



**Mylan Laboratories Limited - [Hosur Steriles Facility]**  
Plot No 13A,14 & CP2, Sipcot Phase - II, Krishnagiri Main Road  
HOSUR - 635 130. Tamilnadu , INDIA .  
Ph. +91 4344 - 661400 Fax +91 4344 - 661499  
E-mail : mylan.india@mylan.in Web : www.mylanlabs.in  
CIN : U 2 4 2 3 1 T G 1 9 8 4 P L C 0 0 5 1 4 6

Date: 27/06/2022

To

The District Environmental Engineer,  
Tamilnadu Pollution Control Board,  
Hosur – Tamilnadu.

Sir,

Sub: Mylan Laboratories Limited, plot No.13A&14, SIPCOT-II, Krishnagiri road,Hosur –  
**Submission of Bio Medical Waste Annual Returns in Form IV for the period of  
January 2021 to December 2021 - Reg**

Ref: Compliance for the special condition No:25 of Schedule A under Bio Medical Wastes  
(Management and Handling) Rules, 2016

With reference to the above, please find herewith duly filled in the prescribed **Form -IV ie., Form for filling returns regarding Handling of Bio Medical Waste** for Mylan Laboratories Limited, plot No.13A&14, SIPCOT-II, Krishnagiri road,Hosur for the period of January 2021 to December 2021.

Kindly acknowledge the receipt of the same.

Thanking You,

Yours faithfully,

For Mylan Laboratories Limited

  
Authorized 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-2021 to December-2021 of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

Annual Report for the Period: January-2021 to December-2021

S.No	Particulars	
1.	Particulars of the <b>Occupier</b>	
	(i) Name of the authorized person (occupier or operator of facility)	: Mr. Jeswanth M V Senior Director-Manufacturing
	(ii) Name of HCF or CBMWTF	: Mylan Laboratories Limited
	(iii) Address for Correspondence	: M/s Mylan Laboratories Limited Plot no 13 A, 14 & CP2, SIPCOT phase-II Krishnagiri Main Road Hosur 635130
	(iv) Address of Facility	: M/s Mylan Laboratories Limited Plot no 13 A, 14 & CP2, SIPCOT phase-II Krishnagiri Main Road Hosur 635130
	(v) Tel. No, Fax. No	: Ph: 04344-661400 Fax: 04344-661499
	(vi) E-mail ID	: <b>Suresh.Anandan@viatris.com</b>
	(vii) URL of Website	: <b>http://www.mylan.in</b>
	(viii) GPS coordinates of HCF or CBMWTF	: Latitude : 12°43'31.997"N Longitude : 77°51'46.768"E
	(ix) Ownership of HCF or CBMWTF	: ( <del>State Government</del> or <del>Private</del> or <del>Semi Govt.</del> or any other)
	(x). Status of Authorization under the Bio-Medical Waste (Management and Handling) Rules	: BMW Authorization No : 18BAZ12313797, Dated: 18.06.2018 and valid up to: Life Time.
	(xi). Status of Consents under Water Act and Air Act	: Air Consent No: F.0001HSR/OL/DEE/TNPCB/HSR/A/2018 Dated: 28.02.2018, Validity: 31.03.2023 Water Consent No: F.0001HSR/OL/DEE/TNPCB/HSR/W/2018 Dated: 28.02.2018, Validity: 31.03.2023
2.	Type of Health Care Facility	: It is Occupational Health Center, First Aid treatment only

	(i) Bedded Hospital	:	No. of Beds: <b>NA</b>
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	<b>NA</b>
	(iii) License number and its date of expiry	:	<b>NA</b>
3.	Details of CBMWTF	:	
	(i) Number healthcare 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> Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	<b>NA</b> Kg/day
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	:	Yellow Category: <b>3348.03 kgs /A</b> <b>Refer Annexure-1</b>
			Red Category: <b>NA</b>
			White: <b>NA</b>
			Blue Category: <b>NA</b>
			General Solid waste: <b>NA</b>
5.	Details of the Storage, treatment, transportation, processing and Disposal Facility		
	(i) Details of the on-site storage facility	:	Size: <b>NA</b>
			Capacity: <b>NA</b>
			Provision of on-site storage: (cold storage or any other provision) - <b>NA</b>

