

Ref.: USPIPL/TSPCB/Form-IV/BMW/Annual Report/JUNE-2023  
Date:

To,  
The Environmental Engineer,  
Regional Office, TSPCB  
H. No.6-3-1219, Street No: 1,  
Block C Ward 91, Second Floor  
Uma Nagar, Begumpet  
Hyderabad.

- Sub** : Submission of Form-IV Biomedical Waste Annual Report for the Calendar year 2022–M/s. **United States Pharmacopeia India Pvt. Ltd.**, R & D facility located at Plot No.DS-6 & DS-8, Sy No: 242, IKP Knowledge Park, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri District, Telangana State - Reg.,
- Ref** : 1. BMW Authorization Order No.:760/RR-II/TSPCB/ZOH/BMWA/2023-2110 dated 16-03-2023 valid up to 31-07-2027.  
2. BMW Authorization Order No.: TSPCB/BMWA/MDCL-3352832/HO/2021-1631 dated 29-12-2021 valid up to 31-07-2022

Sir,

We are herewith submitting Biomedical Waste Annual Report Form-IV for the Calendar year 2022 from January 22 to December 22 for our R & D Facility as per authorization under Bio-Medical Waste Management Rules, 2016 Bio-Medical Waste Management (Amendment) Rules 2018 and Bio- Medical Waste Management (Amendment) Rules, 2019.

Kindly acknowledge the same.

Thanking You,

For **United States Pharmacopeia India Pvt. Ltd.**,



**AUTHORIZED SIGNATORY**

Enclosure:

1. Duly filled & signed copy of Form IV.
2. BMW authorization copy.
3. Annexure I.
4. Annexure II.
5. Annexure III.

**Form -IV**  
**(See Rule 13)**  
**ANNUALREPORT**

Sl. No.	Particulars	
1	Particulars of the Occupier	
	(i) Name of the authorized person (occupier or operator of facility)	: <b>Girish Kapur</b>
	(ii) Name of HCF or CBMWTF	: <b>M/s. United States Pharmacopeia India Pvt. Ltd.,</b>
	(iii) Address for Correspondence	: <b>Plot No. DS-6&amp;8, IKP Knowledge Park, Genome Valley, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri District, Telangana - 500 101.</b>
	(iv) Address of Facility	: <b>M/s. Medicare Environmental Management Pvt. Ltd., (Formerly Known as Sembli Ramky Environmental Management Pvt. Ltd), Sy.No.619, Isnapur (V), Patancheru Mandal, Medak District, Telangana State.</b>
	(v) Tel. No, Fax. No	: <b>Tel: 040-44488880</b>
	(vi) E-mail ID	: <b>sxs@usp.org</b>
	(vii) URL of Website	: <b>www.usp.org</b>
	(viii) GPS coordinates of HCF or CBMWTF	: <b>17°39'47.56"N 78°36'47.18"E</b>
	(ix) Ownership of HCF or CBMWTF	: <b>Private</b>
	(x) Status of Authorization under the Bio-Medical Waste (Management and Handling) Rules	: <b>1. BMW Authorization Order No.: TSPCB/BMWA/MDCL-3352832/HO/2021-1631 dated 29-12-2021 valid up to 31-07-2022 2. BMW Authorization Order No.:760/RR-II/TSPCB/ZOH/BMWA/2023-2110 dated 16-03-2023 valid up to 31-07-2027</b>
(xi) Status of Consents under Water Act and Air Act	: <b>CFO Order No.: 760-RR-II/TSPCB/ZOH/CFO/TS-iPASS/CFO/2022- 210 dated 22-06-2022 valid up to 31-07-2027</b>	
2.	Type of Health Care Facility	: <b>R &amp; D Facility</b>
	(i) Bedded Hospital	: <b>No. of Beds: NA – R &amp; D Facility.</b>
	(ii) Non bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	: <b>Not Applicable</b>
	(iii) License number and its date of expiry	: <b>Not Applicable</b>
3.	Details of CBMWTF	
	(i) Number health care facilities covered by CBMWTF	: <b>NA</b>
	(ii) No of beds covered by CBMWTF	: <b>NA</b>
	(iii) Installed treatment and disposal capacity of CBMWTF:	: <b>NA</b>
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	: <b>NA</b>
4	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	: <b>Yellow Category: 193.5</b>
		: <b>Red Category: 165.5</b>
		: <b>White: 0</b>
		: <b>Blue Category: 18</b>
		: <b>General Solid waste: NA</b>
		: <b>BMW Disposal details for the calendar year 2022 along with manifest numbers is enclosed as Annexure - I</b>

