07/07/2016 MPCB gave directions vide letter MPCB/ROK/TB/MIDC to all units of Addl. Ambernath MIDC to stop the effluent discharge to CETP immediately. Thus due sudden notice and without any alternative given that time we stopped the discharge of treated water to CETP as directed and maintained the discharge condition of discharge water for recycling it in cooling towers and gardening purpose thereafter as per our previous CTO dated 06/05/2011, as our treated water quality was as good as potable water. In response to above letter we responded by our letter dtd. 09/07/2016; the same is attached herewith.

(Attached Annexure 03 (a) & 03 (b))

At the same time the MPCB officials started visiting all the major manufacturing industries in Addl. Ambernath MIDC including that of our company to verify the new condition of non-disposal of effluent treated water to CETP. Our industry was visited by MPCB officials on 25/07/2016. During the visit the MPCB

Page 1 of 5



Corporate Office
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2181, 2582 1399
 +91-22-6797 7896
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambernath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambernath (East), Pin - 421 501.
 Tel. : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambernath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village,
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist. Thane, Pin - 421 302.
 Tel. : +91-22-2663 026 / 27

11/2/2020
 प्रादेशिक कार्यालय, कल्याण
 म.प्र.नि. मंडळ,
 सिद्धी विनायक संकुल,
 रसायन इंधन मंडळ, ओक घाट,
 कल्याण (प.)
 कल्याण



BHARAT SERUMS AND VACCINES LIMITED

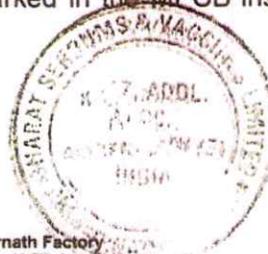
(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

authorities found that we were not discharging any water in CETP as per the notice given, whereas it was explained by our officials that we are using the treated water for cooling tower and excess water for gardening purpose as per previous consent to operate. The inspection report dated is attached herewith for year reference. (Attached Annexure 04)

5. We immediately appealed to the MPCB Officials regarding our 'Product process and its storage condition and its relation to the criticality to the society. Considering & verifying our appeal the board granted us restart on 20/06/2017 with a condition that we shall not charge fresh batch of manufacturing till further orders.
(Attached Annexure 05 (a) & 05 (b))
6. Our manufacturing batch/batches are originating from Equine biological raw materials which is the raw material majorly used for formulation at Ambernath plant. This raw material is derived out by separating plasma derivatives from Blood component of Equines who are attaining the maximum titres of immunity. This process is lengthy and attained after a certain period of immunization of antigens prepared from venom of snakes, Scorpion and rabies virus into the bodies of equines. To complete such a batch-cycle it takes long period of 2-3 years, since during this period the hyper immune equine are bled and the venomous characteristics get neutralized phase wise in their bodies. Hence no fresh batch is charged till further permission. (Attached Annexure 06)
7. We have already communicated and brought into notice time and again that:-
 - a) Our treated water quality was very good hence MPCB Board had permitted us to use the same for Gardening purpose In the previous issued consent.
 - b) To Comply with the direction, given by the Board dated 20/06/2017 we installed and commissioned new ETP with MBR support which gives excellent water quality in its outlet. Only since we are manufacturing lifesaving injections, we cannot reuse this treated water for manufacturing, else its quality is very equivalent to potable water.
 - c) From 20/06/2017 we have been following the directions given by board to not to use the treated water for Gardening too. Instead we are using the same for cooling towers, chillers, vacuum pumps, Boiler soft, manufacturing back wash, etc.
 - d) We have not charged fresh batch and completing the continued batches of manufacturing. The same have been remarked in the MPCB inspections time to time.

Page 2 of 5



Corporate Office
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2181, 2582 1399
 +91-22-6797 7696
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village,
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist. Thane. Pin - 421 302.
 Tel. : +91-22-2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

8. During the period from 20/06/2017 to till date there have been many visits and inspection from MPCB officials and the reports of the same shall give you the clear picture that we have been following the Boards directions.
9. As mentioned above at point No. 6, the equines (Ponies-Small Horses) are housed at our unit in village Khoni, Tal. Kalyan, Dist. Thane, which is 8 KM apart from the Ambernath plant. After the directions given by board on 20/06/2017 we decided to scale down the equine quantities and ultimately stop the plasma manufacturing there completely. To inform you, that on 20/06/2017 there were 578 ponies and as of today there are 374 ponies remaining in the above farm. In the period of next two to three months all the equines shall be disposed off carefully and our manufacturing site at Khoni shall be closed completely. Meanwhile we have stopped bleeding totally from 01/12/2019 and the plasma transferred that time to Ambernath unit is now being consumed for completing the remaining batch process. The same shall be completed in due course of time.