(ii) disposal facilities		Type of treatment equipment	No of units	Capacity Kg/day	Quantity Treated / disposed in kg per annum
		Incinerators	Nil	Nil	Nil
		Plasma Pyrolysis	Nil	Nil	Nil
		Autoclaves	NA	NA	NA
		Microwave	Nil	Nil	Nil
		Hydroclave	Nil	Nil	Nil
		Shredder	Nil	-	-
		Needle tip cutter or destroyer	NA	-	-
		Sharps encapsulation or concrete pit	Nil	-	Nil
		Deep burial pits:	Nil	Nil	Nil
		Chemical disinfection:	2	1	-
		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	:	NA			
(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	NA	NA	
		ETP Sludge	NA	NA	
(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	<b>M/S. RAMKY ENERGY ENVIRONMENT LTD</b>			

	(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.	Yes, Minutes of Meeting Attached as Annexure 2
7.	Details trainings conducted on BMW	Training on SOP No: SOP-000549389
	(i) Number of trainings conducted on BMW Management.	Classroom training and My University training Provided.
	(ii) number of personnel trained	41
	(iii) number of personnel trained at the time of induction	34
	(iv) number of personnel not undergone any training so far	NIL
	(v) whether standard manual for training is available?	Yes, SOP available (SOP-000549389)
	(vi) any other information)	NA
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)	NA
	(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	Yes, Meeting the log 4 standards.

	have not met the standards in a year?		
12.	Any other relevant information	:	(Air Pollution Control Devices attached with the Incinerator) NA

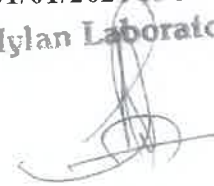
**Certified that the above report is for the period from 01/01/2021 to 31/12/2021**

**For Mylan Laboratories Limited**

Date : 27/06/22

Place : Hosur







**Name and Signature of the Head of the Institution**



<b>Annexure-1</b>					
<b>Mylan Laboratories Ltd , Hosur</b>					
<b>DETAILS OF BIOMEDICAL WASTE SENT TO M/S RAMKY ENERGY AND ENVIRONMENT LTD</b>					
<b>Year : 2021</b>					
<b>Month</b>	<b>Category wise Disposed in Kgs</b>				
	<b>Yellow</b>	<b>Red</b>	<b>White</b>	<b>Blue</b>	<b>General Solid waste</b>
January	286.01	Nil	Nil	Nil	Nil
February	290.00	Nil	Nil	Nil	Nil
March	283.6	Nil	Nil	Nil	Nil
April	285.3	Nil	Nil	Nil	Nil
May	289.1	Nil	Nil	Nil	Nil
June	248.85	Nil	Nil	Nil	Nil
July	285.26	Nil	Nil	Nil	Nil
August	290.86	Nil	Nil	Nil	Nil
September	285.05	Nil	Nil	Nil	Nil
October	251.1	Nil	Nil	Nil	Nil
November	270.4	Nil	Nil	Nil	Nil
December	282.5	Nil	Nil	Nil	Nil
<b>Total</b>	<b>3348.03</b>	<b>Nil</b>	<b>Nil</b>	<b>Nil</b>	<b>Nil</b>
<b>Average</b>	<b>279.003</b>	<b>Nil</b>	<b>Nil</b>	<b>Nil</b>	<b>Nil</b>

## BIO MEDICAL WASTE MANAGEMENT COMMITTEE

The Bio medical waste management committee meeting was held on 18.06.2021 at 15:30 and 16:00 at conference hall. The following members were present during the meeting.

