

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: U24231TG1984PLC005146

Date: 25-06-24

To

District Environment Engineer,
Tamilnadu Pollution Control Board,
Plot No:149-A, SIPCOT- Phase 1, Dharga,
Hosur-635126
Krishnagiri District.
Tamilnadu.

Sir,

Sub: Mylan Laboratories Limited, plot No.13A&14, SIPCOT-II, Krishnagiri road, Hosur S.F.No. 428 (Part), 429 (Part), 430 (Part), 431 (Part), MORANAPALLI Village, HOSUR Taluk, Krishnagiri District - Submission of Bio Medical Waste Annual Returns in Form IV for the period of January 2023 to December 2023 - 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 2023 to December 2023.

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-2023 to December-2023 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)	:	Mr. Gopusankar T Director-Manufacturing									
	(ii) Name of HCF or CBMWTF		Mylan Laboratories Limited									
	(iii) Address for Correspondence	:	M/s Mylan Laboratories Limited S.F.No. 428 (PT),429 (PT),430 (PT),431 (PT), MORANAPALLI Village, HOSUR Taluk, Krishnagiri District									
	(iv) Address of Facility	:	M/s Mylan Laboratories Limited S.F.No. 428 (PT),429 (PT),430 (PT),431 (PT), MORANAPALLI Village, HOSUR Taluk, Krishnagiri District.									
	(v)Tel. No, Fax. No	:	Ph: 04344-661400 Fax: 04344-661499									
	(vi) E-mail ID	:	Sujay.bv@viatris.com									
	(vii) URL of Website	:	http://www.viatris.in									
	(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	•	(State Government or Private or Semi Government 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: One Time.									
	(xi). Status of Consents under Water Act and Air Act	•	Air Consent No: 2309250275354 DATE:03/03/2023 Valid up to 31/03/2029									
			Water Consent No : 2309150275354 DATE:03/03/2023 Valid up to 31/03/2029									
2.	Type of Health Care Facility	8.	It is Occupational Health Center, First Aid treatment only									
	(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)	:	NA
1	(iii) License number and its date of expiry	:	NA
3.	Details of CBMWTF	:	
	(i) Number healthcare facilities covered by CBMWTF		NA
a	(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	:	Yellow Category: 3059.69 kg /Annum Refer Annexure-1
	monthly average basis)		Red Category: NA
			White: NA
			Blue Category: NA
			General Solid waste: NA
5.	Details of the Storage, treatment, t	ransp	ortation, processing and Disposal Facility
	(i) Details of the on-site storage	:	Size: 3.5M*1.6M*2.5M
	facility		Capacity: 300 kg
			Provision of on-site storage: (cold storage or
	×*		any other provision) – Packed in non-
			chlorinated color coded plastic bags and
			stored with secondary containment in a dedicated biomedical waste storage area.
			dedicated biblifedical waste storage area.

(ii)disposal facilities		Type of treatment equipment	No of units	Capa City Kg/ day	Treated /disposed in kg per
я		Incinerators	Nil	Nil	annum Nil
		Plasma Pyrolysis	Nil	Nil	Nil
		Autoclaves	1	10kg	3059.69 kg
		Microwave	Nil	Nil	Nil
		Hydroclave	Nil	Nil	Nil
_		Shredder Needle tip	NA NA	Nil	Nil -
		cutter or destroyer Sharps encapsulation or concrete	Nil	:=:	Nil
		pit Deep burial pits:	Nil	Nil	Nil
12.		Chemical disinfection:	Nil	Nil	Nil
		Any other treatment equipment:	Nil	Nil	Nil
(iii) Quantity of recyclable wastes sold to	:	Red Category ((like plas	stic, gl	ass etc.)
authorized recyclers after treatment in kg		Nil			
(iv) No of vehicles used for collection and transportation of biomedical waste	1	NA		41	
(v) Details of incineration ash and ETP sludge generated and disposed		Incineration	Quantity generate NA		Where disposed NA
during the treatment of wastes in Kg per annum		Ash ETP Sludge	NA		NA
(vi) Name of the Common Bio- Medical Waste Treatment Facility Operator through which wastes are disposed of	•	M/S. Re Susta limited (Ramk ltd)			