10. Current Status:

The current status of On-going batch is herewith which shows that we have received final slot of the Raw material Plasma bled in December 2019. The same shall be processed and the batch will be completed by Fourth Week of March 2020.

Snake venom antiserum plasma – Khoni			
Month	Receipt at Ambernath (L)	Bulk processing (L)	Remark
Jun-19	831.54	1,557.00	Previously c/f plasma used for processing
Jul-19	295.41	990.44	
Sep-19	-	-	
Oct-19	594.11	-	
Nov-19	-	-	
Dec-19	-	-	
Jan-20	322.08	1,417.64	Bulk processed in Jan 20, will be formulate as per production plan. 84.39 L Plasma in stock at plant

Page 3 of 5



Corporate Office
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2181, 2582 1399
 +91-22-6797 7696
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village,
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist. Thane. Pin - 421 302.
 Tel. : +91-22-2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

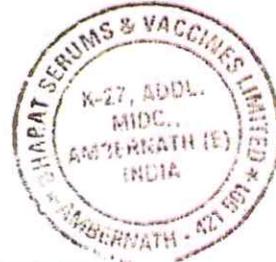
Rabies antiserum equine plasma – Khoni			
Month	Receipt at Ambernath (L)	Bulk processing (L)	Remark
Jun-19	1,296.15	720.00	
Jul-19	714.20	-	
Aug-19	762.66	1,080.00	
Sep-19	1,179.10	1,080.00	
Oct-19	-	-	
Nov-19	-	-	
Dec-19	-	-	
Jan-20	-	-	1195.54 L Plasma in Stock at Ambernath will be use as per production plan

11. Water Budgetary & proposal for treated water disposal for land Gardening is as follows:

Category	MPCB Limit (CMD)	Water Consumption (Proposed) (CMD)		
		Fresh MIDC Water	Recycle	Recycled water Utilization
Domestic	20	07	26.1	10.6 (Urinals – 31 Nos.) 15.5 (Toilet flushing – 20 Nos.)
Industrial	90	30	166	120 – (Cooling Tower) 46 – (Vacuum pumps, Chiller, Boiler Soft, Mfg. Back wash)
Process	72	24	-	-
Other	-	-	50	Gardening
Total	182	61		

The total area of plot is 29149 sq.m and approximate 9000 sq.m is total free area. This area can be used for using the treated effluent for gardening purpose.

Page 4 of 5



Corporate Office
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2181, 2582 1399
 +91-22-6797 7696
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village,
 Mumbai - Nasik Highway,
 Taluka - Bhivandi,
 Dist. Thane, Pin - 421 302.
 Tel. : +91-22-2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

Considering all the above genuine facts you are requested to kindly issue us the Permanent Restart Order so that we can start with fresh batches and assist the society by providing lifesaving medicines in time.

As requested, vide letter no. ROK/TB/40/200206-PSO/22 dated ___ / 02/2020, we are enclosing herewith bank guarantee of Rs. 5,00,000/- (Rupees Five Lakh Only) Bank Guarantee No. 200783IBGP000036 from 10/02/2020 to 31/10/2022 towards the compliance of consent condition of as per the MOM dated. 06.01.2020

It is learnt that some non-related persons to our activity are calling / demanding for our confidential data with your office to which we have already raised our strong objection and requested you to not to issue any such documents. You are therefore again requested as per section 8 (1) (d) of the Right to Information Act, 2005 to accept our request.

Thanking You.

For Bharat Serums and Vaccines Ltd.

(Authorized Signatory)



Page 5 of 5

Corporate Office
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604.
 Tel. : +91-22-2582 2181, 2582 1399
 +91-22-6797 7696
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonale Village,
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist. Thane, Pin - 421 302.
 Tel. : +91-22-2663 026 / 27



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
E-mail : corporate@bharatserums.com Website : www.bharatserums.com

Ref: BSVL/MPCB/2019-20/Reply-004

Date: 15/02/2020

To,
Regional Officer,
Maharashtra Pollution Control Board,
Kalyan – II.