Bio medical waste management committee members			
S. No	Name of the Employee	Department	Signature
1	Seenivasan R	Microbiology	
5	Bhuvana	OHC	
6	Vignesh	OHC	
7	Varadaraj K	HR	
8	Saktivel A	EHS	
9	Anbarasan A	EHS	



## Annexure - 2

## BIO MEDICAL WASTE MANAGEMENT COMMITTEE







Date: 18.05.2024

The MOM of the following meeting follows

S.no	Points discussed	Related Department/Location	Point Raised by	Corrective Action	Responsible Person	Target completion date (TCD)	Status
1	Media waste disposal bags are damaged condition	Microbiology	Anbarasan	Ensure there is no damage in media waste disposal bags and if required use double bags	Sreenivasan	Immediate	Completed
2	Sufficient yellow bags not available	EHS	Sreenivasan	Provided sufficient yellow bags for disposal	Anbarasan	Immediate	Completed
3	Some of the bags don't have the type of waste	Microbiology	Suresh	Labels to be provided for all the bags	Sreenivasan	Immediate	Completed
4	Collection bins are required	EHS	Bhuvana/Sreenivasan	Collection bins to be provided with different color	Sakthivel	Immediate	Completed

## BIO MEDICAL WASTE MANAGEMENT COMMITTEE

The Bio medical waste management committee meeting was held on 30.12.2021 at 16:00 and 16:30 at conference hall. The following members were present during the meeting.

Bio medical waste management committee members			
S. No	Name of the Employee	Department	Signature
1	Seenivasan R	Microbiology	
5	Bhuvana	OHC	
6	Vignesh	OHC	
7	Varadaraj K	HR	
8	Sakthivel A	EHS	
9	Anbarasan A	EHS	

**BIO MEDICAL WASTE MANAGEMENT COMMITTEE**

The MOM of the following meeting follows

S.no	Points discussed	Related Department/Location	Point raised by	Corrective Action	Responsible Person	Target completion date (TCD)	Status
1	Gloves not used during the shifting of BMW bags	Microbiology	Anbarasan	Adequate Gloves provided and ensure the same	Sreenivasan	Immediate	Completed
2	Heat resistant gloves to be used while handling of autoclave equipment	Microbiology	Anbarasan	Heat resistant gloves provided and ensure the same	Sreenivasan	Immediate	Completed
3	Few of the Biomedical waste bags stored without secondary Containment	ZLD Plant	Sreenivasan	Secondary Containment provided	Anbarasan	Immediate	Completed

Date: 30/12/2021

**Training Summary and Attendance Sheet**

Topic : *Biomedical waste disposal procedure & Biomedical waste management*

<b>Name of the Trainer(s)</b>	<i>Anbarasan.A</i>	<b>Sign of the Trainer(s) &amp; Date</b>	<i>[Signature] 12/11/21</i>
<b>Date of Training</b>	<i>12/11/21</i>	<b>Start Time</b>	<i>11:00 hrs</i>
		<b>End Time</b>	<i>11:30 hrs</i>
<b>MODE OF TRAINING</b>	<input checked="" type="checkbox"/> Classroom training	<input type="checkbox"/> On the job training	<input type="checkbox"/> Self-study
	<input type="checkbox"/> Virtual training (Microsoft Teams based, WebEx training, Video Conferencing)	<input type="checkbox"/> External training (Conducted by experts such as consultants, vendors, customers and personnel from Mylan Global)	

<b>References, If Any</b>	<i>M LCBCEP-SOP-EHS-ENV-001 (SOP-000549289)</i>	<b>Version no. / Revision no.</b>	<i>V4.0</i>
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<b>Training Need</b>	<input type="checkbox"/> Annual appraisal process	<input type="checkbox"/> Requirements arising from audits (internal/ external)	<input type="checkbox"/> Re-fresher training	<input type="checkbox"/> Corrective/ Preventive Actions (CAPA)
	<input type="checkbox"/> Unusual occurrences/ Incidents / failures / LIR	<input type="checkbox"/> Change Control / CR (SOP Revision/ Introduction)	<input type="checkbox"/> Re-training	<input checked="" type="checkbox"/> Company requirements
	<input type="checkbox"/> Others (Specify)			

**BRIEF SUMMARY OF THE TRAINING:**

- a) Explained about Biomedical waste disposal.
- b) Explained about Hazardous waste disposal
- c) General Scrap waste disposal.

