



GPCB BMW ID: 367461

24th June 2019

To,
The Member Secretary
Gujarat Pollution Control Board
Sector 10 A
GANDHINAGAR-382 043

Dear Sir,

**Sub: Submission of returns regarding disposal of
Bio-Medical Wastes for the year 2018**

We are enclosing herewith the returns regarding disposal of Bio-Medical Wastes for the year 2018 (January to December) as per Form - IV (Rule 13) of Bio Medical Wastes Rules.

We hope you will find the same in order.

Thank you.

Yours faithfully
For Sanofi India Limited

AUTHORIZED SIGNATORY

Encl:

1. Annual report : Form IV & XGN statement.
2. Annexure I : BMW generation & disposal statement.
3. Annexure II : Membership certificate of
M/s Globe Bio care, Ankleshwar
4. Annexure III : Copy of BMW authorization.

CC : The Regional Officer, GPCB, Ankleshwar

Gujarat Pollution Control Board
Head Office
Sector No. 10-A,
Gandhinagar-382010.



GPCB BMW ID: 367461

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Received
Gujarat Pollution Control Board
RO Ankleshwar
26/6/19



ANNUAL REPORT (2018)

[TO be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

Sr No:	Particulars	
I.	Particulars of the Occupier	
(i)	Name of the authorized person :	Dr. Mahesh Mistry
(ii)	Name of HCF or CBWTF :	Sanofi India Ltd (Formally Aventis Pharma Limited)
(iii)	Address for Correspondence :	Plot No. 3501, 3503-15, 6310B-14, GIDC Estate, Ankleshwar-393002, Dist: Ankleshwar, Tal: Ankleshwar
(iv)	Address of Facility :	Globe Bio Care (CBWTF-Incinerator) P.no. 144/B, GIDC Sachin, Surat, Dist: GIDC Ankleshwar-394230
(v)	Tel. No. Fax. No.:	9426748449
(vi)	E-mail ID :	
(vii)	URL or Website :	
(viii)	GPS coordinates of HCF or CBWTF:	Leti: , Long:
(ix)	Ownership of HCF or CBWTF :	Private
(x)	Status of Authorization under BMW Rules:	Auth No: BMW-328040, Valid Upto: 4/12/2019
(xi)	Status of Consent under Water, Air Act :	Consent No: , Valid Upto:

Type of Health Care Facility

2	(i) Bedded Hospital	4
2	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	ANA-Anaesthesiology
2	(iii) License number and its date of expiry	BMW-328040 valid till 12/04/2019

Quantity of waste generated or disposed in Kg per annum (on monthly average basis)

4	(i) Yellow Category	4.243
4	(ii) Red Category	5.231
4	(iii) White Category	0.339
4	(iv) Blue Category	2.053

Details of the Storage, treatment, transportation, processing and Disposal Facility

5	(i) Details of the on-site storage facility	NA
5	(ii) Treatment Facility	NA
5	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of waste in Kg per annum	NA
5	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which waste are disposed of	Globe Bio Care (CBWTF-Incinerator)

BMW management committee

6	Do you have bio-medical waste management committee ? If yes, attach minutes of the meetings held during the reporting period.	Yes Hard copy of minutes attached with annual report
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Details trainings conducted on BMW

7	(i) Number of trainings conducted on BMW Management	1
7	(ii) Number of Personnel trained	5
7	(iii) Number of personnel trained at the time of induction	15
7	(iv) Number of personnel not undergone any training so far	0



ANNUAL REPORT (2018)

7	(v) Whether standard manual for training is available	Yes
Details of the accident occurred during the year		
8	(i) Number of Accident occurred	0
8	(ii) Number of the persons affected	0
8	(iii) Remedial Action taken (Please attach details if any)	NA
8	(iv) any Fatality Occurred . details	NA
9	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met No. the standards?	Not applicable
9	Details of Continuous online emission monitoring systems installed	NA
10	Liquid waste generated and treatment methods in place . How many times you have not met the standards in a year	0
11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	Not applicable
12	Any other relevant information	New factory medical officer appointed Dr. Moin Patel full time

Certified that the above report is for the period from

Date: 22/06/19
Place: Ankleshwar

Name and Sign of The Head of HCF

Dr. Mahesh Mistry

for
MCD
22/06/2019

Annexure - I

BIO MEDICAL WASTE DISPOSAL DATA FOR THE PERIOD JANUARY-18 TO DECEMBER -19

Sr.No	Waste Description		Waste Category	Unit	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Total
	Type of Waste																
1	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components. (d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc. (g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Yellow	Kgs	0.058	0.355	0.124	0.136	0.255	0.613	0.137	1.34	0.119	0.246	0.72	0.14		4.243
2	Contaminated Waste (Recyclable) : (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacuometers with their needles cut and gloves.	Red	Kgs	0.065	0.268	0.126	0.245	0.037	0.285	0.26	2.345	0.375	0.515	0.335	0.375		5.231
3	Waste sharps including Metals: Needles, syringes, with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	White (Translucent)	Kgs	0.016	0.016	0.004	0.014	0.016	0.015	0.021	0.134	0.044	0.035	0.013	0.011		0.339
4	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Blue	Kgs	0.021	0.099	0.016	0.026	0.01	0.089	0.261	0.808	0.359	0.28	0.074	0.01		2.053