Sub: Clarification to Visit report dtd.13/02/2020

Ref: Our letter BSVL/MPCB/2019-20/Reply-002 dated. 11.02.2020

Dear Sir,

With reference to your visit conducted dtd. 13/02/2020 and points mentioned in your visit report, we would like to clarify as follows:

Point No 06: Industry found in operation in Anti-Rabies Injection manufacturing fresh batch. As reported industry representative. This fresh batch was in operation since 11.2.2020 till date of visit. Previous batch was completed by end of 31.12.2019.

Explanation:

We have specified in our referred letter dated 11/02/2020 at point No. 06, point no.09 and point no.10, that,

Point no.06: "Our manufacturing batch/batches are originating from Equine biological raw materials which is the raw material majorly used for formulation at Ambernath plant. This raw material is derived out by separating plasma derivatives from Blood component of Equines who are attaining the maximum titres of immunity. This process is lengthy and attained after a certain period of immunization of antigens prepared from venom of snakes, Scorpion and rabies virus into the bodies of equines. To complete such a batch-cycle it takes long period of 2-3 years, since during this period the hyper immune equine are bled and the venomous characteristics get neutralized phase wise in their bodies. Hence, no fresh batch is charged till further permission."

Point No 07: During visit industry representative reported as load the fresh batch on 11.2.2020 for the product of Anti Rabies – (Khoni Plasma)

Explanation:

Also please refer Point no.07, 08, 09 and point no.10 as attached herewith.

Ongoing through our explanation in the points of the letter referred above and referring it with the information given by our representative you will realize that the representative has explained and provided information of the same batch of Anti Rabies which is divided into various slots of the anti-rabies plasma last batch, which is derived out of the lot received for Anti Rabies from the Khoni unit in the month of September 2019 (Refer table at sr.no 10).

Page 1 of 2

Corporate Office
3rd Floor, Liberty Tower,
Behind Reliable Plaza,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3456
Fax : +91-22-4504 3200

R & D Centre
3rd Floor, Liberty Tower,
Behind Reliable Plaza,
Airoli, Navi Mumbai,
Pin - 400 708.
Tel. : +91-22-4504 3000
Fax : +91-22-4504 3200

Thane Factory
Plot No. A-371/372, Road No. 27,
Wagle Industrial Estate,
Thane (West), Pin - 400 604.
Tel. : +91-22-2582 2181, 2582 1399
+91-22-6797 7696
Fax : +91-22-2582 3640
E-mail : factory@bharatserums.com

Ambernath Factory
Plot No. K-27, Anand Nagar,
Additional M.I.D.C.,
Ambernath (East), Pin - 421 501.
Tel. : 0251-262 7000
Fax : 0251-262 7008
E-mail : ambernath@bharatserums.com

Warehouse
Building No. H-4, Premise No.1
Survey No. 15, Sonala Village,
Mumbai - Nasik Highway,
Taluka - Bhiwandi,
Dist. Thane. Pin - 421 302.
Tel. : +91-22-2663 026 / 27

15/2/2020
प्रदेशिक कार्यालय, कल्याण.
म.प्र.नि. संकुल,
सि.टी. विनयक संकुल,
सि.टी. मजला, ओक बाग
सि.टी. रोड, कल्याण (प).
जि. उरण



BHARAT SERUMS AND VACCINES LIMITED

(CIN : U24230MH1971PLC015134)

Registered Office : 17th Floor, Hoechst House, Nariman Point, Mumbai - 400021, India
 Tel. : +91-22-6656 0900 / 6656 0980 Fax : +91-22-6656 0933
 E-mail : corporate@bharatserums.com Website : www.bharatserums.com

Our batch was expected to complete by the end of December 2019, but due to some market demand it is prolonged for next 2-3 months, the same is informed in our letter 11/02/2020 at point no.09 and point no.10. (uploaded)

It seems that due to communicating gap the information you have considered the current segment of manufacturing as Fresh Batch.

This is for your information and clarification. You are therefore kindly requested to acknowledge the same and do the needful please.

Thanking You.

For Bharat Serums and Vaccines Ltd.