	(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. (ii) number of personnel trained	08 Classroom trainings and online trainings were conducted. (Training details attached as annexure-3) 185
	(iii) number of personnel trained at the time of induction	65
	(iv) number of personnel not undergone any training so far	NIL
	(v) whether standard manual for training is available?	Yes, SOP available Procedure for EHS Of Bio Medical Wastes (SOP-000549389)
	(vi) any other information)	NA
8.	Details of the accident occurred during the Year	No incident occurred during the reported year.(Refer Annexure-4)
	(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 have not met the standards in a year?		Yes, Meeting the log 4 standards.
12.	Any other relevant information	:	(Air Pollution Control Devices attached with the Incinerator) NA

Certified that the above report is for the period from 01/01/2023 to 31/12/2023

Date:

Place : Hosur

Name and Signature of the Head of the Institution

Annexure - 4

FORM - I

[(See rule 4(0), 5(i) and 15(2)]

ACCIDENT REPORTING

(for the Period of 1st January 2023 to December 2023)

- 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 the 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

Date: 25/06/24

Place: Hosur

Signature:

Designation: Hoad Corupley-3

Annexure-1

Mylan Laboratories Ltd, Hosur

DETAILS OF BIOMEDICAL WASTE SENT TO M/S. RE SUSTAINABILITY IWM SOLUTIONS LIMITED (RAMKY ENERGY AND ENVIRONMENT LTD)

Year: 2023

	Category wise Disposed in Kgs										
Month	Yellow	Red	White	Blue	General Solid waste						
January	256.82	Nil	Nil	Nil	Nil						
February	247.48	Nil	Nil	Nil	Nil						
March	260	Nil	Nil	Nil	Nil						
April	273.25	Nil	Nil	Nil	Nil						
May	259.95	Nil	Nil	Nil	Nil						
June	217.7	Nil	Nil	Nil	Nil						
July	266.74	Nil	Nil	Nil	Nil						
August	249.75	Nil	Nil	Nil	- Nil						
September	267	Nil	Nil	Nil	Nil						
October	266	Nil	Nil	Nil	Nil						
November	248	Nil	Nil	Nil	Nil						
December	247	Nil	Nil	Nil	Nil						
Total	3059.69	Nil	Nil	Nil	Nil						
Average	254.974	Nil	Nil	Nil	Nil						

Annexure-2

7	Us.	4	ယ	2	_		-		S.No	1	
There is no Bio medical waste authorization copy displayed in Microbiology.	There is no waste bin for general waste in OHC	To ensure the bio medical waste and its handling at source .Internal audit shall be conducted in Microbiology and OHC	To create awareness on handling of bio medical waste to the new employees training shall be imparted in frequency.	To ensure the Bio medical waste compliance at site third party audit shall be conducted.	To ensure immunization for New joinees and left ourt personnel in site.		Immunization shall be be done for all bio medical handlers in the site protect from Hepatitis and Tetanus.		Observation	1000000000000000000000000000000000000	
Authorization copy shall be displayed in Microbiology department	White colour dust bin container shall be procured and placed in the OHC.	Audit to be conducted in microbiology and OHC.	Classroom training shall be provided in regular interavl to cover the new employees.	Third party audit shall be conducted.	List shall be prepared and vaccine should be administrated for new joinees and left out personnel.	Present M	Vaccination shall be administration to all bio medical waste handlers at the site	Previous M	Action Plan/Corrective action	Biomedical Waste Committee meeting MOM 22.12	AIII
EHS	EHS	EHS	EHS	EHS	EHS	Present Meeting CAPA's	EHS	Previous Meeting CAPA's	Responsibility Person/Department	ttee meeting MOM 22.12.2023	Annexure-2
Completed	Completed	As and when required	As and when required	Vendor to be finalized	Completed		3rd dose Vaccination in progress		Current Status		
30.12.24	NA	NA	NA	20.06.24	31.01.24	-	31.07.24		Timeline		
Z Ei	Z:	Z	Z:	<u>Z</u> .	Z:		Z.		Remarks		