SIGNATURE & NAME:

HSE

Manoj Kumar
Manoj Kumar





Membership Certificate

*This is to certify that Sanofi India Ltd. Occupational Health Center
Located at 3501, 3503-15, 6310 B-1A, GIDC Estate, Post Box No.
136, Ankleshwar is enrolled as a member for Biomedical Waste
Management, at our Common Biomedical Waste Treatment Facility
located at plot no.144/B, G.I.D.C., Ankleshwar, Bharuch.*

*They have agreed to give Biomedical Waste generated from their
unit, at our disposal facility as per Biomedical (M & H) rules and
pay the charges for the same.*

Membership Code: IN0031

No. Of beds: 04

Valid Upto: 31/12/2022

For,

Globe Biocare

General Manager

Place: Ankleshwar

Date: 01/01/2018

Note: Please send an application for fresh certificate 15 days before expiry date.

**BMW AUTHORIZATION FORM-III(Rule 10)**

Gujarat Pollution Control Board
Cleaner Tech. Development Centre Bldg
(ARAIL), 1st Flr, Plot # 1501- GIDC Estate,
Ankleshwar 393002

Sanofi India Ltd (Formally Aventis Pharma Limited) (
367461)

Under the Rule-10 of the Biomedical waste (Management and Handling) Rules, 2016 framed under the EPACT'86

Authorization for operating a facility for Collection, Disposal OR destruction use, Storage, Transportation of biomedical wastes.

BMW AUTH NO : BMW-346582. VALID UPTO : 12/04/2024

PCB Id : 14948

Application Inward No : 51155, Date: 19/03/2019

BMW Id : 367461

CCA No: BW-35663 (12/04/2024)

File No : BRCH-297, (Out No : 15430)

No of Beds : 4,

Investment (in lakh) : 71.00,

Act : B,W

No of H.W : 0,

Water Consumption (klpd) : 1.00,

Scale : S

In exercise of power conferred by this Board and after scrutiny of above referred application, Superintendent/ Incharge of Sanofi India Ltd (Formally Aventis Pharma Limited) at Plot No. 3501, 3503-15, 6310B-14, GIDC Estate, Ankleshwar Tal : Ankleshwar Dist : Ankleshwar is here by granted an Authorisation to operate Health Care facility for Collection, Disposal OR destruction use, Storage, Transportation of biomedical wastes on the premises of M/S. Globe Bio Care (CBWTF-Incinerator) situated at P.no. 144/B, GIDC Sachin, Surat Dist : GIDC Ankleshwar Under CBWTF Reg. No : IN0031, Valid Upto :

1. The Authorisation is granted for 4 nos. of beds with generation of

Type of Waste Category (Kgs/Month)	YELLOW	WHITE (Translucent)	RED	BLUE
Qty permitted for Handling	2.00	0.50	1.00	0.50

category of biomedical wastes. (Unit - Kgs/Month)

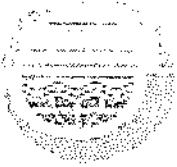
2. This BMW Authorisation shall be in force for a period of (5 year, Valid Upto 12/04/2024)

This CCA Authorisation shall be in force for a period of 5 year [up to 12/04/2024]

3. This Authorisation is subject to the conditions stated in the Annexure-I attached here with and to such other conditions as may be specified in the Rules for the time being in force under the Environment (Protection) Act 1986.

4. The authorization shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.

5. The authorization or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.



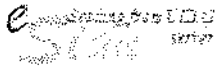
BMW AUTHORIZATION FORM-III(Rule 10)

Gujarat Pollution Control Board
Cleaner Tech. Devlpmt Centre Bldg
(ARAIL), 1st Flr, Plot # 1501- GIDC Estate,
Ankleshwar 393002

Sanofi India Ltd (Formally Aventis Pharma Limited) (
367461)

Under the Rule-10 of the Biomedical waste (Management and Handling) Rules, 2016 framed under the EPACT'86

6. The person authorised shall not rent, lend, sell, transfer or otherwise transport the biomedical waste without obtaining prior permission of the prescribed authority.
7. Any unauthorised changes in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
8. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.


Digitally signed by Sanofi India Ltd
14-01-1966

14-01-1966
e-Signed On 16/04/2019 19:32:37
(Organic Authentication on AADHAR from UIDAI Server)
TPAV # L74K5RVWGF

For & On behalf of
Gujarat Pollution Control Board

R.O Head: Ankleshwar

Remark: -

Specific Condition :

Encl.: Annexure-I

Issued to , Dr. Mahesh Mistry, Sanofi India Ltd (Formally Aventis Pharma Limited), Plot No. 3501,
3503-15, 6310B-14, GIDC Estate , Ankleshwar Tal :Ankleshwar Dist :Ankleshwar (BMW Id:
367461)

Copy to Regional Office - Ankleshwar/ H.O

With a request to carry out periodically monitoring of above said hospital/clinic and submit the visit report
to this Office.

