

o/c



Mylan Laboratories Limited

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Web : www.mylanlabs.in
CIN : U24231TG1984PLC005146

MLLU8/PCB/2020/630

June 09, 2020

To, ..
The Member Secretary,
A.P. Pollution Control Board,
D.No.33-26-14 D/2,
Near Sunrise Hospital,
Pushpa Hotel Centre,
Chalamvari Street, Kasturibai pet,
Vijayawada – 520008.



Sir,

Sub: Mylan Laboratories limited, Unit-8, Pusapatirega (M), Vizianagaram(D) - submission of Biomedical Waste Annual Returns (Form-IV) for the year 2019 - Reg.

With Reference to the above cited, we are herewith submitting the Bio Medical Waste Annual Returns (Form -IV) for the CY-2019 as per the Bio Medical Waste Management Rules,2016.

Kindly acknowledge the receipt of the same.

Thanking you,

Yours faithfully,
For Mylan Laboratories Limited, Unit-8



[Handwritten signature]
09/06/2020

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AUTHORIZED SIGNATORY

Encl. As above

Cc: to APPCB, RO, Vizianagaram

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)]

S.No.	Particulars	:	
1	Particulars of the Occupier		
	(i) Name of the authorized person (occupier or operator of facility)	:	G. CHINNIKRISHNA REDDY Head – API Site Operations, Unit-8.
	(ii) Name of HCF or CBMWTF	:	Mylan Laboratories Limited, Unit -8.
	(iii) Address for Correspondence	:	G. Chodavaram (Post),
	(iv) Address of Facility	:	Pusapatirega (Mandal), Vizianagaram (Dist.) -535204.
	(v) Tel. No, Fax. No	:	Phone: 08922-258001/258002 & Fax: 08922-258004
	(vi) E-mail ID:	:	<u>Chinnikrishnareddy.Gangireddy@mylan.in</u>
	(vii) URL of Website	:	<u>www.mylan.com</u>
	(viii) GPS coordinates of HCF or CBMWTF	:	18.1147° N, 83.5770° E
	(ix) Ownership of HCF or CBMWTF	:	State Government or Private or Semi Govt. or any other)
	(x). Status of Authorization under the Bio-Medical Waste (Management and Handling) Rules	:	Authorization No.: PCB/ROVZ/BMW/Z-114/2018-2340, Dated:12.03.2018, valid up to: 31.05.2023. Amendment order No: PCB/ROVZ/BMWA/Z-114/2019-173, Dated:26.02.2019 valid up to: 31.05.2023.
(xi). Status of Consents under Water Act and Air Act	:	Order.No.APPCB/VSP/VSN/13392/HO/CFO/2018 Dated: 12.10.2018 & Amendment order Dated 22.2.2019 & 26.3.2019, Valid Up to 31.08.2020	
2	Type of Health Care Facility	:	Occupational Health Center in API Manufacturing
	(i) Bedded Hospital	:	No. of Beds: NA
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	Occupational Health Center & Microbiology Lab
	(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																																																
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	NA																																																
4	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)		Category Disposed																																																
		:	Yellow Category: 136.59 Kgs/Month																																																
		:	Red Category: 1.91 Kgs/Month																																																
		:	White Category: 1.21 Kgs/Month																																																
		:	Blue Category: 0.70 Kgs/Month																																																
		:	General Solid waste: Nil																																																
Details of the Storage, treatment, transportation, processing and Disposal Facility																																																			
5	Details of the Storage, treatment, transportation, processing and Disposal Facility	:	Size : NA																																																
		:	Capacity : NA																																																
		:	Provision of on-site storage : (cold storage or any other provision) provided Secure storage Facility																																																
5	disposal facilities	:	<table border="0"> <thead> <tr> <th>Type of treatment equipment</th> <th>No of units</th> <th>Capacity Kg/day</th> <th>Quantity Treated or disposed in kg per annum</th> </tr> </thead> <tbody> <tr> <td>Incinerators</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Plasma Pyrolysis</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Autoclaves</td> <td>- 01</td> <td>75 Liters</td> <td></td> </tr> <tr> <td>Microwave</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Hydroclave</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Shredder</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Needle tip cutter or Destroyer</td> <td>- 01</td> <td></td> <td></td> </tr> <tr> <td>Sharps encapsulation or concrete pit -</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Deep burial pits:</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Chemical disinfection: -</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Any other treatment equipment:</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Type of treatment equipment	No of units	Capacity Kg/day	Quantity Treated or disposed in kg per annum	Incinerators				Plasma Pyrolysis				Autoclaves	- 01	75 Liters		Microwave				Hydroclave				Shredder				Needle tip cutter or Destroyer	- 01			Sharps encapsulation or concrete pit -				Deep burial pits:				Chemical disinfection: -				Any other treatment equipment:			
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	(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum	:	Red Category (like plastic, glass etc.) Not Applicable																																																