(Authorized Signatory)

Page 2 of 2

Corporate Office
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3456
 Fax : +91-22-4504 3200

R & D Centre
 3rd Floor, Liberty Tower,
 Behind Reliable Plaza,
 Airoli, Navi Mumbai,
 Pin - 400 708.
 Tel. : +91-22-4504 3000
 Fax : +91-22-4504 3200

Thane Factory
 Plot No. A-371/372, Road No. 27,
 Wagle Industrial Estate,
 Thane (West), Pin - 400 604
 Tel. : +91-22-2582 2181, 2582 1399
 +91-22-6797 7696
 Fax : +91-22-2582 3640
 E-mail : factory@bharatserums.com

Ambarnath Factory
 Plot No. K-27, Anand Nagar,
 Additional M.I.D.C.,
 Ambarnath (East), Pin - 421 501.
 Tel. : 0251-262 7000
 Fax : 0251-262 7008
 E-mail : ambarnath@bharatserums.com

Warehouse
 Building No. H-4, Premise No.1
 Survey No. 15, Sonate Village,
 Mumbai - Nasik Highway,
 Taluka - Bhiwandi,
 Dist. Thane, Pin - 421 302.
 Tel. : +91-22-2663 026 / 27

ANNEXURE -XV

M/s. Bharat Serums & Vaccines Ltd., K-27, Addl. MIDC Ambernath, Dist. Thane

JVS Results

Date	Standards	27.1.2016	19.12.2017	10.1.2018	13.8.2018	27.8.2018	7.10.2020
Parameter		Outlet	Other (primary Clarifier)	Outlet	Outlet	Outlet	Outlet
pH	5.5-9.0	6.9	8	7.3	7.3	6.8	8
BOD	100 mg/l	8	28	18	12	5	6
COD	250 mg/l	24	96	88	44	20	20
SS	100 mg/l	8	22	28	12	10	12
O & G	10 mg/l	BDL	BDL	BDL	BDL	BDL	BDL

M/s. Bharat Serums & Vaccines Ltd., K-27, Addl. MIDC Ambernath, Dist. Thane

JVS Results

Date	Standards	27.1.2016	19.12.2017	10.1.2018	13.8.2018	27.8.2018	7.10.2020
Parameter		Outlet	Other (primary Clarifier)	Outlet	Outlet	Outlet	Outlet
pH	5.5-9.0	6.9	8	7.3	7.3	6.8	8
BOD	100 mg/l	8	28	18	12	5	6
COD	250 mg/l	24	96	88	44	20	20
SS	100 mg/l	8	22	28	12	10	12
O & G	10 mg/l	BDL	BDL	BDL	BDL	BDL	BDL

ANNEXURE -XVI



केन्द्रीय प्रदूषण नियंत्रण बोर्ड
CENTRAL POLLUTION CONTROL BOARD
(पर्यावरण एवं वन मंत्रालय, भारत सरकार)
(MINISTRY OF ENVIRONMENT & FORESTS, GOVT. OF INDIA)

No.B-29012/ESS(CPA)/2015-16/

March 07, 2016

To

The Chairman
All the State Pollution Control Boards / Pollution Control Committees
(List Attached)

SUB: MODIFIED DIRECTIONS UNDER SECTION 18(1)(b) OF THE WATER (PREVENTION & CONTROL OF POLLUTION) ACT, 1974 and THE AIR (PREVENTION & CONTROL OF POLLUTION) ACT, 1981 REGARDING HARMONIZATION OF CLASSIFICATION OF INDUSTRIAL SECTORS UNDER RED / ORANGE / GREEN / WHITE CATEGORIES.

WHEREAS, under section 16 (2)(b) of the Water (Prevention and Control of Pollution) Act, 1974 and under Section 16 (2)(c) of the Air (Prevention & Control of Pollution) Act, 1981, one of the functions of the Central Pollution Control Board (CPCB), constituted under the Water (Prevention and Control of Pollution) Act, 1974, is to coordinate activities of the State Pollution Control Boards (SPCBs) and Pollution Control Committees (PCCs); and

WHEREAS, under section 16 (2)(c) of the Water (Prevention and Control of Pollution) Act, 1974 and under Section 16 (2)(d) of the Air (Prevention & Control of Pollution) Act, 1981, one of the functions of the CPCB is to provide technical assistance and guidance to SPCBs and PCCs; and

WHEREAS, it was brought to the notice of CPCB, that different SPCBs /PCCs were following different criteria for classification of industrial sectors under Red/Orange/ Green category and that classification was being used by the SPCBs/PCCs for grant of consents to industries and for Inventorization / surveillance of industries.