Annexure-2

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bags shall be issued to generators	Permanent label shall be pasted in the Containers.	To ensure bio medical wastes are properly destruction or not .Off site disposal audit shall be performed .	To increase awareness on Bio medical waste, training shall be imparted for Microbiology and OHC Personnel		While handling bio medical waste .Proper mask is not using by handlers	Immunization shall be be done for all bio medical handlers in the site protect from Hepatitis and Tetanus.		Observation	
Yellow colour non chlorinated bags shall be procured	Label for waste container shall be procured.	Off-Site audit shall be performed for treatment storage disposal facility	Class room training shall be imparted to microbiology & OHC personnel to create awareness about handling and disposal of biomedical waste	Present Me	Adequate PPE's Provided to the Health Care Workers handling Biomedical waste	Vaccination shall be administration to all bio medical waste handlers at the site	Previous Me	Action Plan/Corrective action	Biomedical Waste Committee meeting MOM 30,06
EHS	EHS	EHS/Microbiology	EHS	Present Meeting CAPA's	EHS	EHS	Previous Meeting CAPA's	Responsibility Person/Department	tee meeting MOM 30,06,2023
Completed	Completed	Pending	Completed		Completed	3rd dose Vaccination in progress		Current Status	
30.08.23	31.07.23	30.08.23	31.07.23		NA	31.07.23		Timeline	
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s.No: 17687

Mylan La Corpora	Mylan Laboratories Limited Corporate, Bangalore, India						ning Summary and Attendance Sheet						
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Date of	Date of Training 20/06/23					Start Time End Time			14		1		
i la l	Classroom training tr					оь С	Self-stu	dy	Others				
MODE O	MODE OF TRAINING Virtual training (Microsoft Teams base training, Video Confere					Ex C	External (Conduct vendors,	ed by	experts such a	s cons	sultants, rom Mylan Global)		
References, If Any							ersion no. /		NA				
	Annual appraisal process				arising fr	nirements or from audits mal / external)		Re- fresher training		Corrective/ Preventive Actions (CAPA)			
Training	Need		Unusual or Incidents /	ccurrences/ failures /		Change Control / CR (SOP Revision/ R Introduction)			Re-training	g	Company requirements		
- 2	8 2		Others (sp	ecify)									
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Mylan Laboratories Limited Corporate, Bangalore, India

Training Summary and Attendance Sheet

Sr.No.	Name of The Participant	MID/EMP.	Department	Location	Signature / Date
01	J. Annald	8415952	H·K	BI	N. Andol
09	Syral Marandi	0522494	HK	HSF	Barandi
10	Anil Baskey	0522488	HK	HSF	A30866733
-11	More of onto	0458145	14.16	14.D	20108/23
12	Abdul wenced	0458492	Hile	HSF	120/06/23
13	Bimon DAS	0518601	#.14	H.S.F	Bix 26106123
14	su Adabal	0482317	H-14	14.5. E	70/06/23
15	Rohy Bardhern	0506487	H.K	H·SF	20/06/25
16	Bahajan Akura	0510634	H:K	H-3F	8/20/06/23
17	Abrahim Idhalle	0523653	HK	HSF	IR/20106/28
18	Paritogn sels	0H38196	HW	HSF	P.Delo 201842
८५	Roggin Momasudeza	0231822	HK	H3F	B12018L
29	Sammet puth	0489310	H-K	H3F	de 20106)2
21	Billal Aci	039150	HiK	H.S.F	B2006/23
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Topic:	Safety	au	ume	ners	ti	ain	ing	7	ton	1	tu pe	ue	wel-
Name of Trainer(s	the		n. m			Sign of the				20/06/23			
Date of	201	20/06/23.				Start Time			15		3 ····································		
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MODE C	-	Virtual tra (Microsof training, V	t Teams			Ex	(External Conductorendors,	ed by	experts such a	s con	sultants, from Mylan Global)	
Referen	References, If Any								sion no. / ision no.		NO	_	
				al appraisal ess			. ~	from	nts audits xternal)		Re- fresher training		Corrective/ Preventive Actions (CAPA)
Training) Need			ual occurrences/ ents / failures /			Change Control / CR (SOP Revision Introduction)		evision/		Re-training		Company requirements
			Others (specify	<i>(</i>)								
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Mylan Laboratories Limited Corporate, Bangalore, India

