



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 : https://pcb.ap.gov.in

RED CATEGORY
CONSENT & HAZARDOUS WASTE AUTHORIZATION ORDER

Consent Order No : APPCB/VSP/155/HO/CFO/2009-

18/11/2022

CONSENT is hereby granted for Operation under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21/22 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,

Anakapalli District(Earlier Visakhapatnam District)

E-mail:srinivas.gangavarapu@mylan.in; Sunilroy.wadhwa@viatris.com

(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 in KLD	Point of Disposal
1)	High TDS effluents (Process effluents – 62.03)	62.03	The industry shall send the pretreated effluent routing through M/s. Andhra Pradesh Environment Corporation Limited (APEMCL) to MEE of CETP, JN Pharmacy for forced evaporation.
2)	Low TDS Effluents Process effluents – 45.23 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	78.23	The industry shall send the pretreated effluent routing through M/s. APEMCL to CETP, JN Pharmacy, for further treatment and disposal after pre- treatment.
	Total	140.26	

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow (m ³ /hr)
1.	Attached to 1 x 3 TPH & 1 x 6 TPH Coal Fired Boilers	--
2.	Attached to 1x1500 KVA + 1x1250 KVA DG Sets	--
3.	Process Emissions from scrubbers-9 No.s	

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

M/s. Mylan Laboratories Ltd., Unit – 9, Plot No. 5, JNPC, Parawada, Anakapalli District (Earlier Visakhapatnam District) 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 (Process organic residue & Distillation bottom residue)	28.1 of Schedule I	9189 Kg/day	Shall be routed through M/s. APEMCL to TSDF Parawada for incineration / Authorised Cement Industries for Co-Processing/Authorized pre-processing units
2.	Spent Carbon	28.3 of Schedule I	428.52 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.	Contaminated cotton rags	33.2 of Schedule I	0.5 TPM	
6.	Spent mixed Solvents (Coloured)	28.6 of Schedule I	10,000 Kg/day	Shall be routed through M/s. APEMCL to Authorised Cement Industries for Co-Processing/authorized pre-processing units
7.	ETP sludge	35.3 of Schedule I	1000 Kg/day	Shall be routed through M/s. APEMCL to TSDF, Parawada for secured land filling / Authorised
8.	Inorganic Solid waste	28.1 of Schedule I	2444.37 Kg/day	Cement Industries for Co-

	(from process)	Schedule – I	Kg/day	Processing/Authorized pre-processing units.
9.	Thermo coal	33.2 of Schedule – I	50 kg/day	Shall be disposed to TSDF/ Authorised Cement Industries for Co-Processing/Authorized pre-processing units
10.	Insulation waste	33.2 of Schedule – I	50 kg/day	
11.	Glass wool	33.2 of Schedule – I	50 kg/day	
12.	Spent discarded resins	35.2 of Schedule – I	400 kg/month	
13.	Discarded Personal protective equipment	33.2 of Schedule – I	1000 Kg/month	
14.	Discarded Thermocool	33.2 of Schedule – I	1000 kg/month	
15.	HEPA Filters / Oil filters	33.2 of Schedule – I	50 Nos./Annun	
16.	Discarded UF/RO membranes	33.2 of Schedule – I	30 Nos./Annun	

• 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 to authorized recyclers/ Authorized Cement Industries for Co-Processing/Authorized pre-processing units
2.	Container & Container liners of	33.1 of Schedule - I	Containers – 5000 Nos. /Month (or)	After detoxification, containers, shall be routed through M/s. to

	Hazardous Waste & Chemicals		50 TPM & Liners – 10000 Kgs/Month	recyclers / outside agencies / Authorized Cement Industries for Co-Processing/Authorized pre-processing units.
3.	PPFRP Waste	33.1 of Schedule - I	50 kg/day	
4.	Recovered solvents (Distilled Colourless)	28.6 of Schedule - I	350 TPM	Shall be routed through M/s. APEMCL to reuse / sale to authorized SRS units / Cement Industries for Co-Processing / Authorized pre-processing units.

