



ANDHRA PRADESH POLLUTION CONTROL BOARD
D.No.33-26-14D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamalavari Street, Kasturibaipet, Vijayawada - 520 010
Phone. No.0866-2463200, Website : www.pcb.ap.gov.in

RED CATEGORY
CONSENT & HAZARDOUS WASTE AUTHORIZATION ORDER

Consent Order No : APPCB/VSP/VSP/155/HO/CFO/2020- 18/09/2020

CONSENT is hereby granted for Operation under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation under Rule 6 of the Hazardous & Other Wastes (Management and Transboundary, Movement) Rules, 2016 and the rules and orders made there under (hereinafter referred to as 'the Acts', 'the Rules') to:

M/s. Mylan Laboratories Ltd., Unit - 9,
(Change of product mix)
Plot No. 5, JNPC, Parawada,
Visakhapatnam
E-mail:srinivas.gangavarapu@mylan.in

(Hereinafter referred to as 'the Applicant') authorizing to operate the industrial plant to discharge the effluents from the outlets and the quantity of emissions per hour from the chimneys as detailed below:

i. Outlets for discharge of effluents:

Outlet No.	Outlet Description	Quantity	Point of Disposal
1)	High TDS effluents (Process effluents)	62.39 KLD	The industry shall send the pre-treated effluent routing through M/s. Andhra Pradesh Environment Corporation Limited (APEMCL) so as to send to MEE of CETP, JN Pharmacy for forced evaporation.
2)	Low TDS Effluents Process effluents - 45.60 KLD + Process Washings - 5.00 KLD + Cooling tower blow down - 6.00 KLD + Boiler blow down - 4.00 KLD + Softener & DM Plant - 4.00 KLD + Domestic - 14.0 KLD	78.6 KLD	The industry shall send the pre-treated effluent routing through M/s. Andhra Pradesh Environment Corporation Limited (APEMCL) so as to send to MEE of CETP, JN Pharmacy, for further treatment and disposal.

ii) Emissions from chimneys:

Chimne	Description of Chimney	Quantity of Emissions at peak
--------	------------------------	-------------------------------

Sl. No.		flow (m ³ /hr)
1	Attached to 1 x 3 TPH & 1 x 6 TPH Coal Fired Boilers	--
2	Attached to 2 Lakh K.Cal/hr Thermic Fluid heater	--
3	Attached to 1x500 + 1x1500 KVA + 1x1250 KVA DG Sets	--
4	Process Emissions	--

iii) HAZARDOUS WASTE AUTHORISATION (FORM - II) [See Rule 6 (2)]:

M/s. Mylan Laboratories Ltd., Unit - 9, Plot No. 5, JNPC, Parawada, Visakhapatnam is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

• HAZARDOUS WASTES WITH DISPOSAL OPTION:

S.No	Name of hazardous waste	Stream	Quantity	Method of disposal
1.	Organic solid waste	28.1 of Schedule I	9770.1 Kg/Day	Shall be routed through M/s. APEMCL so as to dispose to TSDF Parawada for incineration / Authorised Cement Industries for Co-Processing
2.	Spent Carbon	28.3 of Schedule I	576.97 Kg/day	
3.	Stripper Distillation (SRU)	28.1 of Schedule I	2000 Kg/day	
4.	Off specified & discarded raw materials, chemicals & products	28.4 of Schedule I	50 Kg/day	
5.	Spent mixed Solvents (Coloured)	28.6 of Schedule I	10,000 Kg/day	
6.	ETP sludge	35.3 of Schedule I	1000 Kg/day	Shall be routed through M/s. APEMCL so as to send to TSDF, Parawada for secured land- filling.
7.	Inorganic Solid waste (from process)	28.1 of Schedule I	1714.76 Kg/day	

• HAZARDOUS WASTES WITH RECYCLING OPTION:

S.No	Name of hazardous waste	Stream	Quantity	Method of disposal

1.	Used oil	5.1 of Schedule I	2000 LPM	Shall be routed through M/s. APEMCL so as to send to authorized recyclers
2.	Container & Container liners of Hazardous Waste & Chemicals	33.1 of Schedule I	Containers - 5000 nos/month Liners - 10,000 Kg/Month	-After detoxification, containers, shall be routed through M/s. APEMCL so as to send to outside agencies.
3.	Recovered solvents (Distilled Colourless)	28.6 of Schedule I	350 TPM	Shall be routed through M/s. APEMCL so as to send to reuse / sale to authorized recyclers.