Details of the Storage, treatment, transportation, processing, and Disposal Facility					
5	(i) Details of the on-site storage facility	:	Size : - NA		
		:	Capacity: - NA		
		:	Provision of on-site storage : NA		
	Disposal Facilities		:	<b>Type of treatment Equipment</b>	<b>No. of units</b>
			:	<b>Capacity kg/day</b>	<b>Quantity Treated (or) dispose in Kg per annum</b>
			:	Incinerators	
			:	Plasma Pyrolysis	
			:	Autoclaves	
			:	Microwave	
			:	Hydroclave	
			:	Shredder	
			:	Needletip cutteror Destroyer	
			:	Sharps	
		:	encapsulation or concrete Pit		
		:	Deep burial pits		
	:	Chemical Disinfection			
	:	Any other treatment equipment:			
	(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	:	NA		
	(iv) No. of vehicles used for collection and transportation of biomedical waste	:	NA		
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum	:	NA		
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	NA		
	(vii) List of members HCF not handed over bio-medical waste.	:	NA		
6	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period	:	<b>We have a Biomedical Waste Management Committee and attached the meeting minutes as Annexure-II</b>		
7	Details trainings conducted on BMW	:			
	(i) Number of trainings conducted on BMW Management.	:	2		
	(ii) number of personnel trained	:	22		
	(iii) number of personnel trained at the time of induction	:	6		
	(iv) number of personnel not undergone any training so far	:	0		
	(v) whether standard manual for training is available?	:	Yes		
	(vi) any other information	:	--		
8	Details of the accident occurred during the year	:	<b>Form – I enclosed as Annexure-III</b>		

	(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?	:	NA
	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?	:	NA
11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	:	Nil
12	Any other relevant information	:	--

**Certified that the above report is for the period from January 2022 to December 2022.**

**Date: 21/6/23**

**Name and Signature of the Head of the Institute**

**Place: Hyderabad**





## TELANGANA STATE POLLUTION CONTROL BOARD

### ZONAL OFFICE, HYDERABAD,

H.No.6-3-1219, Sy.No.TS No.1 Part, Block - C, Ward No.91,  
Near Country Club, Uma Nagar, Begumpet, Hyderabad -16.  
Email: jcee-zhyd-tspcb@telangana.gov.in

### AUTHORISATION

(Issued under Rule 10 of the Bio-Medical Waste Management Rules, 2018)

Order No. 760/RR-II/TSPCB/ZOH/BMWA/2023 2110

Date: 16.03.2023

1. M/s. United States Pharmacopeia India Pvt. Ltd., an occupier or operator of the facility located DS-6 & DS-8, Sy. No. 242, IKP Knowledge Park, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri District is here by granted an authorization for Generation, Segregation, Collection & Storage of Bio-Medical Waste.
2. M/s. United States Pharmacopeia India Pvt. Ltd., is here by authorized for handling of biomedical waste as per the capacity given below :
  - i) Number of beds of HCF : (R&D Unit)
  - ii) Quantity of Biomedical waste handled, treated or disposed :

Type of Waste Category	Quantity permitted for Handling
Yellow	195 Kg/month
Red	180 Kg/month
White (Translucent)	35 Kg/month
Blue	35 Kg/month

3. This authorization shall be in force for a period up to 31.07.2027.
4. This authorization is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

**JOINT CHIEF ENVIRONMENTAL ENGINEER**

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.

To

M/s. United States Pharmacopeia India Pvt. Ltd.,  
DS-6 & DS-8, Sy. No. 242, IKP Knowledge Park,  
Turkapally (V), Shameerpet (M), Medchal-Malkajgiri District.

Copy submitted to the Member Secretary, TSPCB, Hyderabad for favour of information.

Copy to the EE, Regional Office, Medchal -Malkajgiri District for information and necessary action.

