ENVIRONMENTAL CLEARANCE

PARIVESH

(Pro-Active and Responsive Facilitation by Interactive, and Virtuous Environmental Single-Window Hub)

Government of India
Ministry of Environment, Forest and Climate Change
(Issued by the State Environment Impact Assessment Authority(SEIAA), Maharashtra)

To,

The Vice President Technical

M/S. CIPLA LIMITED

Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai -400013 -400013

Subject: Grant of Environmental Clearance (EC) to the proposed Project Activity under the provision of EIA Notification 2006-regarding

Sir/Madam,

This is in reference to your application for Environmental Clearance (EC) in respect of project submitted to the SEIAA vide proposal number SIA/MH/IND2/200138/2021 dated 25 Feb 2021. The particulars of the environmental clearance granted to the project are as below.

1.	**EC Identification No.**	**EC23B058MH176768**
2.	**File No.**	SIA/MH/IND2/200138/2021
3.	**Project Type**	Expansion
4.	**Category**	B2
5.	**Project/Activity including Schedule No.**	5(f)-API
6.	**Name of Project**	Proposed expansion through scale up and process optimization of existing Active Pharmaceutical Ingredients (API) Manufacturing unit from 160 MT/Yr to 250 MT/Yr (Increase by 90 MT/Yr) by M/s. Cipla Limited (Unit - I), Plot No. D - 7, MIDC Kurkumbh, Ta
7.	**Name of Company/Organization**	M/S. CIPLA LIMITED
8.	**Location of Project**	Maharashtra
9.	**TOR Date**	N/A

The project details along with terms and conditions are appended herewith from page no 2 onwards.

(e-signed)
Pravin C. Darade , I.A.S.
Member Secretary
SEIAA - (Maharashtra)

Date: 18/05/2023

Note: A valid environmental clearance shall be one that has EC identification number & E-Sign generated from PARIVESH.Please quote identification number in all future correspondence.

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STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY

No. SIA/MH/IND2/200138/2021
Environment & Climate Change Department
Room No. 217, 2nd Floor,
Mantralaya, Mumbai- 400032.

To
M/s. Cipla Limited (Unit - I),
Plot No. D - 7, MIDC Kurkumbh,
Ta-Daund, Dist-Pune.

Subject : Environment Clearance for Proposed expansion through scale up and process optimization of existing Active Pharmaceutical Ingredients (API) Manufacturing unit from 160 MT/Yr to 250 MT/Yr (Increase by 90 MT/Yr) at Plot No. D - 7, MIDC Kurkumbh, Ta-Daund, Dist-Pune by M/s. Cipla Limited (Unit - I)

Reference : Application no. SIA/MH/IND2/200138/2021

This has reference to your communication on the above mentioned subject. The proposal was considered by the SEAC-1 in its 203rd meeting under screening category 5(f) as per EIA Notification, 2006 and recommend to SEIAA. Proposal then considered in 258th (Day-2) meeting of State Level Environment Impact Assessment Authority (SEIAA).

2. Brief Information of the project submitted by you is as below:-

Sr. No.	Particulars Required	Details
1	Name of the project & Address along with all corner latitude and longitude	**Cipla Limited (Unit - I), Plot No. D - 7, MIDC Kurkumbh, Taluka : Daund, District : Pune, State : Maharashtra.**
2	Type of Organization (Private / Government / Semi Government etc.)	**Private**
3	Correspondence Address and contact details of Project Proponent.	**Cipla Limited (Unit - I), Plot No. D - 7, MIDC Kurkumbh, Taluka : Daund, District : Pune, State : Maharashtra..** **Contact Details:** 8238633344
4	Type of project (ToR / EC / Amendment in ToR / Amendment in EC / Revalidation / Expansion / Process change etc.)	EC

5	Category of project as per EIA Notification 2006 amended from time to time (Pl. mention category A,B,B1,B2 etc. whichever is applicable)	The project comes under **B2 Category** as per EIA Notification 2006 amended from time to time.
6	If earlier ToR is obtained pl. mention details (ToR letter No. & Date, SEAC / EAC Meeting No.)	**Not Applicable Since B2 Category Project**
7	If earlier EC is obtained pl. mention EC Number & Date	EC Letter No.: F.No.J-11011/48/2005-IA II (I) dated 5th April, 2006
8	Whether the proposal is a violation case (yes/no)	No
9	Applicability of CRZ clearance (yes/no)	No
10	Whether General / Specific Conditions are applicable to the project (Yes/No) If yes pl. give details.	No
11	Whether Scrutiny fees paid as per SEIAA guidelines (Yes/No); If yes pl give payment details	Yes, Rs. 7,00,000/- Paid
12	Name of accredited Environmental Consultant & address along with Accreditation No. & Validity.	**Accredited Environmental Consultant**: Equinox Environments India Pvt. Ltd. **Address:** F-11, Namdev Nest, 1160-B, 'E' ward, Sykes Extension, Opp. Kamala College, Kolhapur- 416 001. **Accreditation No.:** NABET/EIA/1821/RA-0135 dated 2.8.2019 valid till 21.10.2021.
13	Name of layout plan approving Authority	MIDC
14	Estimated cost of Project (in Rs. Lakhs)	Rs. 150 Crores
15	Area of project (in Sq.m.)	159104.00 Sq.M

16	Whether 33% green belt is provided (Yes/No)	Yes Proposed Green Belt Area - 59600.00 m2(37.45 % of total plot area)	
17	Area of Green Belt & No. of trees in the proposed project in Sq.m. (Pl. provide 2000 trees per hectare of green belt area)	Area of Green Blet: 15.91 ha. Existing No. of Trees: 11920	
18	Width of internal roads and turning radius	Width of internal roads: 6 M Turning Radius: 9 M	
19	Details of proposed construction	**Total Built-up Area (in Sq.M)**	27006.00 Sq.M
		No. of Buildings & its height in meter.	--