Other Wastes:

S.No	Name of the Hazardous waste	Quantity	Method of disposal
1.	Thermo coal	50 kg/day	To TSDF
2.	Insulation waste	50 kg/day	
3.	Glass wool	50 kg/day	
4.	E - waste	5 TPM	To authorized collection center / recyclers / dismantler / disposal facility
5.	Paper, cotton waste & packing materials i.e., wood, carton, ropes etc	16 TPM	Sale to agencies / recyclers
6.	Ply wood boxes, tins	10 TPM	
7.	Metal scrap (MS, SS, GI, Aluminium)	25 TPM	
8.	Spent discarded resins	400 kg/month	
9.	Discarded Personal protective equipment	1000 kg/month	
10.	Discarded Thermocool	1000 kg/month	To TSDF
11.	Discarded Tube Lights	50 kg/month	
12.	HEPA Filters / Oil filters	50 Nos. / Annum	
13.	Discarded UF/RO membranes	30 Nos. / Annum	
14.	Broken glassware, glass	1.0 TPM	

	bottles, glass vials, etc		
15.	PPFRP Waste	50 kg/day	To TSDF
16.	Waste paint materials	100 kg/month	
17.	Coal Ash	250 TPM	To TSDF to use as a stabilizing agent / brick manufacturers

This consent order is valid for manufacturing the following products along with quantities indicated only:

S. No	Name of the products	Production capacity (kg/day)	No's of Stages	Starting raw materials	Quantity (kg/day)
Group-1					
1	SetralineHCl	100	5	Tetralone	263.48
2	Levofloxacin	300.00	3	Levo ethyl ester (LFX)	176.60
3	Zidovudine	733.00	2	Beta Thymidine	1184.27
4	Sevelamer Carbonate	400.00	1	SevelamerHCl	354.40
5	Abacavir	467.00	3	AFC	810.54
	Total	2000			
Group-2					
1	Dolutegravir	333.33	3	Dolutegravir sodium DOS I	489.57
2	Celecoxib	600	3	4-Methyl acetophenone (4-MAP)	391.70
3	Etoricoxib	133.33	3	Methyl- 6methylnicotinate	20.31
4	Lamivudine	400.00	3	Cyclo Hexyl Ester	771.42
5	Emtricitabine	195	1	FCE	520.00
	Total	1661.66			
Campaign products					
1	Lamotrigine	100.00	4	2,3-Dichlorobenzoyl Chloride	282.67
2	Tenofavir	200	3	Adenine	174.80
3	Valacyclovir	267	3	Acyclovir	313.77
4	Esomeprazole	85	3	2-Chloromethyl - 4- methoxy-3,5-dimethyl pyridine HCl	153.51
5	Piperaquine phosphate	200	3	4,7-Dichloro Quinoline	240.00
6	Sildenafil Citrate	207	3	Sildenafil Citrate (SDC) I EMP	96.52
7	Lumefantrine	200	3	LMN (2-Chloro-1- (2,7-dichloro-9H- Flourene- 4-yl) ethanone	250.05
8	Sevelamer HCl	154	1	Polyallyl amine HCl (50% solution)	356.89
9	Moxifloxacin	10	5	Moxifloxacin acid	13.88
10	Colesevelam HCl	50	1	SevelamerHCl	25.60

