



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/>

Consent amendment order No: APPCB/VSP/250/HO/CFO/2021 02/05/2022

Sub: APPCB – UH-IV - CFO - M/s. Mylan Laboratories Ltd(Unit – 10), SEZ, Plot No. 86, JNPC, Parawada, Visakhapatnam – Industry’s request for amendment of CFO order for production and Hazardous wastes quantities with disposal option – **Issued** - Reg.

Ref:-

1. CFO order Dt.09.03.2021 valid up to 31.03.2026.
2. Industry’s representation received on 02.03.2022
3. RO, Visakhapatnam report dated 02.03.2022 &.
4. CFO committee meeting held on 30.03.2022.
5. RO, Visakhapatnam report on 20.04.2022 on industry fee payment

- I. The Board issued CFO on 09.03.2021 for operating a Bulk Drug manufacturing industry to produce 7 products with maximum production capacity of 5066.67 kg/day valid up to 31.03.2026. The industry on 02.03.2022 requested for CFO amendment for change of quantities in hazardous waste and products. The RO, Visakhapatnam submitted the report.
- II. The issue of CFO (Amendment) to the industry was placed in the CFO committee meeting held on 30.03.2022 and the committee recommended to **issue CFO & HWA (Amendment) to the industry, subject to payment of balance fee, as per revised Fee structure.**
- III. The RO, Visakhapatnam vide letter dt. 20.04.2022 informed that the industry has paid the Rs.20,42,070/- towards balance fee to consider the issue of CFO Amendment.
- IV. The Board after careful examination on the request of the industry and recommendations of CFO Committee, hereby issues amendment to the CFO & HWA order dated dt.09.03.2021 (ref 1st) under Section 25/ 26 of the Water (Prevention & Control of Pollution) Act, 1974 under section 21/22 of the Air (Prevention and Control of Pollution) Act, 1981 and amendments thereof & under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and amendments thereof., as follows:

The table below the “Emissions from chimneys” shall be replaced with the following table:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow (m³/hr)
1.	Attached to 1x12 TPH Coal fired boiler	--
2.	Attached to 1x4 TPH Coal fired boiler	--
3.	Attached to 1500 KVA + 500 KVA & 4x2000 KVA DG Sets	--
4 to 7	Process emissions	--

The table below the “hazardous waste with disposal option” shall be replaced with the following table:

S.No	Name of the Hazardous Waste	Stream	Quantity of Hazardous Waste	Method of disposal
Utilisable waste				
1.	Stripper Distillate	28.1 of Schedule - I	2000 Kg/day	Shall be routed through M/s. APEMC so as to send to preprocessors / cement industries for co processing (as utilizable waste) / disposed to TSDF for incineration or AFRF.
2.	Process Organic Waste (includes distillation residue)	28.1 of Schedule - I	14694 Kg/Day	
3.	Spent Carbon	28.3 of Schedule - I	2199 Kg/Day	
4.	Spent Mixed Solvents (colored)	28.6 of Schedule - I	25000 Kg/Day	
5.	Contaminated cotton rags	33.2 of Sch-1	0.5 TPM	
6.	Spent Mixed Solvents / Recovered Solvents (colorless)	28.6 of Schedule - I	60 KLD	Shall recover Solvent recovery within the premises / Shall be routed through M/s. APEMC so as to disposed to Authorized solvent recovery units (as utilizable waste).
7.	Off specification & discarded products / raw materials/ intermediates / lab chemicals	28.4 Schedule - I	250 Kg/day	Shall be routed through M/s. APEMC so as to send to preprocessors / cement industries for co processing (as utilizable waste) / disposed to TSDF for incineration or AFRF.
8.	Off specified & discarded raw material, lab chemicals & products	28.4 Schedule - I	250 Kg/day	
9.	Filtration bags	28.1 of Schedule - I	1500 Kgs / month	
10.	Container liners.	33.1 of Schedule-I	20000 Kg/month	
Recyclable waste				
11.	Used oil	5.1 of Schedule-I	4000 Lts/m	Shall be routed through M/s. APEMC so as to send to authorized recyclers (as recyclable waste).