20 **List of Raw materials & Storage Details (Pl. add on in the list if necessary)**

Sr. No.	Name of Raw material	Consumption (MT/M)	Max. Storage Details	Hazard category	Proposed precautions to prevent accident	Remarks
1	ACETONE	195975	195975	Flammable liquid	**Organizational Controls:** 1.Labelling of content 2.Physical Data 3.Chemical Data 4. Tox. Data **Precautions:** 1.Store in the underground tanks With Vent & Flame Arrester 2.Restricted Entry 3.Area under lock and key with Surveillance Camera 4.Well equipped with firefighting systems	**Have a flash point:** Higher than 60°C but lower than 90°C **Threshold quantity:** 15000 MT **Note:** Industrial site storage is well within
2	ACETONITRILE	42	42			
3	Ethyl Acetate**	4.80	4.80			
4	DIMETHYL ACETAMIDE	10184	10184			
5	DIMETHYL FORMAMIDE	6917	6917			
6	DIMETHYL VILANTEROL TRIFENTATE	1.0	1.0			
7	ETHYL ALCOHOL AR	13255	13255			
8	ETHYL ACETATE	98172	98172			
9	ISOPROPYL ALCOHOL	4239	4239			
10	METHANOL	383249	383249			
11	METHYL ETHYL KETONE	1920	1920			
12	METHYLENE CHLORIDE	115458	115458			
13	TOLUENE	38658	38658			
14	(R)-2-METHYL-	1.0	1.0			

	OXAZOBOROLIDINE					
15	BORON TRICHLORIDE 1 MOLAR SOLN IN MDC	0.03333	0.10000			
16	BORON TRIFLUORIDE DIETHYL ETHERATE	0.02381	0.07143			
17	BROMOFLUORO METHANE	0.04050	0.12150			
18	BUTYRALDEHYDE	0.04000	0.12000			
19	DI ISO PROPYL ETHER	1.12500	3.37500			
20	DI-ISOPROPYL ETHYL AMINE	0.16667	0.50000			
21	DIETHYL ETHER COMMERCIAL GRADE	1.66667	5.00000			
22	16- ALPHA HYDROXY PREDNESOLONE	8280	8280	Toxic	**Precautions:** 1.Store in the isolated & well ventilated storage place 2.Antidotes information to be displayed in the area 3.Restricted Entry 4.Area under lock and key 5.Survillence	**Dermal toxicity LD50:** 200-1000 mg / kg **Inhalation toxicity LC50:** 2-10mg/l **Threshold quantity:** 5 - 500 MT
23	16 ALPHA METHYL EPOXIDE	720	720			
24	1-METHYL-3-PYRROLIDINOL	1.0	1.0			
25	25% METHYL BROMIDE SOLUTION IN ACETONE	1.0	1.0			
26	5,6-DIETHYL-2,3-DIHYDRO-1H-INDEN-2-AMINE HYDROCHLORIDE	1.0	1.0			
27	50 % METHYL BROMIDE IN ACETONITRILE	1.0	1.0			
28	ACETIC ACID - GLACIAL	3240	3240			
29	ACTIVATED CHARCOAL AR GRADE	228	228			

	30	ACTIVATED CHARCOAL SX ULTRA	126	126		Camera provision 6.Well equipped with firefighting systems 7. MSDS and handling SOPs to be provided at the entry point of the area.	**Note:** Industrial site storage is well within MSIHC limits
	31	AMMONIUM FORMATE	1.0	1.0			
	32	BETA METHYL EPOXIDE	900	900			
	33	BORANE DIMETHYL SULPHIDE COMPLEX	1.0	1.0			
	34	BROMOFLUORO METHANE	366	366			
	35	BUTYRALDEHYDE	2333	2333			
	36	CDI (N, N CARBONYL DI IMIDAZOLE)	1.0	1.0			
	37	CYCLOHEXANE CARBOXALDEHYDE	504	504			
	38	CYCLOPENTYL MANDELIC ACID	1.0	1.0			**Dermal toxicity LD50:** 200-1000 mg / kg
	39	DI ISO PROPYL ETHER	1080	1080			
	40	DIETHYL AMINE	120	120			**Inhalation toxicity LC50:** 2-10mg/l
	41	FAP COMPLEX	2700	2700	**Toxic**		
	42	FLUTICASONE STAGE I (IMP)	2220	2220		**Precautions:** 1.Store in the isolated & well ventilated storage place 2.Antidotes information to be displayed in the area 3.Restricted Entry 4.Area under lock and key 5.Survillence Camera provision 6.Well equipped with firefighting systems 7. MSDS and handling SOPs	**Threshold quantity:** 5 - 500 MT
	43	FLUTICASONE STAGE III (COMPLEX ROUTE)	1200	1200			
	44	FUROYL CHLORIDE	522	522			**Note:** Industrial site storage is well within MSIHC limits
	45	HMPA (HEXAMETHYL PHOSPHORAMIDE)	1.0	1.0			
	46	HYDROBROMIC ACID(AQUEOUS 47%)	70740	70740			
	47	HYDROCHLORIC ACID - CP	14809	14809			
	48	HYDROCHLORIC ACID AR GRADE	7875	7875			