11	FBN-I	66.67	2	Febantel (DM) I	44.02
12	BCI-II	66.67	2	Thiourea	14.19
13	Milnaciprone	100	4	POBH	61.27
14	Etravirine	200	7	Ethyl cyanoacetate	73.26
15	Pantoaprozole Sodium	267	3	5-Difluoro Methoxybenzimidazole	134.84
16	Pirferidone	96	4	2-Amino-5-methyl pyridine Or Amino Compound	123.87
17	Dipyramidole	267	2	2,6dichloro 4-8di(piperidin-1-yl)pyrimido[5,4-d] pyrimidine	404.55
18	Efavirenz	166.67	3	MMAA	272.00
19	Mirtazapine	150	1	Mirtazapine Acid	185.08
20	Tadalafil	170.5	4	D-Tryptophan	358.05
21	Pretomanid	150	2	Benzyloxy propyl pivalate (PRT-III)	232.50
22	Chlorthalidone	160	3	3-(4'-Chlorophenyl) Phthalimide (CHL-III)	144.00
23	Validation products	33.33			
	Any one product	267			
	Group-1 OR Group-2 along with one product from campaign products	2267			

The industry shall manufacture products from either Group-1 OR Group-2 along with one product from campaign products at any given point of time with a maximum production capacity of 2267 kg/day.

Byproducts:

S. No	Products name	Stage	By products Name	Quantity (kg/day)
Group-1				
1	Zidovudine	I	TEA salts	1126.40
		II	TTA salts	2186.54
2	Setraline HCl	II	Trans isomer	23.70
		III	Cis isomer	102.78
	Total			3439.42
Group-2				
1	Lamivudine	I	Potassium orthophosphate salts	1791.71

2	Emtricitabine	I	DPHOP	844.35
	Total			2636.06
Campaign products				
1	Tenofovir	II	Spent odium bromide and acetate salts	1790.00
2	Pretomanid	I	Potassium bromide	34.05
3	Efavirenz	I	Sodium acetate	317.35
	Any one product			1790.0
	Group-1 OR Group-2 along with one product from campaign products			5229.42

This order is subject to the provisions of 'the Acts' and the Rules' and orders made there under and further subject to the terms and conditions incorporated in the schedule A, B & C enclosed to this order.

This combined order of consent & Hazardous Waste Authorization shall be valid for a period ending with the 31st day of October, 2022.

#Approvedby#

To

M/s. Mylan Laboratories Ltd., Unit - 9,
(Change of product mix)
Plot No. 5, JNPC, Parawada,
Visakhapatnam

Copy to :

1. The JCEE, Zonal Office, **Visakhapatnam** for information and necessary action.
2. The Environmental Engineer, Regional Office, **Visakhapatnam** for information and necessary action.

SCHEDULE-A

1. Any up-set condition in any industrial plant / activity of the industry, which result in, increased effluent / emission discharge and/ or violation of standards stipulated in this order shall be informed to this Board, under intimation to the Collector and District Magistrate and take immediate action to bring down the discharge / emission below the limits.
2. The industry should carryout analysis of waste water discharges or emissions through chimneys for the parameters mentioned in this order on quarterly basis and submit to the Board.
3. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 should be followed as applicable.
4. The industry should put up two sign boards (6x4 ft. each) at publicly visible places at the main gate indicating the products, effluent discharge standards, air emission standards, hazardous waste quantities and validity of CFO and exhibit the CFO

- order at a prominent place in the factory premises.
5. Notwithstanding anything contained in this consent order, the Board hereby reserves the right and powers to review / revoke any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
 6. The industry shall ensure that there shall not be any change in the process technology, source & composition of raw materials and scope of working without prior approval from the Board.
 7. The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No.14 of E(P) Rules, 1986 & amendments thereof.
 8. The applicant should make applications through Online for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules at least 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts and detailed compliance of CFO conditions for obtaining Consent & HW Authorization of the Board. The industry should immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions. Any change in the management shall be informed to the Board. The person authorized should not let out the premises / lend / sell / transfer their industrial premises without obtaining prior permission of the State Pollution Control Board.
 9. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules 1982, to Appellate authority constituted under Section 28 of the Water(Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air(Prevention and Control of Pollution) Act, 1981.
 10. The industry shall be liable to pay Environmental Compensation / Other Environmental Taxes, if any environmental damage caused to the surroundings, as fixed by the Collector & District Magistrate or any other competent authority as per the Rules in vogue.
 11. The industry may explore the possibility of tapping the solar energy for their energy requirements.