Sr. No.	Name of The Participant	MID / EMP ID	Department	Location	Signature / Date
01.	<i>M. Kubendran</i>	<i>N13R1</i>	<i>NAWNT</i>	<i>HSF</i>	<i>M. [Signature] 12/11/21</i>
02	<i>V. Sankhuni</i>	<i>100N195</i>	<i>NAWNT</i>	<i>HSF</i>	<i>[Signature] 12/11/21</i>
03	<i>N. V. Venk</i>	<i>02A2R</i>	<i>DTSS</i>	<i>HSF</i>	<i>N. V. Venk 12/11/21</i>
04	<i>R. Jayakumar</i>	<i>16-1336</i>	<i>NAWNT</i>	<i>HSF</i>	<i>R. Jayakumar 12/11/21</i>
					<i>NA [Signature] 12/11/21</i>



### Training Summary and Attendance Sheet

Topic : *Biomedical Waste Disposal Procedure & Biomedical waste management*

Name of the Trainer(s)	<i>Anbarasan.A</i>	Sign of the Trainer(s) & Date	<i>[Signature]</i> 12/11/21
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Date of Training	<i>12/11/21</i>	Start Time	<i>11:00 AM</i>
		End Time	<i>11:30 AM</i>

MODE OF TRAINING	<input checked="" type="checkbox"/> Classroom training	<input type="checkbox"/> On the job training	<input type="checkbox"/> Self-study	<input type="checkbox"/> Others
	<input type="checkbox"/> Virtual training (Microsoft Teams based, WebEx training, Video Conferencing)		<input type="checkbox"/> External training (Conducted by experts such as consultants, vendors, customers and personnel from Mylan Global)	

References, If Any	<i>M LCBCEP-SOP-EHS-ENV-001 (SOP-000549289)</i>	Version no. / Revision no.	<i>V4.0</i>
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Training Need	<input type="checkbox"/> Annual appraisal process	<input type="checkbox"/> Requirements arising from audits (internal/ external)	<input type="checkbox"/> Re-fresher training	<input type="checkbox"/> Corrective/ Preventive Actions (CAPA)
	<input type="checkbox"/> Unusual occurrences/ Incidents / failures / LIR	<input type="checkbox"/> Change Control / CR (SOP Revision/ Introduction)	<input type="checkbox"/> Re-training	<input checked="" type="checkbox"/> Company requirements
	<input type="checkbox"/> Others (Specify)			

**BRIEF SUMMARY OF THE TRAINING:**

- a) Explained about Biomedical waste disposal.
- b) Explained about Hazardous waste disposal
- c) General Scrap waste disposal.

Sr. No.	Name of The Participant	MID / EMP ID	Department	Location	Signature / Date
01.	<i>M. Subendran</i>	<i>N1281</i>	<i>NAWNT</i>	<i>HSF</i>	<i>[Signature]</i> 12/11/21
02	<i>V. Sankar</i>	<i>1001195</i>	<i>NAWNT</i>	<i>HSF</i>	<i>[Signature]</i> 12/11/21
03	<i>N. V. Venk</i>	<i>02A2R</i>	<i>DTSC</i>	<i>HSF</i>	<i>[Signature]</i> 12/11/21
04	<i>R. Jayakumar</i>	<i>11-1336</i>	<i>NAWNT</i>	<i>HSF</i>	<i>[Signature]</i> 12/11/21
					<i>[Signature]</i> 12/11/21



**Items**

**Item:** SOP EHS\_SOP\_MLLBCRP\_000549389 (Rev 4.0 - 4/13/2021 11:32 AM America/New York)  
**Title:** Procedure for EHS of bio medical wastes