	(iv) No of vehicles used for collection and transportation of biomedical waste	:	Not Applicable									
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum	:	<table border="1"> <thead> <tr> <th></th> <th>Quantity Generated</th> <th>Where Disposed</th> </tr> </thead> <tbody> <tr> <td>Incineration Ash</td> <td></td> <td></td> </tr> <tr> <td>ETP Sludge</td> <td></td> <td>Not Applicable</td> </tr> </tbody> </table>		Quantity Generated	Where Disposed	Incineration Ash			ETP Sludge		Not Applicable
	Quantity Generated	Where Disposed										
Incineration Ash												
ETP Sludge		Not Applicable										
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	M/s Rainbow Industries (CBMWTF), Sy.No.21/1, Patha Kunkam (V), Laveru (M), Srikakulam District. Andhra Pradesh.									
	(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	:	Yes, Bio Medical Waste Management Committee Minuets of Meeting reports enclosed as Annexure -I									
7	Details trainings conducted on BMW	:										
	(i) Number of trainings conducted on BMW Management.	:	43 Trainings are conducted on BMW Management.									
	(ii) number of personnel trained	:	102 members are Trained on BMW Management									
	(iii) number of personnel trained at the time of induction	:	76 members are trained at the time of induction									
	(iv) number of personnel not undergone any training so far	:	Nil									
	(v) whether standard manual for training is available?	:	Yes									
	(vi) any other information)	:	----									
8	Details of the accident occurred during the year	:	No accidents have taken place									
	(i) Number of Accidents occurred	:	Nil									
	(ii) Number of the persons affected	:	NA									
	(iii) Remedial Action taken (Please attach details if any)	:	NA									
	(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 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?	:	Not Applicable
11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	:	Yes, Meeting the log 4 standard
12	Any other relevant information	:	Not Applicable

Certified that the above report is for the period from 1st January 2019 to 31st December 2019.



G. CHINNIKRISHNA REDDY,
Head – API Site Operations

Date: 09.06.2020

Name and Signature of the Head of the Institution

Place: Vizianagaram.

MYLAN LABORATORIES LIMITED, UNIT-08
BMW MANAGEMENT COMMITTEE REVIEW MEETING

Date & Time: 04.02.2019, 14.30 hrs.

Venue: Conference hall -01

Agenda of the meeting:

1. Compliance with legal requirements
2. Environmental Performance of the organization
3. BMW Management at site
4. Recommendations for improvement

List of Committee members:

S.No.	Name of the Member	Designation	Department
1	G. Chinni Krishna Reddy	Head – Site Operations	Head – Site Operations
2	A. Srinivasa Sharma	AGM	MR-EMS & Environment
3	S. Rajagopalan	GM	Safety & Health
4	N. Raja Reddy	GM	HR & Admin
5	Varma Venkatasagi	Sr.GM	Quality
6	P. Rangarao	DGM	Production
7	R.V. Suryanarayana	DGM	Production
8	Y. Venu Babu	AGM	Production
9	K.G. Rao	GM	Security & Vigilance
10	A. Sridhar	DGM	Warehouse
11	R.S. Badrinath	DGM	Engineering
12	J. Sathish	DGM	Engineering
13	M. Rajeshkumar	AGM	TSD
14	P. Uday Bhaskar	FMO	Health