Training Summary and Attendance Sheet

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Sr.No.	Name of The Participant	MID/EMP.	Department	Location	Signature / Date
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10	GopPA MMA	0219628	H.K	H.S.F	noppamma
11	SUNANDA-V	0210501	M. K	H.S.F	Surrender 20/16/23
12	J6THI	6479169	17 R	H.S.F	JOTAZ 20/06/23
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15	Billal Hossain	0416078		H.S.F	20/06/23
16	Billd Hossain	0489304	H·K	H.S.F	13/20/06/29
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s.No: 16695

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Topic :	Safety	au	arenes tra	ini	7						
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Date of	Training		22/07/2	3		Start Time		11	(1:36		
		Classroom On the job training				Self-study Othe			7		
MODE	OF TRAINING	- (/irtual training Microsoft Teams ba raining, Video Confe						as consultants, connel from Mylan Global)		
Referen	ferences, If Any					Version no. Revision no		1	M		
製	Annual appraisal process				Requirements arising from audits (internal / external)			Re- fresher training	Corrective/ Preventive Actions (CAPA)		
Training	J Need		Unusual occurrence Incidents / failures LIR	1 .	CR (nge Control / SOP Revision/ duction)		Re-training	Company requirements		
			Others (specify)								
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Sr.No.	Name	of The	e Participant	/ M	ÍD/EM	9		Location	Signature / Date		
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Mylan Laboratories Limited Corporate, Bangalore, India

Training Summary and Attendance Sheet

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1	Corporate, Bangalore, India				Training Summary and Attendance Sheet						
Topic:	Sa	fety Aw	we	nc	so train	ing					
Name of the Trainer(s)		Anbarason	A			Sign of the Trainer(s) & Date			4	11/12/23	
Date of Training		11/12/23		*		Start Time			ι	S:15 ba	
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		lassroom trainin	g	jo	On the ob training	☐ Self-study				Others	
MODE OF TRAINING	(Mic	irtual training rosoft Teams ing, Video Confe					cted	by expe			onsultants, vendors, Iylan Global)
References If Any	,	NA				Version Revisio		- 1		1	A
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Training Need		Unusual occurrences/ Incidents / failures / LIR			Change Co. CR (SOP Revision/ Introduction			Re-tra	ining		Company requirements
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18	JOTHI/	0479169	H.K.	HSE	36TH2 11/12/23
19	Roham Dars/	0536932	H-K	H.S.F	R-5/12/23
20	Nogesh. E	0534554	HIK	H.5F	Juryan 11/12/23
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25	Rakhu Das	0536328	H.K	H.S.F	
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ı •	Corporate, Bangalore, India				Training Summary and Attendance Sheet							
Topic:	Say	lety Aware	ene?	Ø	training	3						
Name of the Trainer(s)		Anbarasem)· [4		Sign of Traine Date		&		4	11/12/23	
Date of		1 . 1 .				Start Time				ŧ	5:15 bys	
Training	Α.	11/12/2	\$			End Ti	me			1	5:35 thrs	
		lassroom trainin	g	jo	On the ob training	☐ Self-study				Others		
MODE OF TRAINING	G (Mic	training, Video Confere			, WebEx	1	cted	by expe	erts sucl		as consultants, vendors, om Mylan Global)	
References If Any	,	NA:				Version Revisio				~IA	100	
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	boratories Limited e, Bangalore, India	Training	Summary a	and Atte	ndance Sheet
Sr. No.	Name of The Participant	MID / EMP. ID	Department	Location	Signature / Date
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09	malaxa	021259	H-K	HSF	Marazm III
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Topic:	Sa	fety as	ją	NE	gness	trai	າບ ເ	ng			
Name of the Trainer(s)	6	fety al Sey ay: B	V		F	Sign of Traine Date		& .	į · .		Signal 13/12/23
Date of	1.	3/12/23				Start Time				1	5:00 Hrs
Training		1 1		*		End Time				I	6:12 Hrg
		lassroom training	5	ic [On the ob training	☐ Self-	-study	У			Others
		Setual testado a		ار	oo tranning	C P.A.	1		4 1		2"
MODE OF TRAINING	(Mic	☐ Virtual training (Microsoft Teams based, training, Video Conferencing)			*	☐ External training (Conducted by experts such customers and personnel from					
References, If Any		Version no. / Revision no.					_	N	A		
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		Others (Specify)								
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20	Pav	itua			544513	4 k	<u> </u>		# S.F		13/12/202