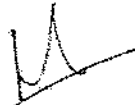
Bio Waste Management Committee Meeting

Date	16 Oct 18	Members Present	Dr. Moin Patel- Factory Medical Officer Kaushal Darji – Asst. Manager - OHC Girish Purohit – Manager – Environment & Regulatory Compliance Rajendra Mahadik – Asst. Manager - HSE
Time	09:30 am to 10:00am	Location	Occupational Health Centre

Sr. No.	Agenda discussed
1	Regular update of Bio Medical Waste Data in the website link
2	Reviewed segregation of Bio Medical Waste according to categories



Kaushal Darji



Dr. Moin Patel



Rajendra Mahadik



Girish Purohit

O/c

19th July 2019

Lr. No: SBL / Medchal / TSPCB/ BMW - Form IV / 2018 /07

To

The Environmental Engineer
TS Pollution Control Board
RR – II, Begampet
Hyderabad

Dear Sir,

Sub: Form IV - Bio medical waste Annual Report - 2018 – reg.

We are herewith enclosing the duly filled in Form – IV, with respect to Bio medical waste Annual report for the period of from January 2018 to December 2018.

Kindly acknowledge the receipt of the same.

Thanking you,

Yours faithfully,
For Shantha Biotechnics Private Limited


D. Madhavi
DGM - HSE

Encl: As above
CC: Member Secretary- TSPCB, Sanathnagar, Hyderabad.



Shantha Biotechnics Private Limited

Corp. Off. : Vasantha Chambers, 3rd & 4th Floor, 5-10-173, Fateh Maidan Road, Basheerbagh, Hyderabad - 500 004, T.S., INDIA.
Tel.: +91 40 6630 1000 - Fax: +90 40 2323 4133 - Email: info@shanthabiotech.co.in

Plant : Post Box No. 4, Medchal - 501 401, Hyderabad, T.S., INDIA.
Tel.: +91- 8418-220922, 220693/4/5 - Fax:+91- 8418-220656

www.shanthabiotech.com

**From –IV
(See rule 13)
Annual Report**

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the Occupier of Health Care Facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

Sl.No	Particulars	
1.	Particulars of the Occupier	:
	(i) Name of the authorized person (occupier or operator of facility)	: Rajasekar Narayanasamy
	(ii) Name of HCF or CBMWTF	: Shantha Biotechnics Private Limited.
	(iii) Address for Correspondence	: Post box No. 4, Medchal, Hyderabad, Telangana State.
	(i) Address of Facility	Sy. No. 274,18, 226, 227, 238, 239, 240 & 273 (Part), Athvelliu (V), Medchal ,Medchal Malkajgiri District, Telangana State, India.
	(ii) Tel. No. Fax. No.	: 0000005303
	(V) E-mail ID	: Satyajagadish.pesala@sanofi.com
	(i) URL of Website	:
	(ii) GPS coordinates of HCF of CBMWTF	Latitude : 17.648201 Longitude: 78.494068
	(iii) Ownership of HCF of CBMWTF	Private
	(iv) Status of Authorization under the Bio-Medical Waste (Management and Handing) Rules.	: Authorization No. TSPCB / BMWA/RR-II-61/2016- 125 Date: 10.04.2017 Valid up to...31.07.2019 Copy enclosed as annexure
	(v) Status of Consents under Water Act and Air Act.	: Valid up to:31.12.2020
2.	Type of Health Care Facility	: Manufacturing of Human Vaccines (Bio process)
	(i) Bedded Hospital	: Not applicable
	(ii) Non-Bedded Hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	: Manufacturing unit & Research institute.
	(iii) License number and its date of expiry.	: Consent Order No.: 310 -RR-II/TSPCB/ZOH/CFO/2016- 7033 Dated: 07.01.2016 Valid up to : 31.12.2020 Copy enclosed as annexure
3.	Details if CBMWTF	: GJ Multiclave (India) Pvt. Ltd.,
	(i) Number healthcare facilities covered by CBMWTF	: Not applicable
	(ii) No. of beds covered by CBMWTF	: Not applicable
	(iii) Installed treatment and disposal capacity of CBMWTF	: Not applicable
	(iv) Quantity of biomedical waste treated or disposal by CBMWTF	: Not applicable
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	: Yellow category: Enclosed Annexure Red Category: Enclosed Annexure White: Enclosed Annexure Blue Category: Enclosed Annexure General Solid waste :Enclosed Annexure
5.	Details of the Storage , treatment, transportation, processing and Disposal Facility	
	(i) Details of the on-site storage facility	: Size : Dedicated storage facility is available (10' X10' room) Capacity: (10' X10' room) Provision of on-site storage : cold storage cabinet is available on site.