	49	HYFLO SUPERCEL	24	24		to be provided at the entry point of the area.	
	50	IND-BROMO COMPOUND	1.0	1.0			
	52	ISOBUTYRYL CHLORIDE	504	504			
	53	LITHIUM CHLORIDE	288	288			**Dermal toxicity LD50:** 200-1000 mg / kg
	54	MALEIC ACID	1.0	1.0			
	55	N N DIMETHYL THIO CABOMYL CHLORIDE	1332	1332			**Inhalation toxicity LC50:** 2-10mg/l
	56	ORTHO-PHOSPHORIC ACID (85%)	1.0	1.0			
	57	OXALIC ACID DIHYDRATE	1.0	1.0			**Threshold quantity:** 5 - 500 MT
	58	PARA TOLUENE SULPHONYL CHLORIDE	792	792		**Precautions:** 1.Store in the isolated & well ventilated storage place 2.Antidotes information to be displayed in the area 3.Restricted Entry 4.Area under lock and key 5.Survillence Camera provision 6.Well equipped with firefighting systems 7. MSDS and handling SOPs to be provided at the entry point of the area.	**Note:** Industrial site storage is well within MSIHC limits
	59	PERCHLORIC ACID 70% GR GRADE	2100	2100			
	60	POTASSIUM CARBONATE POWDER	1722	1722			
	61	PROPIONIC ANHYDRIDE	2316	2316			
	62	PYRIDINIUM PARA TOLUENE SULFONATE	36	36			
	63	RFC 2-OXOETHYL CARBAMATE	1.0	1.0			
	64	RFC PIPRIDINE BIPHENYL CARBAMATE	1.0	1.0			
	65	SCOPINE HYDROCHLORIDE	1.0	1.0			
	66	SILICA GEL 60-120 MESH	288	288			
	67	SODIUM ACETATE ANHYDROUS	225	225			
	68	SODIUM BICARBONATE	8898	8898			
	69	SODIUM	1440	1440			

	CHLORIDE					
70	SODIUM HYDROXIDE FLAKES	252	252			
71	SODIUM METABISULPHITE	1188	1188			
72	SODIUM SULPHATE ANHYDROUS	936	936			
73	SPECIAL DENATURED SPIRIT WITH TOLUENE.	49882	49882			
74	SUCCINIC ACID	1.0	1.0			
75	SULPHURIC ACID COMMERCIAL	1428	1428		**Precautions:** 1.Store in the isolated & well ventilated storage place 2.Antidotes information to be displayed in the area 3.Restricted Entry 4.Area under lock and key 5.Survillence Camera provision 6.Well equipped with firefighting systems 7. MSDS and handling SOPs to be provided at the entry point of the area.	
76	TETRA HYDRO FURAN (THF)	10988	10988			
77	TETRABUTYL AMMONIUM BROMIDE	1	1			
78	TRIETHYL ORTHO PROPIONATE	1332	1332			
79	TRIETHYLAMINE	3509	3509			
80	TTB1	1.0	1.0			
74	HMPA (HEXAMETHYL PHOSPHORAMIDE)					
75	Arformoterol Tartrate					
76	DI METHYL SULPHOXIDE	0.62500	1.87500			
77	DIMETHYLAMINE HYDROCHLORIDE	0.40000	1.20000			
78	DISODIUM EDETATE	0.02646	0.07938			
79	VALSARTAN USP	0.11111	0.33333			
80	(R)-2-METHYL-OXAZOBOROLIDINE	0.00008	0.00025			
81	16- ALPHA HYDROXY	0.69000	2.07000			

	PREDNESOLONE					
82	16 ALPHA METHYL EPOXIDE	0.06000	0.18000			
83	1-METHYL-3-PYRROLIDINOL	0.00008	0.00025			
84	25% METHYL BROMIDE SOLUTION IN ACETONE	0.00008	0.00025	Toxic		**Dermal toxicity LD50:** 200-1000 mg / kg **Inhalation toxicity LC50:** 2-10mg/l **Threshold quantity:** 5 - 500 MT **Note:** Industrial site storage is well within MSIHC limits
85	5,6-DIETHYL-2,3-DIHYDRO-1H-INDEN-2-AMINE HYDROCHLORIDE	0.00008	0.00025			
86	50 % METHYL BROMIDE IN ACETONITRILE	0.00008	0.00025			
87	HMPA (HEXAMETHYL PHOSPHORAMIDE)	0.00008	0.00025			
88	HYDROBROMIC ACID(AQUEOUS 47%)	5.89500	17.68500			
89	HYDROCHLORIC ACID - CP	1.23408	3.70225			
90	HYDROCHLORIC ACID AR GRADE	0.65625	1.96875			
91	HYFLO SUPERCEL	0.00200	0.00600			
92	LITHIUM CHLORIDE	0.02400	0.07200			
93	MALEIC ACID	0.00008	0.00025			
94	PYRIDINIUM PARA TOLUENE SULFONATE	0.00300	0.00900			
95	RFC 2-OXOETHYL CARBAMATE	0.00008	0.00025			
96	RFC PIPRIDINE BIPHENYL CARBAMATE	0.00008	0.00025			

97	SCOPINE HYDROCHLORIDE	0.00008	0.00025			
98	SILICA GEL 60-120 MESH	0.02400	0.07200			
99	SODIUM ACETATE ANHYDROUS	0.01875	0.05625			
100	SODIUM BICARBONATE	0.74150	2.22450			
101	SODIUM CHLORIDE	0.12000	0.36000			
102	SODIUM METABISULPHITE	0.09900	0.29700			
103	SODIUM SULPHATE ANHYDROUS	0.07800	0.23400			
104	SPECIAL DENATURED SPIRIT WITH TOLUENE.	4.15683	12.47050			
105	SUCCINIC ACID	0.00008	0.00025	**Toxic**	**Precautions:** 1.Store in the isolated & well ventilated storage place 2.Antidotes information to be displayed in the area 3.Restricted Entry 4.Area under lock and key 5.Survillence Camera provision 6.Well equipped with firefighting systems 7. MSDS and handling SOPs to be provided at the entry point of the area.	**Dermal toxicity LD50:** 200-1000 mg / kg **Inhalation toxicity LC50:** 2-10mg/l **Threshold quantity:** 5 - 500 MT **Note:** Industrial site storage is well within MSIHC limits
106	SULPHURIC ACID COMMERCIAL	0.11900	0.35700			
107	TETRABUTYL AMMONIUM BROMIDE	0.00008	0.00025			
108	TRIETHYL ORTHO PROPIONATE	0.11100	0.33300			
109	TRIETHYLAMINE	0.29242	0.87725			
110	TTB1	0.00008	0.00025			
111	REC DIMETHYL FORMAMIDE FRM MEBENDAZOLE.	0.31250	0.93750			
112	SCOPINE HYDROCHLORIDE	0.00174	0.00521			
113	TRIAZOLO COMPOUND	1.00000	3.00000			
114	TTB-1	0.00833	0.02500			
11	VENLAFAXINE	2.25000	6.750			