Members present	
Mr. G.Chinnikrishna Reddy	Head -Plant Operations
Mr. A. Srinivasa Sharma	AGM
Mr. S. Rajagopalan	GM
Mr. N. Raja Reddy	GM
Mr. Varma Venkatasagi	Sr.GM
Mr. R.V. Suryanarayana	DGM
Mr. K.G. Rao	GM
Dr. Uday Bhaskar. P	FMO
R.S. Badrinath	DGM
Mr. J. Satish	DGM
Mr. M. Rajeshkumar	AGM
Mr. B. Ravi Kumar	Sr. Manager
Mr.P.Mahesh	Manager
Mr.V.Vikram	Asst. Manager
Mr.K.V.Naraslinga Rao	Asst.Manager
Mr.G.Suryanarayana	Executive

1. Compliance with legal requirements

S. No	Description of Environmental Legal Permit	Issuing Authority	Date Issued	Ref. No	Validity period	Remarks
1	Environmental Clearance	MoEF	01.11.2006	F.NO. J-11011/236/2006-I-A-11(1)	---	---
2	Coastal Regulation Zone clearance for Marine Disposal	MoEF	12.09.2007	NO. 10-53/2007-1A-111	---	---
3	Consent for Establishment (CFE)	APPCB	13.11.2018	APPCB/VSP/VZN/91/CFE/HO/2012	08.08.2025	----
4	Consent for Operation (CFO)	APPCB	12.10.2018	APPCB/VSP/VZN/13392/CFO/HO/2018	31.08.2020	CFO amendment applied w.r.t. CFE amended
5	BMW (M& H Rules)	APPCB	12.03.2018	PCB/ROVZ/BMW/Z-114/2018-2340	31.05.2023	---
6	Public Liability Insurance	Tata AIG Insurance	01.04.2018	Policy No. - 0300004683	31.03.2019	---

7	E-Waste Management Rules	APPCB	12.10.2018	APPCB/VSP/VZN/13392/CFO/HO/2018	31.08.2020	---
8	Hazardous and Other Wastes (M&TM) Rules	APPCB	12.10.2018	APPCB/VSP/VZN/13392/CFO/HO/2018	31.08.2020	---

2. Environmental Performance of the organization

S.No.	Performed
1	Annual Hazardous waste returns submitted to the board in FORM-4 for FY 2017-18, on 2 nd June 2018 against due date of 30 th June 2018. Next submission date for FY 2018-19 before 30 th June 2019
2	EC Half-yearly compliance report submitted to MoEF on 30 th Nov 2018, Next due on April' 2019
3	CFO Half-yearly compliance reports are submitted to the Board on 25 th Aug 2018, Next due is Mar' 19
4	New CFO Received after product Mix and CFO Amendment Applied w.r.t to Amended CFE.
5	Half yearly battery returns submitted to the board on 18 th Dec 2018, next due on April 2019.
6	Water consumption details are being submitted to the board in form-I, on or before 5 th of every month for previous month.
7	Hazardous waste statement & manifest details are submitting within the specified time (on or before 10 th of every month).
8	Monthly Third-party analysis is carrying as per schedule and submitting reports to the Board in time (on or before 10 th of every month).
9	Environmental statement submitted (in Form-V) on 24 th September 2018, next due 30.09.2019.
10	BMW Annual report (Form-IV) submitted to APPCB on 2 nd June 2018 for the period of Jan to Dec 2018, and next due on 30 th June 2019.
11	BMW Authorization Amendment applied for the increase of Yellow category on 11.01.2019.

3. Biomedical waste management at site

Authorization:

- BMW Authorization valid up to 31.05.2023
- BMW Authorization Amendment applied for the increase of Yellow category from 3.0 kgs. to 15.0 Kgs / Month due to internal operations are increased and generation qty of Microbiology waste also increased
- Bio-Medical Waste Management Rules 2016 amended as

Bio Medical Waste Management (Amendment) Rules, 2018

- Training given to the Concern persons about the Renewal authorization conditions and Bio-Medical Waste Management (Amendment) Rules, 2018

Source of waste:

- Source of BMW generation in site is OHC and Microbiology.

Segregation of BM waste:

- Segregating all the wastes as per BMWM rules

In-house treatment of BMW:

- All microbiology wastes are pre-treating in Autoclave as per rules and record maintained.
- Treatment facility available for OHC and Microbiology wastes as per the rules
- All needles and syringes shredding before disposing as prescribed in BMWM amended rules 2018

Collection & transportation of BM waste by CBMWTF:

- Collecting the Bio medical waste in color coded bags/containers as per the BMWM amendment rules 2018
- Wastes are collecting from site by CBMWTF within prescribed period.
- All labelling system and color coding for BMW containers/bags followed as per BMWM rules.
- Transporting wastes from site to CBMWTF through designated CBMWTF vehicle
M/s Rainbow industries, Srikakulam.