WHEREAS, the issue regarding classification of industries was deliberated upon in the 56th Conference of Chairmen & Member Secretaries of CPCB & SPCBs/PCCs held on August 31, 2010 and a working group comprising of representatives from SPCBs & CPCB was constituted to prepare a consolidated list of industrial sectors falling under Red/Orange/Green category to bring uniformity in classification of industrial sectors across the country;

'परिवेश भवन' पूर्वी अर्जुन नगर, दिल्ली-110032

'Parivesh Bhawan', East Arjun Nagar, Delhi - 110032

दूरभाष, Tel: 43102030, फॉक्स / Fax: 22305793, 22307078, 22307079, 22301932, 22304948

ई-मेल / e-mail: cpceb@nic.in, वेबसाइट / Website: www.cpceb.nic.in

WHEREAS, the report prepared by the Working Group was discussed in the 57th Conference of Chairmen & Member Secretaries of CPCB & SPCBs/PCCs held in Delhi on September 15, 2011, wherein some modifications were proposed;

WHEREAS, the final report of the working group was prepared, incorporating the suggestions/observations made in the 57th Conference of Chairmen and Member Secretaries of CPCB & SPCBs/PCCs and in exercise of the powers delegated to the Chairman, CPCB under Section 18(1)(b) of the Water Act, 1974, following directions were issued for compliance to all SPCBs/PCCs to maintain uniformity in categorization of industries as red, orange and green as per list finalized by CPCB, which identified 85 types of industrial sectors as 'Red', 73 industrial sectors as 'Orange' and 86 sectors as 'Green':

a). To maintain uniformity in categorization of industries under Red/Orange/Green category, the SPCBs /PCCs shall adopt the list as finalized by CPCB based on the recommendations of that Working Group for grant of Consent, inventorization of industries under Red, Orange and Green categories and other related activities.

(b). The SPCBs/PCCs shall revise the list of Red, Orange and Green categories of industries operating in their jurisdiction based on the criteria specified in the final report of that Working Group and submit the same to CPCB within 90 days in hard copy as well as soft copy;

WHEREAS, later-on, it was observed that the process of categorization thus far was primarily based on the size of the industries and consumption of resources and pollution due to discharge of emissions and effluents and its likely impact on health was not considered as primary criteria;

WHEREAS, there have been proposals from the SPCBs / PCCs and industrial associations for categorization of the industrial sectors in a more pragmatic manner. The issue was discussed during the national level conference of the Environment Ministers of the States, held in New Delhi during April 06-07, 2015 and also during the Conference of the Chairmen and Member Secretaries of CPCB and SPCBs/PCCs held in New Delhi on April 08, 2015. Accordingly, a 'Working Group' comprising of the Members from Central Pollution Control Board and State Pollution Control Boards representing the States of Andhra Pradesh, Punjab, Tamilnadu, West Bengal, Madhya Pradesh and Maharashtra, was constituted to revisit the criteria of categorization of industries and suggest rationale based on pollution potential for categorization of industrial sectors and adopting it for implementation of pollution control plan;

WHEREAS, the Working Group has developed the criteria of categorization of industrial sectors based on the concept of Pollution Index which is a function of the emissions (air pollutants), effluents (water pollutants), hazardous wastes generated and consumption of resources. For this purpose the references are taken from the the Water (Prevention and Control

of Pollution) Cess (Amendment) Act, 2003, Standards so far prescribed for various pollutants under Environment (Protection) Act, 1986 and Doon Valley Notification, 1989 issued by MoEFCC. The Pollution Index (PI) of any industrial sector is a number from 0 to 100 and the increasing value of PI denotes the increasing degree of pollution load from the industrial sector;

WHEREAS, based on the series of consultations with SPCBs, different Government / Non-government Institutions including industries and MoEFCC, the following criteria on 'Range of Pollution Index' for the purpose of categorization of industrial sectors has been finalized:

- o Industrial Sectors having Pollution Index score of 60 and above - Red category
- o Industrial Sectors having Pollution Index score of 41 to 59 -Orange category
- o Industrial Sectors having Pollution Index score of 21 to 40 -Green category
- o Industrial Sectors having Pollution Index score incl. & upto 20 -White category

WHEREAS, based on the revised criteria, the 'Final Report on Revised Categorization of Industrial Sectors under Red/Orange/Green/White' has been evolved. The 'Categorization' is based on the relative pollution potential of the industrial sectors and grouping of the industrial sectors based on the use of raw materials, manufacturing process adopted and pollutants likely to be generated;