	(ii) Disposal Facilities	: Type of treatment Equipment No of Units Capacity Kg/day Quantity treated or disposed In Kg per Annum Incinerators Plasma Paralysis Autoclaves : 26 No. Autoclaves are available on site Microwave Hydroclave Shredder Needle tip cutter or Destroyer : 4 No. available on site Sharps encapsulation or concrete pit Deep Burial pits: Chemical disinfection: Chemical disinfection SOPs are available on site. Any other treatment equipment: ---
	(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	: All categories of biomedical waste disposing to authorized third party (GJ Multiclave) only.
	(iv) No of vehicles used for collection and transportation of biomedical waste.	: Collection & transportation of biomedical waste is under authorized third party responsibility.
	(v) Details of incineration ash and ETP sludge generated and disposal during the treatment of wastes in Kg per annum)	Not applicable
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	: GJ Multiclave (India) Pvt. Ltd.,
	(vii) List of member HCF not handed over bio-medical waste.	: Not applicable
6.	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period.	: Not applicable
7.	Detail trainings conducted on BMW	
	(i) Number of training conducted on BMW Management.	05 times
	(ii) Number of personnel trained	Approximately 250 members
	(iii) Number of personnel trained at the time of induction	Approximately 50 members
	(iv) Number of personnel not undergone any training so far.	0
	(v) Whether standard manual for training is available ?	Yes, Site SOPs are available
	(vi) Any other information)	Exposure control plans (ECPs) are available for the individual organism, which are being handled in production.
8.	Details of the accident occurred during the year	NIL
	(i) Number of Accidents occurred	NIL
	(ii) Number of the persons affected	NIL
	(iii) Remedial Action taken (Please attach details if any)	NIL
	(iv) Any Fatality occurred, details.	NIL
9.	Are you meeting the standards of air Pollution from the incinerator?. How many times in last year could not met the	Not applicable

	standards?	
	Details of Continuous online emission monitoring systems installed	Not applicable
10.	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year.	Zero Liquid Discharge (ZLD) system is established on site to treat the liquid waste.
11.	It the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	Meeting the log 4 standards. No deviation on site so far.
12.	Any other relevant information	Applied for renewal of Biomedical waste authorization.

Certified that the above report is for the period from January 2018 to December 2018

D. Madhavi 
Name and Signature of the Head of the Institution

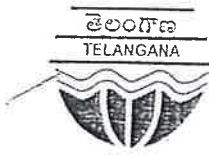
Date: 19.07.2019
Place: Hyderabad
Medchal

SHANTHA BIOTECHNICS PRIVATE LIMITED
Medchal

Disposal status of Bio-Medical waste to Authorised third party-year 2018

Sl. No.	MONTH	Description/Category of waste	Disposed quantity in KG	Disposed Qty. in Kg To GJ Multiclave (India) Pvt. Ltd.,
1	January	Dead animals, used syringes, sharps & Plastics	2140	13019
2		Cell debris	2352	
3		Corn cob	4990	
4		Hepa filters	3008	
5		Expired chemicals	529	
6	February	Dead animals, used syringes, sharps & Plastics	2266	16436
7		Cell debris	789	
8		Corn cob	9540	
9		Hepa filters	379	
10		Expired chemicals	3482	
11	March	Dead animals, used syringes, sharps & Plastics	2107	17346
12		Cell debris	0	
13		Corn cob	13395	
14		Hepa filters	274	
15		Expired chemicals	1570	
16	April	Dead animals, used syringes, sharps & Plastics	2529	19113
17		Cell debris	0	
18		Corn cob	16325	
19		Hepa filters	0	
20		Expired chemicals	259	
21	May	Dead animals, used syringes, sharps & Plastics	2600	17267
22		Cell debris	0	
23		Corn cob	12780	
24		Hepa filters	23	
25		Expired chemicals	1864	
26	June	Dead animals, used syringes, sharps & Plastics	2374	15540
27		Cell debris	0	
28		Corn cob	10765	
29		Hepa filters	18	
30		Expired chemicals	2383	
31	July	Dead animals, used syringes, sharps & Plastics	3162	20410
32		Cell debris	0	
33		Corn cob	15140	
34		Hepa filters	731	
35		Expired chemicals	1377	

Sl. No.	MONTH	Description/Category of waste	Disposed quantity in KG	Disposed Qty. in Kg To GJ Multiclave (India) Pvt. Ltd.,
36	August	Dead animals, used syringes, sharps & Plastics	2752	17998
37		Cell debris	0	
38		Corn cob	14040	
39		Hepa filters	134	
40		Expired chemicals	1072	
41	September	Dead animals, used syringes, sharps & Plastics	3610	19707
42		Cell debris	1650	
43		Corn cob	11950	
44		Hepa filters	2150	
45		Expired chemicals	347	
46	October	Yellow Category	13792	25741
47		Red Category	5557	
48		White Category	4295	
49		Blue Category	1761.7	
50		Expired chemicals	335	
51	November	Yellow Category	20606	30427
52		Red Category	6039	
53		White Category	22	
54		Blue Category	393	
55		Expired chemicals	2517	
56		Paper waste (Controlled labells)	850	
57	December	Yellow Category	14813	19600
58		Red Category	4618	
59		White Category	2.38	
60		Blue Category	166	
61		Expired chemicals	1	
TOTAL			232624	232624