SCHEDULE-B

1. The industry shall handover the original Consent order No. APPCB/VSP/VSP/155/HO/CFO/2017 - 178, dated 26.10.2017, having validity upto 31.10.2020 to RO, Visakhapatnam after receipt of this order and the same stands cancelled from the date of receipt of this order.
1. The industry has a total area of 6.67 acres and supposed to develop green belt in an area of 2.2 acres (33% of the total area), whereas the industry has developed green belt in an area of 1.0 acre and the balance 1.2 acres need to be developed. The industry shall develop the balance green belt of 1.2 acres within 1 month, i.e., by 18.10.2020 and submit proof.
2. The industry has not installed data logger to pH meter attached to the scrubber. The industry shall install data logger to pH meter attached to the scrubber within 1 month, i.e., by 18.10.2020 and submit proof.
3. The industry is having Solvent recovery system with 3 nos. of columns. The industry has not submitted the performance report and not complying with the following as per SOP of CPCB:

- i. The vent of the condenser shall be passed through VOC absorption media like activated carbon.
- ii. Installation of online analyser for TOC at the vent out let in time bound manner

The industry shall comply with the SOPs of CPCB and submit compliance within 1 month, i.e., by 18.10.2020.

4. The industry generates **25,174 kg/day** of Organic solid waste/Stripper Distillation (SRU)/Spent carbon/Spent mixed solvents (Coloured)/ Off specified & Discarded raw materials, lab chemicals & products to authorized cement plants for co-processing / TSDF, Parawada for incineration, **whereas** the industry disposed 960.82 tonnes of the waste in last 6 months i.e., **5,337 Kg/day** to authorized cement plants for co-processing / TSDF, Parawada for incineration.(spent mixed solvents of 693.175 Tons to Bharati/Myhome/Dalmia cement for co-processing and AFRF for CWMP, Spent carbon of 38.85 tons to CWMP for AFRF, Organic solid waste of 170.31 tons to CWMP for AFRF, Packing materials etc., of 55.44 to CWMP for ARF, Off specified & Discarded Raw materials, lab chemicals and products of 1.62 tons to CWMP for ARF/incineration, Discarded PPE of 1.245 tons to CWMP for AFRF, Thermocol waste of 0.15 tons to CWMP for incineration). The industry has to explain the gap. Further, the industry generates **2,050 kg/day** of ETP sludge/ Glass wool/ Spent discarded resins/ Discarded Tube Lights etc., to TSDF, Parawada for land fill, **whereas** the industry disposed 54.56 tonnes of the waste in last 6 months i.e., **303 Kg/day** TSDF, Parawada for land fill (In-organic salts of 4.225 tons to CWMP for landill, ETP sludge/cooling tower sludge of 50.33 tons to CWMP for landfill). The industry has to explain the gap.

The industry shall properly dispose the Hazardous waste and the submit the compliance within 1 month, i.e., by 18.10.2020.

WATER POLLUTION:

2. The LTDS effluents sent to CETP, Pharmacy shall not contain constituents in excess of the tolerance limits mentioned below, as per their MoU with M/s Ramky Pharma City.

Outlet	Parameter	Concentration in mg/l
2	pH	6.50 - 8.50
	Temperature °C	< 45 °C
	TDS	12,000 mg/l
	TSS	600 mg/l
	BOD	3,000 mg/l

COD	8,000 mg/l
Oil and Grease	20 mg/l
Chromium Hexavalent (as Cr+6)	2 mg/l
Chromium (total) (as Cr)	2 mg/l
Ammonical Nitrogen (as N)	30 mg/l
Cyanide (as CN)	0.20 mg/l
Lead (as Pb)	1 mg/l
Nickel (as Ni)	3 mg/l
Zinc (as Zn)	15 mg/l
Arsenic (as As)	0.20 mg/l
Mercury (as Hg)	0.01 mg/l

The industry shall segregate the HTDS and LTDS effluent streams and the effluents which are not meeting the above standards shall be treated as HTDS effluents and shall be sent CETP of Pharmacity for evaporation.