WHEREAS, based on relative Pollution Index, the number of industries in various categories are as under :

- i. The Red category of industrial sectors: 60
- ii. The Orange category of industrial sectors: 83
- iii. The Green category of industrial sectors: 63 and
- iv. The Newly introduced White category: 36

WHEREAS, there shall be no necessity of obtaining the Consent to Operate" for White category of industries and an intimation to concerned SPCB / PCC shall suffice;

WHEREAS, the purpose of categorization is to ensure that the industry is established in a manner consistent with the environmental objectives and to prompt industrial sectors to adopt cleaner technologies, ultimately resulting in generation of no or minimum pollutants.

WHEREAS the new categorization system shall also facilitate in self-assessment by industries;

Now, therefore, in exercise of the powers delegated to the Chairman, CPCB under Section 18(1)(b) of the Water (Prevention & Control of Pollution) Act, 1974 and Section 18(1)(b) of the Air (Prevention & Control of Pollution), Act, 1981 the earlier Directions issued in June 2012 in the context of categorisation of industries as Red, Orange & Green are withdrawn with immediate effect and following 'Directions' are hereby issued for compliance by all SPCBs and PCCs :

1. That the SPCBs and PCCs shall adopt the Revised Criteria of categorization of industrial sectors as detailed in table nos. F1, F2, F3 and F4 and Revised Lists of Red, Orange, Green and White categories of industrial sectors, presented at table no. G2, G3, G4 and G5 respectively, in the 'Final Report' as attached herewith immediately.
2. That all pending applications for consideration of 'Consent to Establish' and 'Consent to Operate' and future such applications shall be processed as per revised criteria.
3. That the SPCBs and PCCs will provide the list of industries identified in each category existing in the State which have been considered for grant of consents. SPCBs/PCCs will forward the list of such industries before 31.05.2016 and the same will be uploaded on the websites of respective SPCB/PCC.
4. That the 'Revised Lists of Red, Orange, Green and White category of industrial sectors' shall be used by the SPCBs and PCCs for Consent Management and inventorization of industries under Red, Orange, Green and White categories. Siting of industries shall be only in conforming areas. SPCBs / PCCs shall evolve sector specific plans for control of pollution and industrial surveillance for verifying compliance.
5. That the SPCBs and PCCs shall revise /prepare the inventory of Red, Orange, Green and White categories of industries operating in their jurisdiction based on the revised criteria specified in the Final Report and submit the same to CPCB within 90 days i.e., before 30.05.2016 in hard copy as well as soft copy.
6. That the listed category of industries or those identified later-on under different categories shall not be linked to sanction of loan /finance or bank proceedings.
7. That any further addition of any new or left-over industrial sector and their categorization which is not listed in the revised list of Red, Orange, Green and White industrial sectors, shall be done at the level of concerned SPCB /PCC following revised criteria & guidelines as detailed in the attached document and no concurrence of CPCB shall normally be required. It is further clarified that while categorizing the industries, fractional numbers shall be rounded off to nearest integer.

The SPCBs/PCCs shall acknowledge the receipt of directions and submit the 'Action Taken Report' in compliance with these directions to CPCB before 15.04.2016.

(Arun Kumar Mehta)
Chairman
7/3/16

Copy to:

1. The Chief Secretary of all the States and UTs
2. The Secretary ,
Ministry of Micro, Small and Medium Entrepreneurs
Udyog Bhawan, Rafi Marg, New Delhi - 110 011
3. The Secretary ,
Ministry of Heavy Industries
Udyog Bhawan, Rafi Marg, New Delhi - 110 011
4. The Secretary,
Ministry of New and Renewable Energy
Block-14, CGO Complex,
Lodhi Road, New Delhi-110 003,
5. The Advisor(CP Division)
Ministry of Environment ,Forests and Climate Change
Indira Paryavaran Bhawan
Jor Bagh Road, New Delhi - 110 003
6. All Zonal Offices of CPCB