Order No.TSPCB /BMWA /RR-II -61 /2016 -125

Date:10.04.2017

RENEWAL OF AUTHORISATION

(Issued under Rule 10 of the Bio-Medical Waste Management Rules, 2016)

Whereas in pursuance of the application of M/s. Shantha Biotechnics Pvt. Ltd., Sy. No. 274 , 18, 226, 227, 238, 239, 240 & 273 (Part), Athvelli (V), Medchal (M), Rangareddy District seeking authorization under Bio Medical Waste Management Rules, 2016, the R.O, Rangareddy - II inspected the premises on 01.07.2016 and after careful scrutiny of application and verification report of the inspecting Officer, this renewal of authorization for generation, segregation and safe-disposal of Bio-Medical Waste is issued to M/s. Shantha Biotechnics Pvt. Ltd., Sy. No. 274 , 18, 226, 227, 238, 239, 240 & 273 (Part), Athvelli (V), Medchal (M), Rangareddy District subject to the terms and conditions mentioned in the Schedule - A & Schedule - B attached to this authorization.

This renewal of authorization is valid upto 31.07.2019 for Production of Human Vaccines, Animal House and R & D unit.

Hyderabad,
Dated:10.04.2017

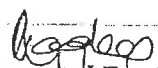
Sd/-
**MEMBER SECRETARY &
PRESCRIBED AUTHORITY**

To
M/s. Shantha Biotechnics Pvt. Ltd.,
Sy. No. 274 , 18, 226, 227, 238, 239, 240 & 273 (Part),
Athvelli (V), Medchal (M),
Rangareddy District.

N.B:

This authorization shall be exhibited in the above premises and should be produced from time to time at the request of the Inspecting Officer.

// T.C.F.B.O //


Senior Environmental Engineer
(Unit - III)

7. The Mercury spillage / losses due to breakage of thermometers, pressure and other measuring equipment in Health Care Establishments shall be collected stored and shall be disposed in accordance with the respective rules and regulations.
8. The occupier of HCE shall take all necessary measures to ensure that the spilled mercury does not become part of bio-medical or other solid waste generated from the HCE.
9. The Bio Medical Waste shall be disposed for treatment after disinfection and segregation to one of the following Common Bio-Medical Waste Treatment Facility:

M/s. GJ Multiclave (India) Pvt., Or M/s. Medicare Environmental Management Ltd., Sy.No. 179 & 181, Eadulapally (V), Kothur (M), Mahaboobnagar district. Pvt., Ltd., Sy.No.619, Isnapur (V), Patancheru (M), Medak district.

M/s. ASE & Co, Sy.No. 63/1, Or M/s. Sattva Global Services Pvt Ltd., Plot No. Maddur (V), Narasapur(M), 36/B, Biotech Park, Phase-III, Karakapatla (V), Medak district Mulugu (M), Medak Dist.

10. No Health Care Establishment shall establish on-site treatment and disposal facility or operate an incinerator without specific authorisation of the Prescribed Authority.
11. Under no circumstances shall incinerable waste (categories 1,2, 6) of the Schedule I of the Rules of 2016 of any kind be openly burnt anywhere.
12. The effluents generated from the Health Care Establishment shall conform to the standards for liquid waste as prescribed in schedule-II of Bio-Medical Waste Management Rules, 2016.
13. The applicant shall make an application for renewal of authorisation under Bio-Medical Waste Management Rules, 2016 at least 60 days before the date of expiry of this order, along with prescribed fee.
14. The applicant shall obtain Consents for Operation (CFO) from TSPCB, as required Under Sec.25/26 of the Water (P&C of P) Act, 1974 and under sec. 21/22 of the Air (P&C of P) Act, 1981.
15. The HCE should provide adequate fire protection equipment (such as smoke detectors, fire extinguishers, sand bucket, fire alarm, water sprinklers etc) at salient places within the HCEs even at Bio Medical Waste storage area, in accordance with fire safety regulations and the HCE should obtain certificate from fire department.
16. The HCE shall follow all the conditions stipulated by Central Pollution Control Board (CPCB), wherever Sharp Blaster (needle blaster) is provided for treatment of Bio Medical Waste (BMW) category no.4 (i.e., waste sharps), listed under schedule-I of Bio Medical Waste Management Rules, 2016.
17. This order is issued without any prejudice to the case in W.P. No. 19727 of 2016 & 19821 of 2016 pending before the Hon'ble High Court, Hyderabad.