	5	STAGE I (VF 1)		00			
	116	4-(PROPYTHIO)-O-PHENYLENEDIAMINE	0.04167	0.12500			
	117	IMIDAZOLE ACETIC ACID	0.00167	0.00500			
	118	EPOXY CARBAZOLE	1.25000	3.75000			
	119	AEP COMPOUND	1.77778	5.33333			
	120	CYCLOPENTYL MANDELIC ACID (P)	0.00833	0.02500			
	121	PALLADIUM ON CARBON 5% WET NMC101NH REC	0.27778	0.83333			
	122	N-METHYL ALS COMPOUND	0.00500	0.01500			
	123	DIBENZYLOXY GUANINE INTERMEDIATE	0.00167	0.00500			
	124	BETA METHYL CHOLINE CHLORIDE	0.08333	0.25000			
	125	VALGANCICLOVIR STAGE - III	0.50000	1.50000			
	126	SACU AMINO ESTER	0.08333	0.25000			
	127	PX-IV COMPOUND	0.00833	0.02500			
	128	R-(+)-NAPTHYL ETHYLAMINE MANDELATE	0.33333	1.00000	Toxic	**Precautions:** 1.Store in the isolated & well ventilated storage place 2.Antidotes information to be displayed in the area 3.Restricted Entry	**Dermal toxicity LD50:** 200-1000 mg / kg **Inhalation toxicity LC50:** 2-10mg/l **Threshold quantity:** 5 - 500 MT **Note:** Industrial site storage is
	129	RMP-3	0.08333	0.25000			
	130	CNC ACTIVE ESTER	0.44000	1.32000			
	131	FUROYL CHLORIDE	0.05000	0.15000			
	132	16- ALPHA HYDROXY PREDNESOLONE	0.14167	0.42500			
	133	FUROYL	0.05000	0.15000			

3	CHLORIDE		00		4.Area under lock and key 5.Survillence Camera provision 6.Well equipped with firefighting systems 7. MSDS and handling SOPs to be provided at the entry point of the area.	well within MSIHC limits
134	ZP III COMPOUND	0.25000	0.75000			
135	1,2,4 TRIAZOLE	0.37500	1.12500			
136	ETHYL TRIFLUORO ACETATE	6.33333	19.00000			
137	ETHYL TRIFLUORO ACETATE	6.33333	19.00000			
138	BETA METHYL EPOXIDE (DB-11)	0.08333	0.25000			
139	RDV TRIHYDROXY CYANO	0.08333	0.25000			
140	RDV PENTAFLUORO	0.16667	0.50000			
141	1-METHYL-3-PYRROLIDINOL	0.00500	0.01500			
142	ARFORMOTEROL TARTRATE	0.00089	0.00267			
143	RISEDRONATE SODIUM HEMIPENTAHYDRATE USP	0.00833	0.02500			
144	VALSARTAN USP	0.11111	0.33333			

21 **Production Details**

No	Product name	Qty. (MT/M) Exist.	Exp.	Total	CAS No.	Chemical Formula	Indications
1	Celecoxib	63.873	36.127	100.00	$C_{17}H_{14}F_3N_3O_2S$	169590-42-5	Anti-Inflammatory
2	Fluticasone Propionate / MDI / DPI	16.83	15.03	1.80	$C_{25}H_{31}F_3O_5S$	80474-14-2	
3	Meloxicam	17.696	5.304	23.00	$C_{14}H_{13}N_3O_4S_2$	71125-38-7	

4	Beclomethasone Dipropionate Monohydrate / ANH	0.412	0.588	1.00	$C_{28}H_{39}ClO_8$	77011-63-3	
5	Mometasone Furoate Monohydrate / ANH	0.818	0.182	1.00	$C_{27}H_{32}Cl_2O_7$	141646-00-6	
6	Budesonide	2.045	0.545	1.50	$C_{25}H_{34}O_6$	51333-22-3	
7	Fluticasone Furoate	0.02	--	0.02	$C_{27}H_{29}F_3O_6S$	397867-44-7	
8	Ciclesonide	0.00	0.2	0.20	$C_{32}H_{44}O_7$	126544-47-6	
9	**Loteprednol Etabonate** (Discontinue)	1.65	-1.65	0.00	--	--	
10	Famciclovir	2.153	7.847	10.00	$C_{14}H_{19}N_5O_4$	104227-87-4	**Anti-Retroviral / Bacterial**
11	Fluconazole	1.65	10.35	12.00	$C_{13}H_{12}F_2N_6O$	86386-73-4	
12	**Lamivudine** (Discontinue)	0.931	-0.931	0.00	--	--	
13	**Ciprofloxacin HCl** (Discontinue)	1.181	-1.181	0.00	--	--	
14	**Norfloxacin** (Discontinue)	1.644	-1.644	0.00	--	--	
15	Pioglitazone Hydrochloride	0.652	2.348	3.00	$C_{19}H_{21}ClN_2O_3S$	112529-15-7	**Anti-Diabetic**
16	**Nateglinide**(Discontinue)	6.218	-6.218	0.00	--	--	
17	Carvedilol	7.383	7.617	15.00	$C_{24}H_{26}N_2O_4$	72956-09-3	**Cardiac**

