



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/>

CFO Amendment Order No: APPCB/VSP/155/CFO/HO/2020 27/07/2022

Sub: APPCB – UH-IV - CFO – M/s. Mylan Laboratories Ltd., Unit – 9, Plot No. 5, JNPC,
- Parawada, Visakhapatnam – Request for CFO amendment for production quantity, etc.,
- CFO & HWA (Amendment) – Issued – Reg.

Ref:-

1. CFO & HWA order dated 18.09.2020 with validity upto 31.10.2022.
2. Industry's representation dated 11.05.2022.
3. RO, Visakhapatnam report dt. 20.06.2022.
4. CFO committee meeting held on 30.06.2022

1. The Board issued CFO on 18.09.2020 to manufacture Bulk Drugs & Drug intermediates - 2267 kg/day for a period upto 31.10.2022. The Board Office on 11.05.2022 communicated the industry's representation for CFO Amendment to the RO, Visakhapatnam. The RO, Visakhapatnam on 20.06.2022 submitted the report on the industry request.
2. The issue of CFO (Amendment) to the industry was placed in the CFO committee meeting held on 30.06.2022 and the committee recommended to issue CFO & HWA (Amendment) for i) production quantity in terms of TPD & TPA; ii) mention no. of scrubbers installed in the premises in CFO order; iii) container liners in terms of nos./month and tons/month; iv) Inclusion of contaminated cotton rags – 0.5 TPM with a disposal option to TSDF for incineration or authorized cement plants for co-processing and not consider the omitting condition, the industry shall comply with the revised SoP issued by the CPCB for SRS units.
3. The Board after careful examination of the request of the industry, hereby issues amendment to combined CFO&HWA Order reference 1st cited 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

Rule 6 of the Hazardous & Other Wastes (Management and Transboundary Movement) Rules, 2016, as follows:

Amendment:

Table below the “This consent order is valid for manufacturing the following products along with quantities indicated only” shall be replaced with the following table:

S. No	Name of the products	Production capacity (kg/day)	Production capacity (MT/Annunm)	No's of Stages	Starting raw materials	Quantity (kg/day)
Group-1						
1	SetralineHCl	100	36	5	Tetralone	263.48
2	Levofloxacin	300.00	108	3	Levo ethyl ester (LFX)	176.60
3	Zidovudine	733.00	263.88	2	Beta Thymidine	1184.27
4	Sevelamer Carbonate	400.00	144	1	SevelamerHCl	354.40
5	Abacavir	467.00	168.12	3	AFC	810.54
	Total	2000	720			
Group-2						
1	Dolutegravir	333.33	119.9988	3	Dolutegravir sodium DOS I	489.57
2	Celecoxib	600	216	3	4-Methyl acetophenone (4-MAP)	391.70
3	Etoricoxib	133.33	47.9988	3	Methyl-6methylnicotinate	20.31
4	Lamivudine	400.00	144	3	Cyclo Hexyl Ester	771.42
5	Emtricitabine	195	70.2	1	FCE	520.00
	Total	1661.66	598.1976			
Campaign products						
1	Lamotrigine	100.00	36	4	2,3-Dichlorobenzoyl Chloride	282.67
2	Tenofavir	200	72	3	Adenine	174.80
3	Valacyclovir	267	96.12	3	Acyclovir	313.77
4	Esomeprazole	85	30.6	3	2-Chloromethyl - 4-methoxy-3,5-dimethyl pyridine HCl	153.51
5	Piperaquine phosphate	200	72	3	4,7-Dichloro Quinoline	240.00
6	Sildenafil Citrate	207	74.52	3	Sildenafil Citrate (SDC) I EMP	96.52
			72		LMN (2-Chloro-1- (2,7-dichloro-9H- Flourene-	