ANY CONTRAVENTION OF THE CONDITIONS OR DIRECTIONS OF AUTHORISATION WILL ATTRACT PROSECUTION UNDER THE PROVISIONS OF THE ENVIRONMENT (PROTECTION) ACT, 1986

Sd/-
MEMBER SECRETARY &
PRESCRIBED AUTHORITY

To
M/s. Shantha Biotechnics Pvt. Ltd.,
Sy. No. 274, 18, 226, 227, 238, 239, 240 & 273 (Part),
Athvelli (V), Medchal (M),
Bangarooddy District.



GJ Multiclave (India) Pvt. Ltd.

7-1-47/1/A, D.K. Road, Ameerpet, Hyderabad - 500 016.

Ph : 23756925, 65556926. E-mail : service@gjmulticlave.com

Web Site : www.gjmulticlave.com

Service Certificate

This is to certify that M/s. SHANTHA BIOTECHNICS PVT.LTD. ATUVELLY MEDICAL HYDRABAD.

Hospital / Nursing Home / Industry is a member of **GJ Multiclave (India) Pvt. Ltd.**
bearing Registration No. GJ/ 3 / 114 GJ Multiclave is providing bio-medical waste
management service to the industry from 01st July 2019 and the certificate is
valid upto 30th JUNE 2020

DIRECTOR



MANAGING DIRECTOR

O/c

19th July 2019

Lr. No: SBL/TSPCB/ BMW/MRP - Form IV/ 2017/10

To

The Environmental Engineer
Telangan a State Pollution Control Board
Regional Office - II
RC Puram
Medak Dist.

Dear Sir,

Sub: Form IV - Bio medical waste Annual Report –2018, Muppireddypally – reg.

We are herewith enclosing the duly filled in Form – IV, with respect to Bio medical waste Annual report for the period of from January 2018 to December 2018.

Kindly acknowledge the receipt of the same.

Thanking you,

Yours faithfully,
For Shantha Biotechnics Private Limited



D Madhavi
DGM - HSE

Encl: As above

CC: Member Secretary- TSPCB, Sanathnagar, Hyderabad.



Shantha Biotechnics Private Limited - SEZ

Corp. Off. : Vasantha Chambers, 3rd & 4th Floor, 5-10-173, Fateh Maidan Road, Basheerbagh, Hyderabad - 500 004, T.S., INDIA.
Tel.: +91 40 6630 1000 - Fax: 91 40 2323 4133 - Email: info@shanthabiotech.co.in

Plant : Survey No.354, Muppireddypally Village, Manoharabad Mandal, Medak District - 502 236, T.S., India.
www.shanthabiotech.com

**From –IV
(See rule 13)
Annual Report**

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the Occupier of Health Care Facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

Sl.No	Particulars	
1.	Particulars of the Occupier	:
	(i) Name of the authorized person (occupier or operator of facility)	: Rajasekar Narayanasamy
	(ii) Name of HCF or CBMWTF	: Shantha Biotechnics Private Limited.
	(iii) Address for Correspondence	: Sy. No. 354, Muppireddypally Village, Toopran Mandal, Medak District, Telangana State, India.
	(i) Address of Facility	: Sy. No. 354, Muppireddypally Village, Toopran Mandal, Medak District, Telangana State, India.
	(ii) Tel. No. Fax. No.	: 9989065383
	(V) E-mail ID	: Satyajagadish.pesala@sanofi.com
	(i) URL of Website	:
	(ii) GPS coordinates of HCF of CBMWTF	: Latitude : 17.741435 Longitude: 78.482168
	(iii) Ownership of HCF of CBMWTF	: Private
	(iv) Status of Authorization under the Bio-Medical Waste (Management and Handing) Rules.	: Order No. 23/TSPCB/RO/RCPM/BMWA/2018-74 Date : 04.05.2018. Valid up to 30.04.2023 Copy enclosed as annexure
	(v) Status of Consents under Water Act and Air Act.	: Valid up to:31.12.2021
2.	Type of Health Care Facility	: Manufacturing of Human Vaccines (Bio process)
	(i) Bedded Hospital	: Not applicable
	(ii) Non-Bedded Hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	: Manufacturing unit
	(iii) License number and its date of expiry.	: Authorization No. TSPCB/ZO/RCP/RCPM/250/W&A/2016-883 Dated 18.10.2016 Valid up to : 31.12.2021 Copy enclosed as annexure
3.	Details if CBMWTF	: M/s. Dharma & Co,
	(i) Number healthcare facilities covered by CBMWTF	: Not applicable
	(ii) No. of beds covered by CBMWTF	: Not applicable
	(iii) Installed treatment and disposal capacity of CBMWTF	: Not applicable
	(iv) Quantity of biomedical waste treated or disposal by CBMWTF	: Not applicable
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	: Yellow category: Enclosed Annexure Red Category: Enclosed Annexure White: Enclosed Annexure Blue Category: Enclosed Annexure General Solid waste :Enclosed Annexure
5.	Details of the Storage , treatment, transportation, processing and Disposal Facility	
	(i) Details of the on-site storage facility	: Size : Dedicated storage facility is available (10' X10' room) Capacity: (10' X10' room)