4. The source of water is JNPC supply. The following is the permitted water consumption:

S. No.	Purpose	Quantity (KLD)
1)	Process & Washings	85.2 KLD
2)	Boiler feed	110.00 KLD
3)	Cooling makeup	247.318 KLD
4)	Softener &DM Plant	4.00 KLD
5)	Domestic	20.0 KLD
6)	Green belt	20.00 KLD
	Total	486.52 KLD

Separate meters with necessary pipe-line shall be maintained for assessing the quantity of water used for each of the purposes mentioned above.

5. The industry shall maintain flow meters preferably Electro Magnetic flow meters with totalisers for water and effluent quantity measurements for different streams of effluents and different categories of water usage stipulated in this order.
6. The industry shall segregate the effluents into HTDS & LTDS effluents.
7. The LTDS and HTDS effluents shall be stored in above ground collection tanks separately.
8. The industry shall maintain HDPE tanks in the effluent collection tank (both locations at block and common collection point). The effluent shall be connected to the HDPE tanks and from the HDPE tanks, effluent shall be pumped to the ETP. Free space shall be maintained around the HDPE tanks to observe leakages if any.
9. The industry shall maintain containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.
10. The industry shall submit the details of quantity of High TDS and Low TDS effluents sent to CETP of Pharmacity every month to the RO, Visakhapatnam.
11. The industry shall maintain proper manifest system for effluent transported to CETP. They shall submit monthly reports to the E.E., RO-Visakhapatnam.
12. Effluents shall not be discharged onland or any water bodies or aquifers under any circumstances. Floor washings shall be admitted into effluent collection system only and shall not be allowed to find their way into storm water drains or open areas.
13. The industry shall maintain flow meters and web camera connecting to APPCB & CPCB server immediately.
14. The industry shall comply with CPCB directions dated 05.02.2014 / 02.03.2015 and

guidelines issued regarding online monitoring systems issued from time to time. The online monitoring system shall be calibrated periodically as per equipment suppliers manual / CPCB guidelines.

AIR POLLUTION:

15.The emissions shall not contain constituents in excess of the prescribed limits mentioned below:

Chimney No.	Parameter	Emission Standards
1 & 2	Particulate Matter	100 mg/Nm ³
4	HCl	35 mg/Nm ³

16.The industry shall comply with ambient air quality standards of PM10 (Particulate Matter size less than 10mm) - 100 micrograms/ m³; PM2.5 (Particulate Matter size less than 2.5 mm) - 60 micrograms / m³; SO₂ - 80 micrograms / m³; NO_x - 80 micrograms /m³, Ammonia 400 micrograms /m³ outside the factory premises at the periphery of the industry.

Standards for other parameters as mentioned in the National Ambient Air Quality Standards CPCB Notification No.B-29016/20/90/PCI-I, dated 18.11.2009.

Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A)

Night time (10 PM to 6 AM) - 70 dB (A)

17.The industry shall comply with emission limits for DG sets of capacity upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 and G.S.R.448 (E), dated 12.07.2004 under the Environment (Protection) Act Rules. In case of DG sets of capacity more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.

18.The industry shall maintain dedicated two stage scrubbers to the process vents to control the process emissions. The industry shall maintain online pH measuring facility with auto recording system to the scrubbers provided to treat the process emissions. Scrubbed liquid shall be recycled as far as possible and finally sent for further treatment as stipulated.

19.The industry shall maintain online VOC analyzer and the monitoring records shall be submitted to the RO-Visakhapatnam.

20.The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.

21.The evaporation losses in solvents shall be controlled by taking suitable measures, which include:

- i. Chilled brine circulation to effectively reduce the solvent losses into the atmosphere.
- ii. Transfer of solvents by using pumps and closed conveyance instead of manual handling.
- iii. Closed centrifuges be used due to which solvent losses are reduced drastically.
- iv. The reactor vents are connected with primary & secondary condensers to catch the solvent vapours.
- v. All the solvent storage tanks are connected with vent condensers to prevent solvent vapours.

GENERAL:

22.The industry shall not manufacture new products and not exceeding the production quantity, other than those mentioned in this order without CFE & CFO of the Board.