7	Lumefantrine	200		3	4-yl) ethanone	250.05
8	Sevelamer HCl	154	55.44	1	Polyallyl amine HCl (50% solution)	356.89
9	Moxifloxacin	10	3.6	5	Moxifloxacin acid	13.88
10	Colesevelam HCl	50	18	1	SevelamerHCl	25.60
11	FBN-I	66.67	24.0012	2	Febantel (DM) I	44.02
12	BCI-II	66.67	24.0012	2	Thiourea	14.19
13	Milnaciprone	100	36	4	POBH	61.27
14	Etravirine	200	72	7	Ethyl cyanoacetate	73.26
15	Pantoaprozole Sodium	267	96.12	3	5-Difluoro Methoxybenzimidazole	134.84
16	Pirferidone	96	34.56	4	2-Amino-5-methyl pyridine Or Amino Compound	123.87
17	Dipyramidole	267	96.12	2	2,6dichloro 4-8di(piperidin-1-yl)pyrimido[5,4-d] pyrimidine	404.55
18	Efavirenz	166.67	60.0012	3	MMAA	272.00
19	Mirtazapine	150	54	1	Mirtazapine Acid	185.08
20	Tadalafil	170.5	61.38	4	D-Tryptophan	358.05
21	Pretomanid	150	54	2	Benzyloxy propyl pivalate (PRT-III)	232.50
22	Chlorthalidone	160	57.6	3	3-(4'-Chlorophenyl) Phthalimide (CHL-III)	144.00
23	Validation products	33.33	11.9988			
	Any one product	267	96.12			
	Group-1 OR Group-2 along with one product from campaign products	2267	816.12			

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 or 816 Tons/annum.

Byproducts:

S.	Products name	Stage	By products Name	Quantity	Quantity
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No				(kg/day)	(MT/annum)
Group-1					
1	Zidovudine	I	TEA salts	1126.40	405.504
		II	TTA salts	2186.54	787.1544
2	Setraline HCl	II	Trans isomer	23.70	8.532
		III	Cis isomer	102.78	37.0008
	Total			3439.42	1238.1912
Group-2					
1	Lamivudine	I	Potassium orthophosphate salts	1791.71	645.02
2	Emtricitabine	I	DPHOP	844.35	303.97
	Total			2636.06	948.9816
Campaign products					
1	Tenofovir	II	Spent odium bromide and acetate salts	1790.00	644.40
2	Pretomanid	I	Potassium bromide	34.05	12.26
3	Efavirenz	I	Sodium acetate	317.35	114.25
	Any one product			1790.0	644.40
	Group-1 OR Group-2 along with one product from campaign products			5229.42	1882.59

Table below the “Emissions from the chimney” shall be replaced with the following table:

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 2 Lakh K.Cal/hr Thermic Fluid heater	--
3	Attached to 1x500 + 1x1500 KVA + 1x1250 KVA DG Sets	--
4	Process Emissions from scrubbers-9 No.s	

Table below the “HAZARDOUS WASTES WITH DISPOSAL OPTION” shall be replaced with the following table:

S.No	Name of the 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. APEMC to TSDF for incineration or AFRF /

2	Spent Carbon	28.3 of Schedule I	576.97 kg/Day	Cement Industries for Co-Processing /Authorized pre-processing units
3	Stripper Distillate	28.1 of Schedule I	2000 kg/Day	
4	Off specified & Discarded Raw material, Lab chemicals & products	28.4 of Schedule I	50 kg/Day	
5	Spent Mixed solvents (colored)	28.4 of Schedule I	10000 kg/Day	
6	ETP Sludge	35.3 of Schedule I	1000 kg/Day	
7	Inorganic solid waste (from process)	28.1 of Schedule I	1714.76 kg/Day	

Table below the “HAZARDOUS WASTES WITH RECYCLING OPTION” shall be replaced with the following table:

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. APEMC to authorized recyclers
2.	Container & Container liners of Hazardous Waste & Chemicals	33.1 of Schedule I	Containers – 5000 nos/month or 50 tons/month Liners – 10,000 Kg/Month	After detoxification, shall be routed through M/s. APEMC to outside agencies/ Cement Industries for Co-Processing/ TSDF for AFRF
3.	Recovered solvents (Distilled Colourless)	28.6 of Schedule I	350 TPM	Shall be routed through M/s. APEMC to reuse / sale to authorized recyclers/cement industries for co processing / pre processing
4.	contaminated cotton rags	33.2 of Schedule I	0.5 TPM	Shall be routed through M/s. APEMC to TSDF for incineration or authorized cement plants for co-processing

Additional conditions:

1. The industry shall comply with the tolerance limits mentioned in MoEF notification dated 09.07.2009 prescribed for Pharmaceutical (Manufacturing and Formulation) industry.
2. **The industry shall take necessary action to comply with MoEF& CC notification vide G.S.R. 541(E) dt. 06.08.2021 for Bulk Drug and Formulation (Pharmaceutical).**
3. The industry shall comply with the revised 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.

All other conditions mentioned in Schedule – A, B & C of the combined CFO &HWA order issued by the Board vide reference 1st cited including the validity i.e., 31.10.2022 will remain same.

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