	(ii) Disposal Facilities	: Type of treatment Equipment No of Units Capacity Kg/day Quantity treated or disposed In Kg per Annum Incinerators Plasma Paralysis Autoclaves : 2 No. Autoclaves are available on site Microwave Hydroclave Shredder Needle tip cutter or Destroyer : 3 No. available on site Sharps encapsulation or concrete pit Deep Burial pits: Chemical disinfection: Chemical disinfection SOPs are available on site. Any other treatment equipment:
	(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	: All categories of biomedical waste disposing to authorized third party (Dharma & Co) only.
	(iv) No of vehicles used for collection and transportation of biomedical waste.	: Collection & transportation of biomedical waste is under authorized third party responsibility.
	(v) Details of incineration ash and ETP sludge generated and disposal during the treatment of wastes in Kg per annum)	Not applicable
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	: Dharma & Co,
	(vii) List of member HCF not handed over bio-medical waste.	: Not applicable
6.	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period.	: Not applicable
7.	Detail trainings conducted on BMW	
	(i) Number of training conducted on BMW Management.	03 times
	(ii) Number of personnel trained	Approximately 50 members
	(iii) Number of personnel trained at the time of induction	Approximately 20 members
	(iv) Number of personnel not undergone any training so far.	0
	(v) Whether standard manual for training is available ?	Yes, Site SOPs are available
	(vi) Any other information)	Exposure control plans (ECPs) are available for the individual organism, which are being handled in production.
8.	Details of the accident occurred during the year	NIL
	(i) Number of Accidents occurred	NIL
	(ii) Number of the persons affected	NIL
	(iii) Remedial Action taken (Please attach details if any)	NIL
	(iv) Any Fatality occurred, details.	NIL
9.	Are you meeting the standards of air Pollution from the incinerator?. How many times in last year could not met the	Not applicable

	standards?	
	Details of Continuous online emission monitoring systems installed	Not applicable
10.	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year.	Zero Liquid Discharge (ZLD) system is established on site to treat the liquid waste.
11.	It the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	Meeting the log 4 standards. No deviation on site so far.
12.	Any other relevant information	Online Thermal decontamination facility is available on site for the liquid waste treatment.

Certified that the above report is for the period from January 2018 to December 2018

D. Madhavi



Name and Signature of the Head of the Institution

Date: 19.07.2019

Place: Hyderabad
Murritheddy pally.

**SHANTHA BIOTECHNICS PRIVATE LIMITED
MUPPIREDDIPALLY SITE**

Disposal status of Bio-Medical waste to Authorised third party for the year- 2018

Sl. No.	MONTH	Description/Category of waste	Disposed quantity in KG	Disposed quantity in Kg To Dharma & Co.
1	January	Used syringes, sharps & Plastics	0	477
2		Cell debris	0	
3		Bio-medical waste from laboratorie, testing and process area	477	
4		Hepa filters	0	
5		Expired chemicals	0	
6	February	Used syringes, sharps & Plastics	0	653
7		Cell debris	0	
8		Bio-medical waste from laboratorie, testing and process area	653	
9		Hepa filters	0	
10		Expired chemicals	0	
11	March	Used syringes, sharps & Plastics	0	541.7
12		Cell debris	0	
13		Bio-medical waste from laboratorie, testing and process area	537	
14		Hepa filters	0	
15		Expired chemicals	4.7	
16	April	Used syringes, sharps & Plastics	0	2473
17		Cell debris	0	
18		Bio-medical waste from laboratorie, testing and process area	2473	
19		Hepa filters	0	
20		Expired chemicals	0	
21	May	Yellow Category	11971.16	11971.16
22		Red Category	0	
23		White Category	0	
24		Blue Category	0	
25		Expired chemicals	0	
26	June	Yellow Category	630.6	630.6
27		Red Category	0	
28		White Category	0	
29		Blue Category	0	
30		Expired chemicals	0	
31	July	Yellow Category	609.3	609.3
32		Red Category	0	
33		White Category	0	
34		Blue Category	0	
35		Expired chemicals	0	

Sl. No.	MONTH	Description/Category of waste	Disposed quantity in KG	Disposed quantity in Kg To Dharma & Co.
36	August	Yellow Category	537	537
37		Red Category	0	
38		White Category	0	
39		Blue Category	0	
40		Expired chemicals	0	
41	September	Yellow Category	650	650
42		Red Category	0	
43		White Category	0	
44		Blue Category	0	
45		Expired chemicals	0	
46	October	Yellow Category	538	538
47		Red Category	0	
48		White Category	0	
49		Blue Category	0	
50		Expired chemicals	0	
51	November	Yellow Category	434	434
52		Red Category	0	
53		White Category	0	
54		Blue Category	0	
55		Expired chemicals	0	
56	December	Yellow Category	893	997
57		Red Category	0	
58		White Category	0	
59		Blue Category	0	
60		Expired chemicals	104	
TOTAL			20512	20512