Other Wastes:

S.No	Name of the Hazardous waste	Quantity	Method of disposal
1.	E – waste	5 TPM	Disposed to authorized collection center / recyclers / dismantler / disposal facility
2.	Paper, cotton waste & packing materials i.e., wood, carton, ropes etc	16 TPM	Sale to outside agencies / recyclers / Authorized Cement Industries for Co-Processing/ pre-processing units
3.	Ply wood boxes, tins	10 TPM	
4.	Metal scrap (MS, SS, GI, Aluminium)	25 TPM	Sale to outside agencies
5.	Discarded Tube Lights	50 kg/month	Disposed to authorized collection center / recyclers / dismantler / disposal facility
6.	Broken glassware, glass bottles, glass vials, etc	1.0 TPM	Disposed to TSDF for encapsulation, Parawada, Visakhapatnam / Sale authorized agencies after complete detoxification for reuse/recycle
7.	Waste paint materials	100 kg/month	Disposed to TSDF for incineration / Cement Industries for Co-Processing / pre-processing units.
8.	Coal Ash	250 TPM	Disposed to TSDF to use as a stabilizing agent / brick manufacturers
9.	Lead Acid Batteries	250 Nos/Annum	Disposed to dealers on buy back system

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

S.No	Name of the products	Qty in Kg/Day	Qty in Kg/annum	Name of the Starting raw material	Qty in Kgs/Day	No's of Stages
Regular products						

1	Celecoxib	166.67	60001.2	4-Methyl acetophenone (Para Methyl acetophenone)	88.58	2
2	Dolutegravir sodium	500.00	180000	DSSI	636.22	3
3	Etoricoxib(ETO)	66.67	24001.2	ketosulphone	80.00	2
4	Lamivudine	733.33	263998.8	Cyclohexyl Ester	1566.05	3
5	Levofloxacin Hemihydrate	233.33	83998.8	Levo ethyl ester	258.54	3
6	Zidovudine	150.00	54000	Betathymidine	209.47	2
7	Sertraline HCL	150.00	54000	Tetralone	801.51	4
	Total	2000.00	720000			
	Campaign products					
1	BCI-II	100.00	36000	Thiourea	61.40	2
2	Febantel (FBN I)	100.00	36000	Febantel (DM) II	81.30	1
3	Dipyridamole	267.00	96120	DiCl.dipiperidinopyrimido[5, 4d]pyin HM*	250.23	2
4	Tadalafil	33.33	11998.8	D-Tryptophan	38.06	4
5	Molnupiravir	166.67	60001.2	Cytidine	148.81	1
6	Milnacipran Hydrochloride	100.00	36000	2 OXO 1 PHENYL 3 OXABICYCLO [3.1.0HEXANE	204.17	4
7	Chlorthalidone	155.00	55800	Chlorthalidone (CHA) II	155.00	3
8	Emitricitabine	185.00	66600	FCE	602.41	2
9	Etoricoxib(ETX)	66.67	24001.2	ketosulphone	82.54	2

10	Etravirine	86.00	30960	6-AMINO-4-CHLORO-2-(4-CY.PA)PYRIMIDINE	160.20	5
11	Felbamate	33.33	11998.8	2-Phenyl-1,3-Propane Diol	81.30	2
12	Lumefantrine	200.00	72000	LMN Lumefantrine (LMF) I	214.77	3
13	Mirtazapine (anhydrous)	83.33	29998.8	Mirtazapine Acid	123.74	2
14	Mirtazapine hemihydrate (ABK)	66.67	24001.2	Mirtazapine Acid II SK	112.04	2
15	Pantoprazole sodium	267.00	96120	2-Chloromethyl 3,4-Dimethoxy Pyridine	257.97	2
16	Pirfenidone	96.00	34560	2-Amino-5-Methylpyridine	123.87	2
17	Pretomanid	150.00	54000	Pretomanid (PTM) II (Benzyloxy Propyl pivalate solution in toluene as 100%)	421.35	2
18	Sildenafil citrate	207.00	74520	Sildenafil Citrate (SDC) I EMP	129.27	3
19	Validation products	33.33	11998.8			
	Any one product	267.00	96120			
	Regular products along with any one product form campaign products	2267.00	816120			

List and Quantities of By Products:

S.NO	Products name	Stage	By products name	Quantity in Kgs /day	Quantity in Kgs / Annum
Regular products					
1	Zidovudine	I	TEA salts	187.5	67500
		II	TTA salts	214.29	77144.4

