FORM III

(See Rule 10)

AUTHORISATION No: 20BAC32015623 Dated 26/09/2020

Proceeding No: T5/TNPCB/F.0169MMN/BWA/RL/MMN/2016 Dated 26/09/2020

Sub: Tamil Nadu Pollution Control Board – Bio-Medical Waste Authorization - One Time Authorisation-HCF - M/s.PHARMAZELL (INDIA) PRIVATE LIMITED,UNIT - 1, S.F.No.S.F.No. 164/1, PLOT NO:B5&B6, MEPZ, KADAPPERI village, TAMBARAM Taluk, Chengalpattu District - Authorization under Rule 10 of the Bio-Medical Waste Management Rules, 2016 enacted under Environment (Protection) Act, 1986 – Issued- Reg.

Ref: 1. Unit's application No. 32015623, dated 12-03-2020.
2. BMW-IR.No: F.0169MMN/BWA/RL/DEE/MMN/2020 dated 02/08/2020

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AUTHORISATION FOR OPERATING A FACILITY FOR GENERATION, COLLECTION, RECEPTION, TREATMENT, STORAGE, TRANSPORT AND DISPOSAL OF BIO-MEDICAL WASTES

1. File number of authorization: 20BAC32015623 and date of issue: 26/09/2020
2. The Managing Director of M/s. PHARMAZELL (INDIA) PRIVATE LIMITED,UNIT - 1, an occupier or operator of the facility located at S.F.No.S.F.No. 164/1, PLOT NO:B5&B6, MEPZ, KADAPPERI Village, TAMBARAM Taluk, Chengalpattu District is hereby granted an Authorisation for Generation, Segregation, Collection, Storage, Packaging, Disposal of Bio-Medical Waste
3. M/s. PHARMAZELL (INDIA) PRIVATE LIMITED,UNIT - 1 is hereby authorized for handling of Bio-Medical waste as per the capacity given below.

i)	Number of beds of HCF	0		Nos
ii)	Quantity of Bio-Medical Waste handled, treated or disposed			
	Category	**Type of Waste**	**Quantity permitted for handling**	**Unit**
	Yellow	a) Human Anatomical Waste	0	Kg/day
		b) Animal Anatomical Waste	0	Kg/day
		c) Soiled Waste	0.2	Kg/day
		d) Expired or Discarded Medicines	0.05	Kg/day
		e) Chemical Solid Waste	0	Kg/day
		f) Chemical Liquid Waste in KLD	0	KLD
		g) Discarded linen, mattresses, beddings contaminated with blood or body fluid routine mask and gown	0	Kg/day
		h) Microbiology, Biotechnology and other clinical laboratory waste	0	Kg/day

	Category	Type of Waste	Quantity permitted for handling	Unit
	Red	Contaminated waste (Recyclable)	0.05	Kg/day
	White(Translucent)	Waste sharps including Metals	0	Kg/day
	Blue	Glassware	0.1	Kg/day
		Glassware Metallic Body		Kg/day

4. This one time authorization is valid for the non bedded Health Care facility only.
5. The authorization is issued 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.

R. Kannan Digitally signed by R. Kannan Date: 2020.09.27 21:52:24 +05'30'

For Member Secretary
Tamil Nadu Pollution Control Board
Chennai

TERMS AND CONDITIONS OF AUTHORIZATION

1. The authorization shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
2. The authorization or its renewal shall be produced for inspection at the request of an officer authorized by the Tamil Nadu State Pollution Control Board.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the Bio-Medical wastes without obtaining prior permission of Tamil Nadu State Pollution Control Board.
4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorization.
5. It is the duty of the authorized person to take prior permission of the Tamil Nadu Pollution Control Board to close down the facility and such other termsand conditions may be stipulated by Tamil Nadu Pollution Control Board.
6. Any other conditions for compliance as per the Guidelines issued by the MoEF&CC or CPCB from time to time.

ADDITIONAL CONDITIONS

1. The unit shall always have valid agreement with Common Bio Medical Waste Facility for disposal of Bio medical waste.
2. This Bio Medical Authorization is issued based on the information furnished by the facility in their application. In the event, that any of the information in the application is found to be incorrect, the authorisation issued shall be withdrawn.
3. Granting of this Bio Medical Authorization would not absolve the requirements of obtaining of permission/ clearances/licenses from other regulatory agencies.
4. The Institute shall ensure to label the containers for collection of Bio Medical Waste according to schedule I of BMW Rules 2016.
5. The Institute shall give adequate training to the staff handling Bio Medical Waste.
6. The Institute shall designate Nodal person for the management of the Bio Medical Waste and inform the same to Tamil nadu Pollution Control Board.
7. The Institute shall ensure that Bio Medical Waste shall not be kept / stored beyond a period of 48