Records/reports:

- CBMWTF issuing Monthly destruction note for BMW collection from site.
- Internal records are being maintained for category wise biomedical waste generation and disposal.
- Annual report submitted to APPCB on 02nd June 2018 for the period of Jan to Dec 2017, and next due on 30th June 2019.
- BMW awareness Training provided to the new joining employees and OHC, Microbiology Employees once in every six months.

4. Recommendations for improvement

- Maintain the stock of Biomedical waste storage non-chlorinated plastic bags for the collection of Biomedical waste.
- Training to be provided to the concerned people

Devi
05/02/2019

BMW- Management Representative

MYLAN LABORATORIES LIMITED, UNIT-08
BMW MANAGEMENT COMMITTEE REVIEW MEETING

Date & Time: 17.08.2019, 14.30 hrs.

Venue: Conference hall -01

Agenda of the meeting:

1. Compliance with legal requirements
2. Environmental Performance of the organization
3. BMW Management at site
4. Recommendations for improvement

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Mr. N. Raja Reddy	GM
Mr. Varma Venkatasagi	Sr.GM
Mr. R.V. Suryanarayana	DGM
Mr. K.G. Rao	GM
Dr. Uday Bhaskar. P	FMO
R.S. Badrinath	GM
Mr. J. Satish	DGM
Mr. M. Rajeshkumar	AGM
Mr. B. Ravi Kumar	Sr. Manager
Mr.P.Mahesh	Manager
Mr.V.Vikram	Asst. Manager
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1. Compliance with legal requirements

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8	Hazardous and Other Wastes (M&TM) Rules	APPCB	26.03.2019	APPCB/VSP/VZN/13392/HO/CFO/2019	31.08.2020

2. Environmental Performance of the organization

S.No.	Performed
1	Annual Hazardous waste returns submitted date for FY 2018-19 before 22 nd June 2019
2	EC Half-yearly compliance report submitted to MoEF on 13 th May, Next due on 30 th Nov'2019
3	CFO Half-yearly compliance reports are submitted to the Board on 30 th July 2019, Next due is Jan'20
4	CFO Amendment copy received on 22.02.2019
5	Half yearly battery returns submitted to the board on 30 th April 19, next due on Oct'19.
6	Water consumption details are being submitted to the board in form-I, on or before 5 th of every month for previous month.
7	Hazardous waste statement & manifest details are submitting within the specified time (on or before 10 th of every month).
8	Monthly Third-party analysis is carrying as per schedule and submitting reports to the Board in time (on or before 10 th of every month).
9	Environmental statement submitted (In Form-V) on 24 th September 2018, next due 30.09.2019.
10	BMW Annual report (Form-IV) submitted to APPCB on 22 nd June 2019 for the period of Jan to Dec 2018, and next due on 30 th June 2020.
11	BMW Authorization Amendment copy received on 26.02.2019

3. Biomedical waste management at site

Authorization:

- BMW Authorization valid up to 31.05.2023
- BMW Authorization Amendment copy received with increasing of Yellow category from 3.0 kgs. to 15.0 Kgs / Month on 26.02.2019
- Bio-Medical Waste Management Rules 2016 amended as Bio-Medical Waste Management (Amendment) Rules, 2018
- Training given to the Concern persons about the Renewal authorization conditions and Bio-Medical Waste Management (Amendment) Rules, 2018

Source of waste:

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- All microbiology wastes are pre-treating in Autoclave as per rules and record maintained.
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- All labeling system and color coding for BMW containers/bags followed as per BMWM rules.
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Records/reports:

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- BMW awareness Training provided to the new joining employees and OHC, Microbiology Employees once in every six months.

4. Recommendations for improvement

- Maintain the stock of Biomedical waste storage non-chlorinated plastic bags for the collection of Biomedical waste.
- Training to be provided to the concerned people and New Joining employees

[Handwritten Signature]
 13/08/2019
 BMW- Management Representative