2	Setraline HCl	II	Trans isomer	450	162000
			Aq. Mandelic Acid (Including water)	351.9	126684
3	Lamivudine	I	potassium orthophosphate salt	704.73	253702.8
		I	Menthol	595.10	214236
		II	Tech Salicylic Acid	937.20	337392
	Total			3440.72	1238659.2
Campaign products					
1	Pretomanid	I	potassium bromide	95.70	34452
2	Emitricitabine	I	DPHOP	397.12	142963.2
		I	Layer TOL + Menthol	574.30	206748
	Any one product			971.42	349711.2
	Regular products along with one product from campaign products			4412.14	158837.4

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, 2025.**

**VIJAY KUMAR GSRKR IAS, MEMBER SECY(GSRKRVK), O/o MEMBER
SECRETARY-APPCB**

To

**M/s. Mylan Laboratories Ltd., Unit – 9,
(Change of product mix)
Plot No. 5, JNPC, Parawada,
Anakapalli District(Earlier Visakhapatnam District)**

Copy to :

1. The JCEE, Zonal Office, **Visakhapatnam** for information and necessary action.

2. The EE, 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. 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.
5. 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.
6. 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.
7. 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.
8. 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 conditions stipulated are without prejudice to the rights and contentions of this Board in any Hon'ble court of law.
11. 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.
12. The industry may explore the possibility of tapping the solar energy for their energy requirements.
13. The industry should educate the workers and nearby public of possible accidents and

remedial measures.

SCHEDULE-B

The industry shall comply with the following:

1. The industry shall not operate SRS unit until completion of installation of VOC absorption Media like Activated Carbon for the vent of the condenser as per SoP for SRS units issued by CPCB.
2. The industry shall operate SRS only after obtaining permission from the Board.

WATER POLLUTION:

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

Sl. No.	Purpose	Quantity (KLD)
1.	Process & Washings	84.09
2.	Boiler feed	110.00
3.	Cooling makeup	247.318
4.	Softener & DM Plant	4.00
5.	Domestic	20.00
6.	Green Belt	20.00
	Total	485.408

4. 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 ⁰ 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 Pharmacy for evaporation.).

5. The industry shall maintain Electro Magnetic flow meters with totalisers for water consumption, effluent generation mentioned in the Order.
6. The industry shall maintain HDPE tanks / tank in tank in the effluent collection tank (both locations at block and common collection point). Free space shall be maintained around the HDPE tanks / Tank in Tank to observe leakages if any.
7. The LTDS and HTDS effluents shall be stored in above ground collection tanks separately.
8. 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.
9. The industry shall provide 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 maintain web camera and flow meters provided for HTDS & LTDS pumped to CETP, Ramky, properly and same connected to CPCB & APPCB website, as per CPCB directions dt. 05.02.2014 / 02.03.2015.
11. Rain water shall not be allowed to mix with either trade or domestic effluents. Industry shall maintain storm water drains, properly.
12. The industry shall maintain rainwater runoff tank with pump for collection and storage of first flush contaminated storm water and the same shall be sent to CETP for further treatment. The industry shall maintain dry condition in outside drains during non-rainy season.

AIR POLLUTION:

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

Chimney No.	Parameter	Emission Standards (mg/Nm³)
1& 2	Particulate Matter	100
3	HCl	35
	NH ₃	30
	Sulphuric acid mist	50
	Chlorine	15
Tank farm vents	HCl	35
	NH ₃	30
	Chlorine	15
	Benzene	5
	Toluene	100
	Acetonitrile	1000
	Dichloromethane	200
	Xylene	100
Acetone	2000	

14. The industry shall comply with ambient air quality standards of PM₁₀ (Particulate Matter size less than 10 micro grams) - 100 micro gram/ m³; PM_{2.5} (Particulate Matter size less than 2.5 micro grams) - 60 mg/ m³; SO₂ - 80 micro gram/ m³; NO_x - 80 micro gram/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)