'CLEAN AND GREEN' TELANGANA

**Terms and conditions of the authorizations:**

1. The HCF shall provide CC Camera at waste storage area and pick up point of CBMWTF vehicle and the recorded data shall be stored for a period of 3 months and available for inspection by the Board Officials.
2. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
3. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the Telangana State Pollution Control Board.
4. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the Telangana State Pollution Control Board.
5. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of this authorisation.
6. It is the duty of the authorised person to take prior permission of the Telangana State Pollution Control Board to close down the facility and such other terms and conditions that may be stipulated by the Telangana State Pollution Control Board.
7. Any other conditions for compliance as per the Guidelines issued by the MoEF & CC or CPCB from time to time.
8. The Bio Medical Waste shall be disposed for treatment after disinfection and segregation to the following Common Bio-Medical Waste Treatment Facility.

**M/s. Medicare Environmental Pvt. Ltd., (Formerly  
Semb Ramky Environmental Management Pvt. Ltd.), Sy. No. 619,  
Isnapur (V), Patancheru (M), Medak District**

9. As per the Rule 10 of BMWM Rules 2016, authorization shall be synchronized with validity of the consent.

## **SPECIAL CONDITIONS**

1. All the provisions of the Bio-Medical Waste Management Rules, 2018 must be complied with.
2. The HCF shall take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with Bio-Medical Waste Management Rules, 2018.
3. The HCF shall make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I of the BMWM Rules, 2018. It shall be ensured that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I of the Bio-Medical Waste Management Rules, 2018.
4. The HCF shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDS Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal.
5. The HCF shall phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of the Bio-Medical Waste Management Rules, 2018.
6. The HCF shall dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time.
7. The HCF shall not to give treated bio-medical waste with municipal solid waste.
8. The HCF shall establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of the Bio-Medical Waste Management Rules, 2018.
9. The HCF shall ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities.
10. The HCF shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974).
11. The HCF shall maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I of the Bio-Medical Waste Management Rules, 2018.
12. The HCF shall inform to TSPCB immediately in case the operator of a facility does not collect the bio-medical waste within the intended time or as per the agreed time.

13. The HCF shall establish a system to review and monitor the activities related to bio-medical waste management by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report to the prescribed authority.
14. It is the responsibility of the occupier of the HCF that the only segregated bio-medical waste as per the Schedule – I of the BMW Management Rules, 2018 shall be handed over to common bio-medical waste treatment facility for treatment, processing and final disposal.
15. It shall be ensured that no untreated bio-medical waste shall be mixed with other wastes.
16. The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I of the BMW Management waste treatment Rules, 2018 prior to its storage, transportation, treatment and disposal.
17. The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV of the BMW Management Rules, 2018. The bar coding and global positioning system shall be added by the Occupier and Common bio-Medical Waste treatment facility in one year time.
18. Un-treated human anatomical waste, animal anatomical waste, soiled waste and biotechnology waste shall not be kept stored beyond a period of 48 hours. Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the prescribed authority (TSPCB) along with the reasons for doing so.
19. Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
20. Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis is at temperature >1200C
21. Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
22. On-site pre-treatment of laboratory waste, microbiological waste, blood samples and blood bags should be disinfected or sterilized as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.



23. Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage.
24. The HCF shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste.
25. The HCF shall submit an annual report to the prescribed authority (TSPCB) in Form – IV, on or before the 30<sup>th</sup> June of every year for the period from January to December of the preceding year.
26. The HCF shall make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of the Bio-Medical Waste Management Rules, 2018.
27. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator of HCF shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of Authorisation.
28. In case of any major accident at HCF facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.
29. The HCF shall ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments.
30. The occupier of the HCF or an operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio-medical wastes. The occupier or operator of common bio-medical waste treatment facility shall be liable for action under section 5 and section 15 of the Act, in case of any violation.
31. The HCF shall adopt the following treatment and disposal methods as described in the Bio-Medical Waste Management Rules, 2018.
  - i. Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log<sub>10</sub>4 reduction efficiency for microorganisms as given in Schedule- III.
  - ii. Mutilation or shredding must be to an extent to prevent unauthorized reuse.
32. The HCF shall provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report.

33. The facility shall immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste, in the manner as prescribed in the National Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time.
34. The facility shall conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same.

  
**JOINT CHIEF ENVIRONMENTAL ENGINEER**



To

**M/s. United States Pharmacopeia India Pvt. Ltd.,  
DS-6 & DS-8, Sy. No. 242, IKP Knowledge Park,  
Turkapally (V), Shameerpet (M), Medchal-Malkajgiri 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.