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Users			
User ID	User Name	Completion Date	Status
20046248	A, ANBARASAN	4/13/2021 11:32 AM America/New York	No Training Required
20047825	KALYANRAO, KARAD PRAVIN	4/13/2021 11:32 AM America/New York	No Training Required
20051594	PERIYASAMY, SURESH KUMAR	4/13/2021 11:32 AM America/New York	No Training Required
20068314	C, MURALI SHANKAR	4/13/2021 11:32 AM America/New York	No Training Required
20068604	R, SEENIVASAN	4/13/2021 11:32 AM America/New York	No Training Required
20070062	RAVI, KARTHI	4/13/2021 11:32 AM America/New York	No Training Required
20071869	KEDARISETTI, L V N V B RAVI	1/27/2022 01:31 AM America/New York	SOP Complete
20071930	M, KARUPPASAMY	4/19/2022 01:16 PM America/New York	SOP Complete
20072120	R, GUGANESH	4/13/2021 11:32 AM America/New York	No Training Required
20072124	P, NAMBI LAKSHMIKANTH	12/9/2021 06:43 PM America/New York	SOP Incomplete
20073040	SINGARAVELU, KANDAKUMAR	4/13/2021 11:32 AM America/New York	No Training Required
20073427	GUNASEKARAN, SELVARAJ	4/13/2021 11:32 AM America/New York	No Training Required
20074236	N, NARAYANASAMY	11/1/2021 03:04 AM America/New York	SOP Complete
20080735	H, MAHBOOB ALI	1/19/2022 12:10 PM America/New York	SOP Complete
20085002	SANTARA, RINKI	11/5/2021 12:45 AM America/New York	SOP Complete
20087139	YASODA, MALLIKARJUNA SHASIKIRAN	10/25/2021 01:03 PM America/New York	SOP Complete
20087166	KUMMITHA, THIRUPATHI REDDY	10/30/2021 04:57 AM America/New York	SOP Complete
20087168	MULASAPU, MALLIKARJUN	10/30/2021 02:59 AM America/New York	SOP Complete

## Users

User ID	User Name	Completion Date	Status
20090525	POTLAPALLI, JAGADEESH	2/28/2022 06:34 AM America/New York	SOP Complete
20097053	V, KIRUBAKARAN	5/20/2022 05:51 AM America/New York	SOP Complete
20097339	PUNDRU, DILEEP	6/8/2022 04:19 AM America/New York	SOP Complete
20097515	GOPISETTY, SURYA SAGAR	6/17/2022 01:42 AM America/New York	SOP Complete
AGI00001041	M N, KAVYASHRI	12/3/2021 02:24 AM America/New York	SOP Complete
AGI00001052	P, SAVITHIRI	11/16/2021 01:24 AM America/New York	SOP Complete
AGI00001052	K, VARADARAJ	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001053	S, SATHESH	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001068	M, MUNILAKSHMI	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001068	T, ROJA	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001068	M, ISHWARYA	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001068	A, SURESH	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001069	Y R, PRASAD	4/13/2021 11:32 AM America/New York	No Training Required
AGI00001072	KUMAR NANDA, PRAFULLA	4/13/2021 11:32 AM America/New York	No Training Required

Annexure - 4

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

**ACCIDENT REPORTING**

(for the Period of 1<sup>st</sup> January 2021 to 31<sup>st</sup> December 2021)

1. **Date** and time of accident: Nil
2. **Type** of accident: Nil
3. **Sequence** of events leading to accident: Not applicable
4. **Has the Authority** been informed immediately: Not applicable
5. **The type** of waste involved in accident: Not applicable
6. **Assessment** of the effects of the accidents on human health and the environment: Not applicable
7. **Emergency** measures taken: Not applicable
8. **Steps** taken to alleviate the effects of accidents: Not applicable
9. **Steps** taken to prevent the recurrence of such an accident: Not applicable
10. **Does you facility** has an Emergency Control policy? If yes give details: Yes, Onsite  
Emergency plan available

**For Mylan Laboratories Limited**

Date : 27/06/22

Signature :



Authorized Signatory

Place: Hosur

Designation: Site Head - Manufacturing