- 15.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.
- 16.The industry shall provide a sampling port with removable dummy of not less than 15 cm diameter in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.
- 17.The industry shall operate the multi stage scrubbers for scrubbing of process emissions at all emission sources. The industry shall maintain online pH meters to the scrubbers. Scrubbed liquid shall be recycled as far as possible and finally sent to CETP of Pharmacy for further treatment.
- 18.The industry shall maintain energy meter to APC. The industry shall connect all the vents of the SSR reactors to the scrubber to control process emissions.
- 19.The evaporation losses in solvents shall be controlled by taking the following measures:
 - 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 are used due to which solvent losses are reduced drastically.
 - iv. The reactor vents 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.
- 20.The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.
- 21.The industry shall maintain VOC meters with real time data transmission facility through internet of things (IoT) and link to the servers of APPCB.
- 22.The industry shall install multi gas detectors (such as NH₃ and other toxic gases) with data loggers at production block and main gate to know the concentrations in the ambient air in the factory premises.

GENERAL:

- 23.The industry shall not manufacture new products and not exceed the consented capacity without CFE/CFO of the Board.
- 24.The industry shall comply with the tolerance limits mentioned in MoEF notification dated 09.07.2009 and G.S.R. 541(E) dt. 06.08.2021 for Bulk Drug and Formulation (Pharmaceutical).
- 25.The industry shall maintain hood on top of the effluent storage tanks and vent connected to the scrubber.
- 26.The industry shall maintain the following records and the same shall be made available to the inspecting officers of the Board:

- a. Daily production details.
 - 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.
- 27.The industry shall maintain records on source of intermediates for each product-wise and the consolidated records shall be submitted to R.O., Visakhapatnam for every month along with invoice copies of the intermediates outsourced.
 - 28.The industry shall maintain good Housekeeping.
 - 29.Green belt with native species of adequate width and density shall be maintained along the boundary of the industry with minimum area of 33% of total area.
 - 30.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 from time to time. The total cumulative losses of solvents shall not be more than 5% of the solvent on annual basis from storage inventory.
 - 31.The industry shall comply with SoPs issued by CPCB time to time for all the wastes.
 - 32.The industry shall maintain valid PLI policy which includes Environmental Relief Fund (ERF) and submit copy to RO, Visakhapatnam on yearly base.
 - 33.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:
 - i. Chlordecone,
 - ii. Hexabromobiphenyl,
 - iii.Hexabromodiphenyl ether and heptabromodiphenyl ether (commercial octa-BDE),
 - iv.Tetrabromodiphenyl ether and pentabromodiphenyl ether (commercial penta-BDE),
 - v. Pentachlorobenzene,
 - vi.Hexabromocyclododecane and
 - vii.Hexachlorobutadine.
 - 34.The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.
 - 35.The industry shall install digital display boards at publicly visible places at the main gate indicating the products manufactured Vs permitted quantities, Treated effluent concentrations Vs discharge standards, Stack emission & AAQ concentrations Vs standards, hazardous waste generation, disposed, stock Vs permitted quantities and validity of CFO; and exhibit the CFO order at a prominent place in the factory premises, as per Hon'ble Supreme Court order by 20.11.2022.
 - 36.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.
 - 37.Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB

shall be followed from time to time.

- 38.The Board reserves its right to modify above conditions or stipulate any further conditions and to take action including revoke of this order in the interest of protection of public health and environment.
- 39.The conditions stipulated are without prejudice to the rights and contentions of this Board in any Hon'ble Court of Law.

Special conditions:

- 40.The industry shall submit a copy of the NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) at concerned Regional Office, APPCB.
- 41.The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.
- 42.The industry shall extend training to the working personnel for the prevention of accidents and necessary antidotes to ensure safety, as per the MSIHC Rules, 1989.
- 43.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.
- 44.The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
- 45.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.
- 46.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.

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 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.
11. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.
12. 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.
13. The industry shall transport the hazardous waste to cement industries only through vehicle fitted with GPS tracking system.
14. 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.
15. 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.
16. The industry shall route all the hazardous waste through APEMCL.

**VIJAY KUMAR GSRKR IAS, MEMBER SECY(GSRKRVK), O/o MEMBER
SECRETARY-APPCB**

To

**M/s. Mylan Laboratories Ltd., Unit – 9,
(Change of product mix)
Plot No. 5, JNPC, Parawada,
Anakapalli District(Earlier Visakhapatnam District)**