hours under any circumstances.
8. All the provisions of the Bio-Medical Waste Management Rules, 2016 must be complied with.
9. The unit 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 the Bio-Medical Waste (BMW) Management Rules, 2016.
10. The unit 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 BMW Rules, 2016. 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 BMW Management Rules, 2016.
11. The unit shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner as prescribed by the World Health Organization (WHO) or National AIDs Control Organization (NACO) guidelines and sent to the common bio-medical waste treatment facility for final disposal.
12. The unit shall phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of Notification of the BMW Management Rules, 2016.
13. The unit 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.
14. The unit shall not give treated bio-medical waste with municipal solid waste.
15. The unit 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 BMW Management Rules, 2016.
16. The unit shall ensure segregation of liquid chemical waste at source and also ensure pre treatment or neutralization prior to mixing with other effluent generated from health care facilities
17. The unit shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974(6 of 1974).
18. The unit 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 BMW Management Rules, 2016.
19. The unit shall inform to TNPCB immediately in case the operator of a CBMWTF does not collect the bio-medical waste within the intended time or as per the agreed time.
20. The unit 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 the committee shall be submitted along with the annual report to the prescribed authority.
21. It is the responsibility of the occupier of the unit that the only segregated bio-medical waste as per the Schedule-I of the BMW Management Rules, 2016 shall be handed over to common biomedical waste treatment facility for treatment, processing and final disposal.
22. It shall be ensured that no untreated bio-medical waste shall be mixed with other wastes.
23. 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 Rules, 2016 prior to its storage, transportation, treatment and disposal.

24. The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV of the BMW Management Rules, 2016. The bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility in one year time.

25. Untreated human anatomical waste, animal anatomical waste, soiled waste and biotechnology waste shall not be stored beyond a period of forty–eight 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 along with the reasons for doing so.

26. 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 biomedical 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.

27. Cytotoxic drug vials shall not be handed over to unauthorized 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 pyrolys is at temperature >1200C.

28. 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.

29. On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organization or National AIDS Control Organization and then given to the common bio-medical waste treatment and disposal facility.

30. 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.

31. The unit shall maintain records related to the generation, collection, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste.

32. The unit shall submit an Annual Report to the prescribed authority (TNPCB) in Form-IV, on or before the 30th June of every year for the period from January to December of the preceding year.

33. The unit 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 BMW Management Rules, 2016.

34. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorization was earlier granted, the occupier or operator of unit 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 Authorization.

35. In case of any major accident at any institution of unit facility or any other site while handling biomedical waste, the authorized 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.

36. The unit 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.

37. The occupier of the unit 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.

38. The unit shall adopt the following treatment and disposal methods as described in the BMW Management Rules, 2016 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 Log104 reduction efficiency for microorganisms as given in Schedule- III. ii. Mutilation or shredding must be to an extent to prevent unauthorized reuse.

SPECIAL CONDITIONS - HCF

1	All the provisions of the Bio-Medical Waste Management Rules, 2016 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 the Bio-Medical Waste (BMW) Management Rules, 2016.
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 BMW Rules, 2016. 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 BMW Management Rules, 2016.
4	The HCF shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner as prescribed by the World Health Organization (WHO) guidelines on safe management of wastes from health care activities and WHO Blue Book, 2014 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(excluding blood bags) and gloves by 27th March, 2019
6	The HCF shall dispose of solid waste other than bio-medical waste inaccordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time.
7	The HCF shall not 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 for the further treatment and disposal in accordance with the guidelines issued by the Central Pollution Control Board by 27th March, 2019
9	The HCF shall ensure segregation of liquid chemical waste at source and also ensure pre-treatment or neutralization 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 BMW Management Rules, 2016.
12	The HCF shall inform to TNPCB immediately in case the operator of a CBMWTF 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 the 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, 2016 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 Rules, 2016 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, 2016. The bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility in one year time.
18	Untreated human anatomical waste, animal anatomical waste, soiled waste and biotechnology waste shall not be stored beyond a period of forty–eight 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 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 unauthorized 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 pyrolys is at temperature $>1200^0$C.
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, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organization or National AIDS Control Organization 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, 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 (TNPCB) in Form-IV, on or before the 30th 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 within a period of two years from the date of publication of Bio-Medical Waste management (Amendment) Rules, 2018

27	In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorization 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 Authorization.
28	In case of any major accident at any institution of HCF facility or any other site while handling bio-medical waste, the authorized 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 BMW Management Rules, 2016 i. Chemical treatment using at least 1% to 2% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log104 reduction efficiency for microorganisms as given in Schedule- III. ii. Mutilation or shredding must be to an extent to prevent unauthorized reuse.

R. Kannan
Digitally signed by R. Kannan
Date: 2020.09.27 21:53:14 +05'30'

For Member Secretary
Tamil Nadu Pollution Control Board
Chennai

To

The Managing Director
PHARMAZELL (INDIA) PRIVATE LIMITED,UNIT - 1
PHARMAZELL (INDIA) PRIVATE LIMITED, UNIT-1, PLOT NO:B5&B6, MEPZ,TAMBARAM, CHENNAI .
Pin: 600045

Copy to:

1. The District Environmental Engineer, Tamil Nadu Pollution Control Board, MARAIMALAI NAGAR
2. The JCEE-Monitoring, Tamil Nadu Pollution Control Board, Chennai

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