- 23.The drums containing chemicals/solvents shall be stored under a roof on elevated platform with a provision to collect leakages/spillages in the collection pit.
- 24.The industry shall submit half-yearly compliance report for the schedule A,B& C conditions stipulated in CFO & HWA order audited through NABL / MoEF accredited laboratories.
- 25.The industry shall submit Risk analysis and risk assessment covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.
- 26.The industry shall ensure compliance of the National Ambient Air quality standards notified by MoE&F, GoI vide notification GSR 826(E), dt. 16.11.2009 at the boundary of the premises during construction and regular operational phase of the project.
- 27.VOC meters with real time data transmission facility through internet of things (IoT) shall be installed near the production blocks and near the chemical storage tanks and link to the servers of APPCB and CPCB, within 3 months.
- 28.The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity / flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (MSIHC) Rules, 1989 and the details shall be furnished to the Factories Department and to the Regional Office, APPCB on monthly basis duly certifying the same.
- 29.The industry shall identify major accident hazard chemicals & list out the hazardous chemicals endangered to human health & environment and the details shall be furnished to the Factories Department and to the Regional Office, APPCB time to time duly certifying the same by the industry.
- 30.The industry shall extend training to the working personnels while handling hazardous chemicals for prevention of accidents and necessary antidotes to ensure the safety, as per the MSIHC Rules, 1989.
- 31.The industry shall submit the copy of the safety audit report and On-Site / Off Site Emergency Plans as applicable after being certified by the Factories Department to the APPCB, Regional Office from time to time, if the storage quantity of hazardous chemicals is equal to or, in excess of the threshold quantities specified in schedule 2 & 3 of MSIHC Rules, 1989.
- 32.The industry shall carryout calibration of safety equipment and leak detection systems at regular intervals and shall certify the same with the Factories Department. That certified copy shall be submitted to the APPCB, Regional Office. The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
- 33.The industry shall inventorize the hazardous wastes and its quantities stored within the industry premises as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 (HOWM Rules, 2016) and shall furnish the details to Regional Office, APPCB on monthly basis duly certifying the same by the industry.
- 34.The industry shall submit the self-certification on compliance of all the conditions stipulated in the CFO & HWA order.
- 35.The industry shall comply with the Standard Operating Procedure (SoP) and Checklist of Minimal Requisite Facilities for Utilization of Spent Solvent for Recovery of Solvent specified for Solvent Recovery Units issued by CPCB.
- 36.The industry shall follow the SOP for Safe and Scientific Spent Solvent Handling, Processing and Storage.
- 37.The industry shall evaluate the performance of solvent recovery system for each stream-wise and shall furnish plan of action to maintain the efficiency of solvent recovery more than 95% for each stream wise.
- 38.The industry shall send the used /spent solvents to the APPCB recyclers (or) shall