**Annexure-I**  
**Statement showing the details of Bio-Medical Waste sent to M/s. Medicare Environmental Management Pvt. Ltd**

S. No	Month & Year	Bio Medical Waste quantity (in kgs) along with manifest number						
		Yellow		Red		Blue		White
Permitted as per BMW Authorization Order Dt: 16-03-2023 & dated 29-12-2021		195 Kg/month	180 Kg/month	35 Kg/month	35 Kg/month	35 Kg/month		
Month & Year	Qty Disposed in Kgs	Manifest Nos	Qty Disposed in Kgs	Manifest Nos	Qty Disposed in Kgs	Manifest Nos	Qty Disposed in Kgs	Manifest Nos
1	Jan-2022	738908,738912,738898,738905	14	738908,738912,738898,738905	2	738908	0	-
2	Feb-2022	738910,738907,738906,738911	15	738910,738907,738906,738911	2	738906	0	-
3	Mar-2022	738915,738914,738913,738909	14	738915,738914,738913,738909	0	-	0	-
4	Apr-2022	738918,738919,738917,738920,738916	20.5	738918,738919,738917,738920,738916	3	738919,738920	0	-
5	May-2022	738928,738924,738921,738927	15	738928,738924,738921,738927	0	-	0	-
6	June-2022	738923,738922,738926,738925	11	738923,738922,738926,738925	3	738922	0	-
7	July-2022	738931,738933,738932,738934	11	738931,738933,738932,738934	0	-	0	-
8	Aug-2022	738937,738938	8	738937,738938	1	738938	0	-
9	Sep-2022	738939,738940,738941,738942	14	738939,738940,738941,738942	0	-	0	-
10	Oct-2022	738944,738943,738945,738946	11	738944,738943,738945,738946	3	738943	0	-
11	Nov-2022	738947,738948,738949	14	738947,738948,738949	2	738948	0	-
12	Dec-2022	738950,738951,738952,738953	18	738950,738951,738952,738953	2	738951	0	-
	<b>Total</b>		<b>193.5</b>		<b>18</b>		<b>0</b>	

**Minutes of Meeting – EHS Committee held on 04<sup>th</sup> Jan 2022**

<b>Present:</b> Dipankar Nagaraja HM Sravan Kumar Sarath Kumar Singaraju	<b>Leave of absence:</b>
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S No	Agenda Item	Discussion points	Action points	Responsible and Timeline
1.	a. As per Bio Medical waste management rules 2016, a Waste disposal committee has been formed and inductory meeting has been held. b. Team Comprises of staff from Biologics and EHS c. Following are minutes of the meeting			
2	Minutes	Minutes of Last meeting	Reviewed all Minutes of meeting.	Nil
3	Annual Returns	Discussed about Annual returns (Jan-22 to Dec-22).	Reviewed the annual returns which were submitted in June 21.	Nil
4	Generation of waste	Frequency of Generation and disposal of BMW	<ul style="list-style-type: none"> <li>As per the current practice the waste is generated on Friday and is handed over to EHS and EHS will be disposing the Bio medical waste on Saturday.</li> <li>Disposal committee suggested that if the frequency of generation can be done twice in a week.</li> <li>Committee decided that Waste can be generated on Thursday also so that we can dispose the waste on Saturday (with in 48 hours)</li> </ul>	BBL/EHS
5	Register at BBL	Generation log register can be maintained at BBL – Microbiology lab	Maintain a register from lab side regarding generation of the waste.	Microbiology Lab
6	Records	Internal waste generation records	<ul style="list-style-type: none"> <li>Record Retention for BMW disposal is 3 years – accordingly we will recommend for disposal the records prior to 3 years.</li> </ul>	BBL/EHS

Prepared by: Sarath/ 4th Jan 2022



**Annexure-III**

**FORM -I**

**[(See rule 4(o), 5(i) and 15 (2))]**

**ACCIDENT REPORTING**

1. Date and time of accident:
2. Type of Accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately:
5. The type of waste involved in accident:
6. Assessment of the effects of the Accidents on human health and the environment:
7. Emergency measures taken:
8. Steps taken to all eviate the effects of accidents:
9. Steps taken to prevent the re-occurrence of such an accident:
10. Does your facility have an Emergency Control policy? If yes give details:



Nil

Date: 21/06/23

Place: Hyderabad

Signature .....

Designation .....

*Sarad*  
*Team lead, EHS*