18	Ramipril	0.635	0.365	1.00	$C_{23}H_{32}N_2O_5$	87333-19-5	
19	**Losartan Potassium** (Discontinue)	0.00	--	0.00	--	--	
20	**Clopidogrel Bisulfate** (Discontinue)	1.65	-1.65	0.00	--	--	
21	Formoterol Fumarate	0.038	0.062	0.10	C23H30N2O9	183814-30-4	Bronchodilator
22	Salbutamol Sulphate	1.65	5.35	7.00	C13H23NO7S	51022-70-9	
23	Glycopyrrolate / Premix	0.01	0.09	0.10	C19H28BrNO3	596-51-0	
24	Vilanterol	0.00	0.05	0.05	C24H33Cl2NO5	503068-34-6	
25	Tiotropium Bromide Monohydrate	0.00	0.1	0.10	C19H24BrNO5S2	139404-48-1	
26	Ondansetron Base / Hydrochloride	1.875	4.125	6.00	C18H20ClN3O	99614-01-4	Anti-Emetic
27	Pramipexole Dihydrochloride	0.055	0.045	0.10	C10H19Cl2N3S	104632-25-9	Anti-Parkinson
28	Olanzapine	0.875	2.125	3.00	C17H20N4S	132539-06-1	
29	Rizartriptan Benzoate	0.165	0.335	0.50	C22H25N5O2	145202-66-0	
30	Arformoterol Tartrate	0.006	-0.004	0.002	C23H30N2O10	200815-49-2	Anti-Asthmatic
31	Alendronate Sodium Trihydrate	13.056	3.944	17.00	C3H11NO7P2	40391-99-9	Bone Resorption Inhibitor
32	Pamidronic Acid	0.011	0.001	0.01	C3H11NO7P2	40391-99-9	
33	Risedronate Sodium Hemipentahy	0.00	3.00	3.00	C14H30N2Na2O19P4	329003-65-8	

	drate						
34	Zoledronic Acid	0.00	0.02	0.02	C5H10N2O7P2	118072-93-8	
35	Cinacalcet Hydrochloride	0.00	4.00	4.00	C22H23ClF3N	364782-34-3	Hyperparathyroidism
36	Bethanechol Chloride	1.50	-0.5	1.00	C7H17ClN2O2	590-63-6	Anti-Viral
37	Sacubitril	1.50	-0.5	1.00	C24H29NO5	149709-62-6	
38	Valganciclovir Hydrochloride	0.00	6.00	6.00	C14H23ClN6O5	175865-59-5	
39	Indacaterol Maleate	0.00	0.05	0.05	C28H32N2O7	753498-25-8	
40	Remdesivir	0.00	1.00	1.00	C27H35N6O8P	180922 49-37-3	
41	Entecavir Monohydrate	0.00	0.02	0.02	$C_{12}H_{17}N_5O_4$	209216-23-9	**Anti-Viral**
42	Mebendazole	0.00	0.10	0.10	$C_{16}H_{13}N_3O_3$	31431-39-7	**Anti-Helmintics**
43	Albendazole	0.00	0.50	0.50	$C_{12}H_{15}N_3O_2S$	54965-21-8	
44	Alosetron Hydrochloride	0.00	0.06	0.06	$C_{17}H_{19}ClN_4O$	122852-69-1	
45	Leflunomide (LF-I)	0.00	2.50	2.50	$C_{12}H_9F_3N_2O_2$	75706-12-6	**Anti-Rheumatic**
46	Venlafaxine (VF-II)	0.00	27.00	27.00	$C_{17}H_{27}NO_2$	93413-69-5	**Anti-Depressant**
47	Revefenacin	0.00	0.10	0.10	$C_{35}H_{43}N_5O_4$	864750-70-9	**Anti-Cholinergics**
48	New R & D products	0.00	0.50	0.50	--	--	--
49	**Citalopram HBr** (Discontinue)	1.65	-1.65	0.00	--	--	**Anti-Psychotic**
50	**Paroxetine HCl** (Discontinue)	1.63	-1.63	0.00	--	--	
51	**Sertraline HCl** (Discontinue)	1.65	-1.	0.00	--	--	

			65				
52	**Quetiapine Fumarate** (Discontinue)	0.104	-0.104	0.00	--	--	
53	**Ziprasidone HCl** (Discontinue)	0.15	-0.15	0.00	--	--	
54	**Aripiprazole** (Discontinue)	1.65	-1.65	0.00	--	--	
55	**Zolpidem Tartrate** (Discontinue)	1.65	-1.65	0.00	--	--	**Sedative**
56	**Sibutramine HCl** (Discontinue)	1.65	-1.65	0.00	--	--	**Anti-Obesity**
57	Tablets as approved by FDA (Millions Nos./A)	2000.00	200.00	2200.00	--	--	**Formulations**
58	Capsules as approved by FDA (Millions Nos./A)	170.00	830	1000.00	--	--	
	Soft Gelatin Product as Approved by FDA (Millions Nos./A)	21.20	38.8	60.00	--	--	**Formulations**
	Sachets as approved by FDA (Millions Nos./A)	85.00	-70.00	15.00	--	--	
	Suppositories and Oral paste approved by FDA (Millions Nos./A) (Operation Discontinued)Sachets as approved by FDA (Millions Nos./A)	12.00	-12.00	0.00	--	--	
	Total						

22 Water Consumption & Effluent generation (All units in CMD)

i. Source & Qty of water requirement (in CMD): Fresh water is taken from MIDC Water Supply.

ii. Water supply permission obtained (Yes/No) & approving Authority:

Particulars	Consumption (CMD)			Loss (CMD)			Effluent generation (CMD)		
	Existing	Proposed	Total	Existing	Proposed	Total	Existing	Proposed	Total
Domestic	84	--	84	8.6	--	8.6	75.4	--	75.4
Processing	102	28	130	-5	-1	-6	107	29	136
Scrubber	23	--	23	2.3	--	2.3	20.7	--	20.7
Lab & Washing	4.5	--	4.5	--	--	--	4.5	--	4.5
Cooling Make up	394	92	486	343	92	343	51	--	51
Boiler Make up	87	--	87	73.5	--	73.5	13.5	--	13.5
WTP Filter Backwash Softener	11.5	--	11.5				11.5	--	11.5
Gardening	200	98	298	--	--	--	--	--	--
Total	906	**218**	**1124**	--			283.6	**29**	**312.5**

23	Quantity of sewage generation (in CMD)	75.4 CMD
24	Details of Sewage Treatment and Disposal of treated sewage:	Sewage will be treated in existing ETP and treated sewage will be recycled.