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Sr. No.	Name of The Participant	MID / EMP. ID	Department	Location	Signature / Date
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89	Billal Aci	0891501	Hik	H.S.P	B 13/12/23
09	moxlisure Rahman	0548562	H·K	H.S.F	13/12/23
10	Dorahin Chaire	0523653	H. K	HSP	D31223
11	HUSSUIM ALLI	0547320	H:K	HSF	13/12/23
12.	Cr. Smart	054213	14.12	HSF	CI. Intale
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14.	V. Maniula	1290	conoche	HISIF	13/12/23
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16	A-Manikanilan	22072	Armitrong	HSF	A-m -3 13/12/23
17	K. SANTHOSH	22/09	Armstrong	HSF	KUS 13/12/23
18	Nagarathre	0489303	H. K	HISF	13/22/23
19	R. Subramanian	N-1255	Nowal	EHS	drunon 23.
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-	oratories Limited Bangalore, India		Training	Summ	ary	and	Atte	nda	nce Sheet
Topic:	Safety a	J Du	eners -	traig	u'z	9			
Name of the Trainer(s)	Safetty au Syry.B.	Ŭ		Sign of Trainer Date	the (s) &	ė.	-	٤	14/12/23
Date of	14/12/200	 23		Start Time					4:07 478
Training				End Ti				-	5:27 Hrg
	🗓 Classroom trainin	_	☐ On the job training	☐ Self-study					Others
MODE OF TRAINING	☐ Virtual training (Microsoft Teams training, Video Conf	base	<i>'</i>	☐ External training (Conducted by experts such as concustomers and personnel from My					
References, If Any	-NA-			Version Revisio		- 1	_	NA	
	Annual apprais	sal	Requirement arising from (internal/ ex	n audits		Re-fre trainir			Corrective/ Preventive Actions (CAPA)
Training Need	Unusual occurrences/ Incidents / failures / LIR		Change Co CR (SOP Revision/ Introduction			Re-tra	iining		Company requirements
	Others (Specif	1							-
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02	Prakash.		01	Prise		ed (4	812	-	A 14/12/2023
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Topic:	Safety De	venenes 6	Euring						
Name of the Trainer(s)	C. Muse Sh		Sign of the Trainer(s) Date	&	St. 2123.				
Date of			Start Time		15-140				
Training	15/12/2	3	End Time		15:59.				
S	Classroom trainin	g On the job training							
MODE OF TRAINING	☐ Virtual training (Microsoft Teams training, Video Conf		☐ External training (Conducted by experts such as consultants, vene customers and personnel from Mylan Global)						
References, If Any	NA		Version no. Revision no	1)				
=	Annual apprais	Requireme arising from (internal/ e	m audits	Re-fresher training	Corrective/ Preventive Actions (CAPA)				
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Sr. No.	Name of The Particip		Departmen						
01	Sazia Ahmea	0536926	HK	H2F	\$3/12/23				
02	M·sivagandhi	0368879	14·K	H ·S·F	12.5/12ga 15/12/23				
03	R. Harish	0510980	H.K	H·sF	15/12/23				
04	C. Moldagh	0222310.	H·K.	H.S.F.	Martis /12/23.				
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