12.	Containers	33.1 of Schedule-I	30 TPM or 3000 No's/Month	Shall be routed through M/s. APEMC so as to disposed to outside agencies after detoxification (as recyclable waste).
13.	Empty glass bottles	33.1 of Schedule-I	500 Kg/ month	
Landfillable waste				
14.	Process Inorganic Waste	28.1 of Schedule - I	3580 Kg/day	Shall be routed through M/s. APEMCL so as to send to TSDF, Parawada, Visakhapatnam District for land filling. (as Landfillable waste) / to APPCB authorized pre-processing units/ Cement industries for co processing (as utilizable waste).
15.	ETP Sludge	35.3 of Schedule - I	1500 Kg/day	
16.	Insulation waste - Glass wool	33.2 of Schedule-I	2500 Kg/ month	
17.	Laboratory vials	---	500 kg/month	
18.	Spill contaminant waste	---	50 Kg/day	
Incinerable waste				
19.	Thermo coal waste	---	5000 Kg/ month	Shall be routed through M/s. APEMC, so as to send to TSDF, Parawada for incineration. (Incinerable waste) / APPCB authorized pre-processing units/ Cement industries for co processing (as utilizable waste).
20.	Pharma dust from clean rooms, Pharma rooms, AHUs, Bag filters and floor sweeping	---	100 Kg/day	
21.	Discarded resins	---	100 Kg/day	
22.	Insulation waste a) Nitrile Rubber	33.2 of Schedule-I	2500 Kg/ month	
23.	Discarded personal protective equipment		200 Kg/day	
24.	HEPA filters / oil filters / paint tins		1500 Kg/month	

The table below the “This consent order is valid for manufacture the following products & By – Products with quantities indicated below” shall be replaced with the following table:

Group	S.No	Product	Quantity (Kg/Day)	Quantity (Ton/Annum)
1	1	Tenofavir	1666.67	600.00
	2	Efavirenz	2000	720.00
	3	Acyclovir	333.33	120.00
	4	Citalopram	333.33	120.00

	5	Abacavir	633.33	228.00
	6	Valacyclovir	200	72.00
	Any 3 products of 4300 Kg/day at any point of time with the specified quantities:		4300	1548.00
2	1	Dolutegravir sodium	333.33	120.00
	2	Valsartan	133.33	48.00
	3	Gabapentine	133.33	48.00
	4	Ritonavir	166.67	60.00
	5	Carvedilol	166.67	60.00
	6	Atazanavir	133.33	48.00
	Any 2 products of 500 Kg/day at any point of time with the specified quantities:		500	180.00
3	1	Trazodone	100	36.00
	2	Lanthanum Carbonate	100	36.00
	3	Clozapine	83.33	30.00
	4	Escitalopram	166.67	60.00
	5	Montelukast	100	36.00
	6	Irbesartan	100	36.00
	7	Atorvastatin	100	36.00
	8	Levofloxacin	100	36.00
	9	Lopinavir	100	36.00
	10	Validation Product	66.67	24.00
Any 2 products of 266.67 Kg/day at any point of time with the specified quantities:		266.67	96.00	
Total Qty			5066.67	1824.00

S.No.	Name of the Product	Name of the By- Product	Qty Kg/Day	Qty Ton/Annum
1	Tenofovir	Chloro Methyl Isopropyl Carbonate	4167	1500.12
		Sodium Sulfate	2000	720
		Sodium Bromide ML's	12495	4498.2
2	Valacyclovir	1,3 Dicyclohexyl Urea	313	112.68
3	Escitalopram	Ammonium Phosphate	110	39.6
4	Citalopram	Sodium phosphate	112	40.32
		Ammonium Phosphate	2692	969.12
5	Atazanavir	Phosphate Salts	265	95.4
6	Lopinavir	Sodium Salts	1420	511.2

The condition no. 14 of air pollution shall be amended as below:

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

- 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. All the reactor vents connected with primary & secondary condensers to catch the solvent vapours.
- v. All the bulk solvent storage tanks connected with vent condensers or nitrogen blanketing to prevent solvent vapours.

Providing TOC analyser condition is revised as the industry shall provide regular VOC monitoring with portable VOC meter at primary and secondary vent condensers and / or online fixed VOC detector connected to data logger in existing SoP, as per revised SoP issued by CPCB.

All other conditions mentioned in Schedules A, B & C of the CFO&HWA order dated 09.03.2021 (ref. 1st) including validity period upto 31.03.2026 will remain the same.

KANDAVALLI VENKATESWARA RAO, CEE(KVR), O/o CHIEF ENVIRONMENTAL
ENGINEER-APPCB

To

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Copy to:

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