(A. B. Aklkar) S.S./
Member Secretary

ANNEXURE -XVII

Visit Report

Name & Address of the Industry	M/s. Bharat Serum & Vaccines Ltd., Plot No. K-27 & K-27/1, Addl. MIDC Ambernath, Dist. Thane
Consent Status	No. MPCB/19/466/1909000025, dtd.03/09/2019, valid up to 30/06/2022
Products	1) Injections & Vaccines (only formulation) – 20.0 Lakh/M 2) Analytical Testing and R&D activity at Plot No. K-27/1 3) r-FSH (Recombinant - Follicle Stimulating Hormone) – 0.009 Kg/A 4) r-HCG (Recombinant - Human Chronic Gonadotropin) – 0.105 Kg/A 5) mAnti-D (Monoclonal Anti Rho-D Immunoglobulin) – 0.3 Kg/A
Industrial Effluent	216.0 CMD (100% Recycle / Reuse)
Domestic Effluent	26.0 CMD
Date of Visit	07/10/2020

Observation:

- 1) During the visit manufacturing activity was not in operation however plant Cleaning, Validation of manufacturing area & maintenance activities were observed.
- 2) Consented water consumption is 243 CMD, however at present water consumption for the month of Aug. 2020 is 5110 M³/M (170 CMD) as per MIDC water bill.
- 3) Industry has provided Effluent Treatment Plant comprises of bar screen, collection tank, primary secondary tank followed by aeration and membrane bio-reactor (MBR), sludge dewatering centrifuge etc.
- 4) During the inspection provided ETP found in operation and treated effluent recycle / reusing in cooling tower. The ETP is operated on SCADA system.
- 5) Overflow of cooling tower is taken to ETP through storm water drain.
- 6) Joint vigilance sample of ETP inlet and outlet collected in presence of industry's representative.
- 7) Industry is having total 5 nos. of cooling towers having capacity 170 TR (2 nos.), 200 TR, 190 TR & 20 TR and total water requirement for these cooling towers is 107 CMD out of this 94 CMD treated effluent water is used and 13 CMD fresh water charged.
- 8) Industry not provided proper leachate collection arrangement at ETP sludge dewatering system.
- 9) At present generated domestic effluent is treated in the existing ETP. The Board has issued Conditional Restart Directions on 21/08/2020 with condition that industry shall provide separate sewage treatment plant on or before 31/12/2020. Accordingly, industry has issued work order for the provision of 50 KLD STP, on 11/09/2020.
- 10) Industry has provided LDO fired boiler having capacity 3 T alongwith stack of height 30 meter. Industry has provided D.G. Set of 750 KVA.
- 11) Industry is regularly monitoring ambient air quality and stack monitoring through NABL approved laboratory.
- 12) There is generation of hazardous waste in the form of 35.3 – ETP sludge, 28.1 – Process Residue & Wastes (generated during ultrafiltration process), 28.5 – Date expired products, 37.2 – Flue gas cleaning residue, which is disposed through CHWTSDF.

Handwritten signature and date: 07/10/2020

Handwritten signature and date: 07/10/2020

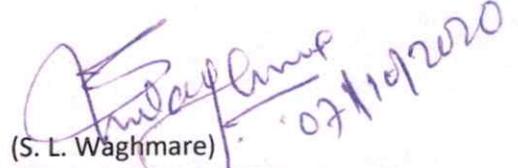
...2..
Handwritten signature and date: 07/10/2020

:2:

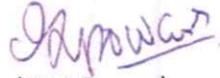
- 13) Last disposal of Hazardous waste 28.1 in the tune of 1607 Kg & 35.3 in the tune of 253 kg through MWML on 20/08/2020.
- 14) Industry has obtained Bio-Medical Waste Authorization vide No. SRO Kalyan-II/BMW_AUTH/1908000179-2019, dtd. 26/09/2019 valid up to 08/08/2022, for generation and segregation of Bio-medical waste i.e. expired plasma which is disposed through Mumbai Waste Management Ltd.
- 15) Industry has submitted Form- on 10/06/2020 & Form-V on 30/09/2020.



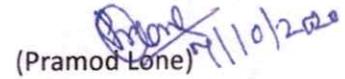
(R. G. Rathod)
Ex. Engg. MIDC Ambernath



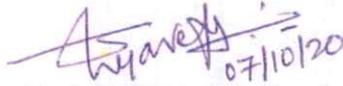
(S. L. Waghmare)
Regional Officer, MPC Board, Kalyan



(S. V. Powar)
Depty. Engg. Addl. MIDC Ambernath
seen on dt. 07/10/2020



(Pramod Lone)
Field Officer, MPC Board, SRO Kalyan-II



(Prajwal Rayandekar)
Asst. Manager-EHS