25 **Detail of Effluent Generation (unit CMD)**

Particular	Existing	Proposed	Total
a) Qty. of Effluent generation: (CMD)	283.6	83	312.6
b) Qty. of high TDS/COD effluent: (CMD)	6	18	22
c) Qty. of low TDS / COD effluent: (CMD)	176.6	114	290.6

26	Whether Zero liquid Discharge Effluent Treatment is proposed (Yes/No)	Yes. The process effluents generated from industrial activities is70 CMD. Same is treated in ETP and reused for cooling tower makeup thereby achieving ZLD.
27	Brief Description of	**Stream-I**(Low TDS & Low COD): 290.6 CMDDomestic,

	Effluent Treatment scheme	Canteen, Boiler & Cooling b/d, Filter B/w, Softener Reg., Process Stream-I-22) **Treatment**:Primary, Secondary &Tertiary Neutralization, Equalization, Flash Mixer, Clarification, Bio-Reactor I, Bio-Clarifier I, Bio-Reactor II, Bio-Clarifier II, Clarifier, PSF, UF, RO. **Disposal**: RO Reject to MEE of Stream -II & Permeate Full Recycle for Cooling **Stream-II**(High TDS & High COD): 22 CMD (Process Stream-II)**Treatment**: MEE followed by ATFD **Disposal**: Condensate to CSTR, Outflow to Stream-I, ZLD and Solids To CHWTSDF
28	Qty of treated effluent proposed to be sent to CETP (pl. mention Name of CETP and its membership Details)	Not applicable
29	Please mention parameters of treated effluent to be achieved as per EP Rule, 1986 and or stipulated by the SPCB	
30	Brief Note on proposed Rainwater harvesting scheme along with budget allocation:	Runoff from **Rooftop & Surface** to be harvested & stored in Underground RCC Tanks. Rooftop Yield is10,154M^3 while Surface Runoff Yield is 20,393M^3 forming total Runoff Yield of 30,547 M^3 Six tanks with capacity of 576 M3, 191 M3, 810 M3, 384 M3, 113 M3, 375 M3 Utilization for Green Belt, Fire Hydrant, Washing & Flushing **Excess RWH Qty. diverted to MIDC Drain through Storage Tank Out lets on Site** **Budget allocated: Rs. 95 Lakhs**
31	**Solid Waste management**	

Parameter	Stream-I	Stream-II
	Inlet Concentration (Mg/L)	Inlet Concentration (Mg/L)
PH	6-8.5	6-8.5
TDS	4000-5000	20,000-25,000
COD	6000-7000	10,000-20,000
BOD	3000-3500	4000-5000

No.	Type of waste	Quantity	Disposal
1	Plastic, Glass, Wooden, Metal Scrap	1350 MT/Yr	Authorized Party
2	Battery Waste	8 MT/Yr	Authorised Re-processor / Buyback
3	E-Waste	5 MT/Yr	
4	Biomedical Waste	15 kg/M	Sale to Authorised Re-processor

32 **Hazardous Waste Generation & Disposal (As per HW Rule 2016)**

No.	Description	Cat.	Quantity Tot. After Exp.	Disposal
1.	Used / Spent oil	5.1	700 Lit./M	Authorized Party / Recycler / CHWTSDF
2.	Spent Solvents	28.6	1200 KL/M	Authorized Party / Recycler / Co processing CHWTSDF
3.	Spent Catalyst	28.2	300 Kg/M	CHWTSDF / Co processing / Authorized Re-processor / Recycler
4.	Spent Carbon	28.3	600 Kg/M	CHWTSDF / Co processing / Authorized Re-processor / Recycler
5.	Date-Expired, discarded drug / medicines / chemicals	28.5	17 MT/M	CHWTSDF
6.	Off-specification drug / medicines / chemicals	28.4	8 MT/M	CHWTSDF / Reprocessing
7.	Empty Barrels / containers / liners contaminated with Hazardous Chemicals / Waste	33.1	600 Nos./M	Authorized Party / Recycler / Re-processor / CHWTSDF
8.	Chemical Sludge from Waste Water Treatment	35.3	23 MT/M	Authorized Party / CHWTSDF / Co processing
9.	Sludge from wet scrubber	37.1	5 MT/M	Authorized Party / CHWTSDF / Co processing
10.	Sludge from MEE system	37.3	43 MT/M	Authorized Party / CHWTSDF / Co processing

33 **Fuel Consumption**

Sr. No.	Type of Fuel	Consumption Qty (TPD)			Used for (Boiler/ DG/ Set etc)	Ash (%)			SO_2 (%)			Air pollution control/equipment provide (Yes/No)
		Existing	Proposed	Total		Existing	Propos	Total	Existing	Propo	Total	

							ed			se d		
1	F.O/ LP G	4.5 KL/ D	-	4.5 K L/ D	For Exist ing 3 TPH Boile rs	5-8%	--	5-8 %	0.0 6-0.1 pp m	--	0. 0 6-0. 1	--
2	HS D/B iodi esel	545 0 Lit/ Hr	–	54 50 Lit /H r	For Exist ing 3TP H Boile r	--	--	--	1 %	1 %	1 %	

34 Brief Note on Air Pollution Control equipment's: Multi Cuclone Separators & Bag filter will be installed as APC equipment.