- process them at their own solvent recovery plant within the plant premises.
- 39.The industry shall take all safety measures and provide firefighting equipment in the plant.
- 40.The industry shall maintain the following log books and the same shall be made available to the inspecting officers of the Board:
- a. Daily production details (ER-1 Central Excise Returns).
 - b. Quantity of Effluents generated, treated, recycled/reused and disposed to CETP.
 - c. Log Books for pollution control systems.
 - d. Characteristics of effluents and emissions.
 - e. Hazardous/non hazardous solid waste generated and disposed.
 - f. Inspection book.
 - g. Manifest copies of effluents / hazardous waste.
 - h. Furnish consolidated daily records on the above periodically once in three months to the RO.
- 41.The industry shall submit AAQ monitoring reports conducted by Authorized Agency every month.
- 42.The industry shall maintain dry condition outside drains in un-rainy season.
- 43.The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.
- 44.The industry shall comply with the Regulation of Persistent Organic Pollutants Rules,2018 notified by the MoEF&CC Notification vide G.S.R. 207 (E) dated 30.05.2018. As per the notification, the following 7 chemicals are prohibited to manufacturer, trade, use, import and export:
- a. Chlordecone,
 - b. Hexabromobiphenyl,
 - c. Hexabromodiphenyl ether and heptabromodiphenyl ether (commercial octa-BDE),
 - d. Tetrabromodiphenyl ether and pentabromodiphenyl ether (commercial penta-BDE),
 - e. Pentachlorobenzene,
 - f. Hexabromocyclododecane and
 - g. Hexachlorobutadine.
- 45.The following rules and regulations notified by the MoF &CC, GoI shall be implemented.
- a. Hazardous Waste and Other Wastes (Management and Transboundary Movement) Rules, 2016.
 - b. Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.
 - c. Fly ash notification, 2016.
 - d. Batteries (Management & Handling) Rules, 2010.
 - e. E-waste (Management) Rules, 2016.
 - f. Construction and Demolition waste Management Rules, 2016.
- 46.The industry shall renew the PLI policy which includes Environmental Relief Fund (ERF) and submit copy to RO, Visakhapatnam on yearly basis.
- 47.The industry shall update the information in OCEMS - Industry Information Data Entry Software for Compliance Reporting Protocol in PART-II (Sections F & G) Every Quarter on 1st January, 1st April, 1st July and 1st October through this software system.
- 48.Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB shall be followed from time to time.
- 49.The industry shall comply to the conditions stipulated in the CFE Order No. 155/APPCCB/CFE/RO-VSP/HO/2014 dated 26.12.2019.

SCHEDULE - C
[See rule 6(2)]

[CONDITIONS OF AUTHORISATION FOR OCCUPIER OR OPERATOR HANDLING HAZARDOUS WASTES]

1. The authorised person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
2. The authorisation shall be produced for inspection at the request of an officer authorised by the State Pollution Control Board.
3. The person authorised shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorisation.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. The person authorised shall implement Emergency Response Procedure (ERP) for which this authorisation is being granted considering all site specific possible scenarios such as spillages, leakages, fire etc. and their possible impacts and also carry out mock drill in this regard at regular interval of time;
6. The person authorised shall comply with the provisions outlined in the Central Pollution Control Board guidelines on “Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty”.
7. It is the duty of the authorised person to take prior permission of the State Pollution Control Board to close down the facility.
8. An application for the renewal of an authorisation shall be made as laid down under these Rules.
9. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.

Specific Conditions:

10. The industry shall enter an agreement with the Cement industries for disposal of incinerable waste or shall dispose to Alternative Fuel Raw material facility (AFRF) OR to TSDF for co-incineration.
11. The industry shall comply with the provisions of HWM Rules, 2016 in terms of interstate transport of Hazardous Waste and manifest document prescribed Under Rule 18 and 19 of the HWM Rules, 2016.
12. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.
13. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal to the manufacturers / dealers on buyback basis.
14. The industry shall transport the hazardous waste to cement industries only through vehicle fitted with GPS tracking system.
15. The industry shall maintain 7 copy manifest system for transportation of waste generated and a copy shall be submitted to concerned Regional Office of APPCB. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter should carry a Transport Emergency (TREM) Card.
16. The industry shall maintain proper records for Hazardous and Other Wastes stated in Authorisation in Form-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc., and file annual returns in Form-4 as per Rule 20 (2) of the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.

17. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.
18. The industry shall submit the self-certification on compliance of all the conditions stipulated in the CFO & HWA order.

The industry shall submit Half yearly compliance reports to all the stipulated conditions in Environmental Clearance (EC), Consent for Establishment (CFE) and Consent for Operation (CFO) through website i.e., <https://pcb.ap.gov.in> by 1st of January and 1st July of every year. The first half yearly compliance reports shall be furnished by the industry and second half yearly compliance reports shall be the audited through MoEF&CC recognized and National Accreditation Board for Laboratory Testing (NABL) accredited third party.

DR. B.MADHUSUDHANA RAO, JCEE(MSRB), O/o JOINT CHIEF ENVIRONMENTAL ENGINEER4-APPCB

To

M/s. Mylan Laboratories Ltd., Unit - 9,
(Change of product mix)
Plot No. 5, JNPC, Parawada,
Visakhapatnam