M/S DHARMA & CO.,

(Common Bio-Medical Waste Treatment Facility)

(Authorised by T.S. Pollution Control Board)

Sy. No.243/A, (V & M) ChinnaKodur, Dist. MEDAK



Service Certificate

This is to Certify that M/s. SHANTA BIOTECHNICS PVT. LIMITED

Hospital / Nursing Home / Diagnostics / Clinic is a member of **M/s Dharma & Co.**, bearing

Registration No. 458/2018-2019 **M/s Dharma & Co.**, is providing bio-medical waste management

service to the institution from DEC-2018 to Nov.2019 for total bed-strength of _____

★ *This certificate valid for one year only*



AUTHORISED SIGNATORY

Form - IV
(See rule 13)
ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

Sl. No.	Particulars		
1.	Particulars of the Occupier	:	
	(i) Name of the authorized person (occupier or operator of facility)	:	Mr. Magno Fernandes
	(ii) Name of HCF or CBMWTF	:	Sanofi India Ltd
	(iii) Address for Correspondence	:	Plot L-121, Phase III, Verna Industrial Estate, Verna Goa.403722
	(iv) Address of Facility	:	Plot L-121, Phase III, Verna Industrial Estate, Verna Goa.403722
	(v) Tel. No, Fax. No	:	(0832)6622300/ 6622399
	(vi) E-mail ID	:	sagar.narvekar@sanofi.com
	(vii) URL of Website	:	www.sanofi.com
	(viii) GPS coordinates of HCF or CBMWTF	:	NA
	(ix) Ownership of HCF or CBMWTF	:	Private Company
	(x). Status of Authorization under the Bio-Medical Waste (Management and Handling) Rules	:	Authorization No.: 13/350/16-PCB/Tech/13642 valid up to 25/10/19
	(xi). Status of Consents under Water Act and Air Act	:	Valid up to: 31/08/2021
2.	Type of Health Care Facility	:	
	(i) Bedded Hospital	:	No. of Beds - 01
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	Other(Occupational Health Centre)
	(iii) License number and its date of expiry	:	NA
3.	Details of CBMWTF	:	NA
	(i) Number healthcare facilities covered by CBMWTF	:	NA
	(ii) No of beds covered by CBMWTF	:	NA
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	__NA__ Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	__NA__ Kg/day
4.	Quantity of waste generated or disposed in Kg per annum	:	Yellow Category : 1672.97 kg
		:	Red Category : 0.224 Kg
		:	White: 0.0322 kg
		:	Blue Category : 0.048 kg
		:	General Solid waste: NIL

5	Details of the Storage, treatment, transportation, processing and Disposal Facility				
(i) Details of the on-site storage facility	:	Size : NA			
		Capacity : NA			
		Provision of on-site storage : (cold storage or any other provision)			
(ii) Details of the treatment or disposal facilities -	:	Type of treatment equipment	No of units	Capacity	Quantity treated or disposed in kg per annum
		Incinerators	-		
		Plasma Pyrolysis	-		
		Autoclaves	01 01	1000 Lit. 175 lit.	1163.4834 kg
		Microwave	-		
		Hydroclave	-		
		Shredder Needle tip cutter or destroyer -	01	2 needle per min.	0.032 kg
		Sharps encapsulation or concrete pit	01	1 m ³	0.0799 kg
		Deep burial pits	01	1 m ³	0.224 kg
		Chemical disinfection:	-		
		Any other treatment equipment	-		
(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	:	Red Category (like plastic, glass etc.) NIL			
(iv) No of vehicles used for collection and transportation of biomedical waste	:	NIL			
(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum			Quantity generated	Where disposed	
		Incineration Ash	NIL	NA	
		ETP Sludge	180 kg	MWML, Taloja	
(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	NOT APPLICABLE			
(vii) List of member HCF not handed over bio-medical waste.		NOT APPLICABLE			

6	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period		NO
7	Details trainings conducted on BMW		
	(i) Number of trainings conducted on BMW Management.		1
	(ii) number of personnel trained		2
	(iii) number of personnel trained at the time of induction		1
	(iv) number of personnel not undergone any training so far		-
	(v) whether standard manual for training is available?		-
	(vi) any other information)		-
8	Details of the accident occurred during the year		
	(i) Number of Accidents occurred		NIL
	(ii) Number of the persons affected		NIL
	(iii) Remedial Action taken (Please attach details if any)		NIL
	(iv) Any Fatality occurred, details.		NIL
9.	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?		NOT APPLICABLE
	Details of Continuous online emission monitoring systems installed		NOT APPLICABLE
10 .	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?		NIL

11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?		NOT APPLICABLE
12	Any other relevant information	:	(Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from Jan.2018 TO Dec.2018

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Name and Signature of the Head of the Institution

Date:
Place