35 **Stack Details (Also include process vent details)**

Sr. No.	Section / Unit	Source pollutions	Stack No.	Height form ground	Internal Diameter (inch)	Temperature exhaustgas
1	Boiler House	Boiler	S-1	30 M	1.40 M	

36 **Energy**

a) Source of power Supply:Maharashtra State Electricity Distribution Company Limited

b) Maximum Demand (KVA): 99,000 K Hr./Day

c) Whether DG sets will be provided (Yes / No):**Yes**

if yes :

Sr. No.	No. of DG Sets		Capacity
	Existing	Proposed	
1	4	–	1250 KVA (3 No's.) & 1500 KV

d) Please Mention if high tension line is passing through the plot:No

If yes, pl. give details of safety measures adopted:

37 **Details of use of renewable energy with budget allocation:**

i. Total Energy Demand : ---------- KVA

ii. Proposed renewable energy source capacity: ---------- KVA

iii. Proposed Budget (in Rs. – Lakhs):

iv. Timeline for implementation:

38 **Details of public hearing (if applicable): Not Applicable since B2 category Project**

i. Place of public hearing :

ii. Date of Public hearing :

Please fill following details

Sr. No.	Issue raised during public	Applicant plan for its compliance/	Budget allocation for	Specific time of complian

	hearing	implementation	implementation		

39 EMP (Please mention specific items proposed in EMP along with specific timeline for its implementation)

Construction Phase:

Sr. No.	Attribute	Specific measure	Budget in (Rs. Lakh)	Remark
1	Air	Water tank, pump- motor, piping & sprinkling arrangement for fugitive dust control	2.50	
2	Water	Safe Drinking water from existing unit	--	
3	Noise	Barricading of the boundary with MS sheet cladding on MS frame. Rs. 600/-	3.78	
4	Soil	Appropriate management of fuels, lubricants & constructions- storage in existing units	--	
5	Solid waste	Dust bins at strategic points	0.25	
6	Hazardous waste	Empty containers of primers, paints, construction chemicals- To be stored atHazardous Waste Storage in existing adjusant unit	--	
7	Fuel & Energy	To be taken from adjusant existing unit	--	
8	Safety & health	Provision of PPEs, display of safety instruction, signs & awareness boards. First aid kit & other facilities from existing adjusant unit	0.75	

Operation Phase

Sr. No.	Attributes	Specific measures	Budget in Rs. Lakh	Time line for 1/5 implement	Responsibility	Remarks
1	Air	Installation of stack, Scrubbers, installation of APC equipment	170	After Procurement of EC	Emvironmental Management Cell	
2	Water	Treatment of Trade & domestic	1000			

		effluent				
3	Noise	Provision of Acoustic enclosures to DG set and high noise generating machinery & Barriers.	60			
4	Soil	--	5			
5	Solid waste	--	10			
6	Hazardous waste	--	20			
7	Fuel & Energy	--	16			
8	Safety & heath	Fire Fighting System, Fire Extinguishers, Personal Protective Equipments&Occupational Health Centre	590			
9	Rain water harvesting	Provision of pipes and drains for transportation, Filter tank & Collection tank	95			
10	Implementation of recommendation of LCA	--	--			
11	Implementation recommendation HA20P/Risk	--	--			

		Assessment					
	12	Any other please specify- Green Belt Development	Avenue, Mass & Shelter belt Plantation	45			
40	Other Relevant Information: (Pl. provide brief note on proposed project)						--
41	Details of skill development program within Organization						Training to workers on fire fighting, Safety etc.
42	Details of environmental Monitoring Cell (Pl. provide organogram with educated Qualification and experience)						EMC Consist of 10 Nos.of persons including Environmental Officer, Safety Officer, ETP Chemist & Operators & Supporting Staff.
43	Details of court cases if pending in any Hon'ble court						No any Court case is pending against the project.

3. The proposal has been considered by SEIAA in its 258th (Day-2) meeting and decided to accord Environment Clearance to the said project under the provisions of Environment Impact Assessment Notification, 2006 subject to implantation of following terms and conditions-

Specific Conditions:

SEAC Conditions-

1. Notarized affidavit for not violating any requirement of EIA Notification, 2006 as amended from time to time.
2. Revised to the scale lay out plan showing all internal roads with minimum six meter width and turning radius of nine meters, PP to show the road towards adjacent plot D-7 on the layout so as to ensure complete road connectivity for fire tender movement.
3. Bilateral agreement with respect to the common facilities to be used with special mention of the responsibility in case of any non-compliance to the requirements of EC condition / Consent condition and/ or any other applicable legal requirements.
4. MoU executed with the brick manufacturer to dispose boiler ash.
5. Techno-economic feasibility study of using alternate technology for MEE such as low temperature/mechanical vapour compressor etc. so as to reduce operation cost and minimize use of heating resources.
6. Details of use of renewable energy with budget allocation in the EMP.
7. Commitment to spend entire CER fund before the commissioning of the manufacturing activity in consultation with the District Collector.
8. PP to complete green belt development with the provision of drip irrigation before the commissioning of the manufacturing activity.
9. PP to complete rain water harvesting facility before the commissioning of the manufacturing activity.
10. PP to provide sliding gate at entry and exit to achieve maximum turning radius of vehicle entering the site.

SEIAA Conditions

1. PP submitted plan approved by MIDC dated 28.06.2022. As per the said plan plot area is 159104.00 m2, green belt area of 29114.61 m2 is provided i.e.18.3 % of the total plot area. To provide the balance green belt PP has purchased a land at Gat. No. 182 of Roti Village in Daund and provided green belt of 237000 m2 making total green belt at 33 % of plot area.PP to undertake Miyawaki plantation of native and indigenous trees such as Banyan, Peeple, Neem, Jamun and other suitable trees as per the Forest Department, Govt. of Maharashtra circular no SaVaVi-2019/C.R.3/F-11, dated 25th June, 2019. The said plantation to be completed in the first year of operation of Environmental Clearance under expert guidance of Miyawaki experts / arborist.
2. PP to strictly observe the Solid Waste Management Rules, 2016 as amended time to time.
3. PP to strictly observe the Hazardous and Other Wastes (Management & Trans boundary Movement) Rules, 2016 as amended time to time.
4. PP to identify all sources of fugitive air pollution on site and provide pollution control measures to mitigate pollution and meet the standard parameters stipulated in the Environment (Protection) Rules, 1986 amended time to time & Air (Prevention and Control of Pollution) Act, 1981 amended time to time.
5. PP to ensure storage of chemicals as per the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 amended time to time to ensure no release of any chemical to the atmosphere and leakage to the soil.
6. PP to ensure transport, storage, handling and use of the flammable/toxic chemicals as per conditions stipulated in license/approval of the Petroleum & Explosive Safety Organization (PESO).
7. PP to obtain approval and License from the Directorate of Industrial Health & Safety (DIHS) for proposed project and implement all condition stipulated therein. PP to carry out Safety Audit as stipulated in the Maharashtra Factories Rules, 1963 and ensure compliance of recommendation of the Audit.
8. PP to provide solar energy for illumination of Administrative Building, Street Lights and parking Area.
9. PP to ensure use of briquette /bio coal/ pellets/ or any such suitable product derived from scientific processing of appropriate stream of dry waste/agricultural waste , not less than 50 % of the total fuel requirement to the boiler.
10. PP to provide roof top Rain Water Harvesting facility.
11. PP to ensure that, proposed project is a ZLD.

General Conditions:

I. The project proponent shall advertise at least in two local newspapers widely circulated in the region around the project, one of which shall be in the Marathi language of the local concerned within seven days of issue of this letter, informing that the project has been accorded Environmental Clearance and copies of Environmental Clearance letter are available with the Maharashtra Pollution Control Board, website of the company and may also be seen at Website at http://parivesh.nic.in

II. The project Proponent shall upload the status of compliance (soft copies) of the conditions stipulated Environmental Clearance letter including monitoring data of air, water, soil, noise etc. on their website and shall update the same periodically. The half yearly compliance report shall simultaneously be submitted to the Maharashtra Pollution Controls Board, SEIAA and the Regional Office off MoEF&CC at Nagpur, on 1st June & 1sr December of each calendar year.

III. Separate fund shall be allocated for the implementation of Environmental Management Plan along with item wise break up and specific time line for its completion. The cost shall be included as part of the project cost. The funds earmarked for the environmental

protection measures shall not be diverted for other purpose and year-wise expenditure should be reported to the MPCB and the SEIAA.

IV. A separate Environmental Management Cell with qualified personnel shall be set up for implementation of the stipulated environmental safeguards.

V. In the event of failure of any pollution control equipment, the manufacturing activity shall be immediately stopped safely till the effective functioning of pollution control equipment's is regained.

VI. PP to strictly follow conditions stipulated in the Consent to Establish/Operate issued by the Maharashtra Pollution Control Board.

VII. PP to provide separate drains for storm water and effluent, and ensure that, the storm water drains are dry all the time and in no case the effluent shall mix with the storm water drain.

VIII. Periodic Monitoring of ground water in the study area as marked in the Environmental Impact Assessment Report shall be undertaken and results analysed to ascertain any change in the quality of water. Results shall be regularly submitted to the Maharashtra Pollution Control Board.

IX. The overall noise levels in and around the factory premises shall be kept within the prescribed standard under the Environment (Protection) Act, 1986 and Rule, 1989 as amended from time to time by providing adequate noise control measures and protective equipment's like ear muff and ear plug etc.

X. Adequate safety measures shall be ensured to limit the risk zone within the factory premises. Leak detection system shall be installed for early detection and mitigation purpose.

XI. PP to scrupulously follow the requirements of Maharashtra Factories Act, 1948 & Rules 1963 as amended from time to time.

XII. The Environmental Statement for each financial year ending on 31st March in Form-V as is mandated to be submitted by the Project Proponent to the concerned Pollution Control Board as prescribed under the Environment (Protection) Rule, 1989 as amended from time to time, it shall also be put on the website of the company along with the status of the compliance of the conditions stipulated in the Environmental Clearance letter.

4. The environmental clearance is being issued without prejudice to the action initiated under EP Act or any court case pending in the court of law and it does not mean that project proponent has not violated any environmental laws in the past and whatever decision under EP Act or of the Hon'ble court will be binding on the project proponent. Hence this clearance does not give immunity to the project proponent in the case filed against him, if any or action initiated under EP Act.

5. In case of submission of false document and non-compliance of stipulated conditions, Authority/ Environment Department will revoke or suspend the Environment clearance without any intimation and initiate appropriate legal action under Environmental Protection Act, 1986.

6. The Environment department reserves the right to add any stringent condition or to revoke the clearance if conditions stipulated are not implemented to the satisfaction of the department or for that matter, for any other administrative reason.

7. Validity of Environment Clearance: The environmental clearance accorded shall be valid as per EIA Notification, 2006, amended time to time.

8. In case of any deviation or alteration in the project proposed from those submitted to this department for clearance, a fresh reference should be made to the department to assess the adequacy of the condition(s) imposed and to incorporate additional environmental protection measures required, if any.

9. The above stipulations would be enforced among others under the Water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and rules there under, Hazardous Wastes (Management and Handling) Rules, 1989 and its amendments, the public Liability Insurance Act, 1991 and its amendments.

10. Any appeal against this Environment clearance shall lie with the National Green Tribunal (Western Zone Bench, Pune), New Administrative Building, 1st Floor, D-Wing, Opposite Council Hall, Pune, if preferred, within 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

Pravin Darade
(Member Secretary, SEIAA)

Copy to:

1. Chairman, SEIAA (Maharashtra), Mumbai.
2. Secretary, MoEF & CC
3. IA- Division MOEF & CC
4. Member Secretary, Maharashtra Pollution Control Board, Mumbai.
5. Regional Office MoEF & CC, Nagpur
6. District Collector, Pune.
7. Regional Officer, Maharashtra Pollution Control Board, Pune.

Signature Not Verified
Digitally signed by Shri Pravin C. Darade , I.A.S.
Member Secretary
Date: 5/18/2023 2:27:46 PM