



**State Environment Impact Assessment Authority, M.P.**  
(Ministry of Environment, Forest and Climate Change, Government of India)

**Environmental Planning & Coordination Organization**

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To,  
Shri Sunil Gandhi, Director,  
M/s Helios Lifesciences Limited,  
17, Shri Ram Colony, Jhansi Road, Gwalior,  
Madhya Pradesh-474002

No.: 1069 /SEIAA/ 21  
Date: 01.6.21

**Sub:- Case No.8451/2021:** Prior Environment Clearance for Manufacturing Unit Bulk Drugs, & API Production at 79 and 100, Industrial Growth Center, Malanpur, Bhind, MP-477117 Project Area- 19789.15 sq.m Production capacity -578 TPA (48.17 MT per month) by Director, M/s Helios Lifesciences Limited, Shri Sunil Gandhi 17, Shri Ram Colony, Jhansi Road, Gwalior, MP- 474002 Mob: 9826267890 Email -[info@helioslifesciences.com](mailto:info@helioslifesciences.com) Mob: 9826267890 Ph- 0753-283312 Env't. Consultant- Creative Enviro Services

**Ref:** Your online application (SIA/MP/IND2/201933/2021) dtd. 06.03.21 received in SEIAA office on 23.03.2021

With reference to the above, the proposal has been appraised as per prescribed procedure & provisions under the EIA notification issued by the Ministry of Environment & Forests vide S.O. 1533 (E), dated 14<sup>th</sup> September 2006 and its amendments, on the basis of the mandatory documents enclosed with the application viz., Form 2, pre-feasibility report, ppt. and additional clarifications furnished in response to observations by the State Expert Appraisal Committee (SEAC) and State Environment Impact Assessment Authority (SEIAA) constituted by the competent Authority.

- (i) This is case of Prior Environment Clearance for Manufacturing of Bulk Drug & API Product having capacity of 578 TPA at Malanpur Industrial Growth Centre, Village - Malanpur, Tehsil - Gohad, Dist. Bhind, (MP).
- (ii) The company proposes to set up a new project to establish a Contract Research and Manufacturing Facility for Bulk Drugs, Intermediate, Specialty Chemical at Plot No. 79 & 100, Industrial Area, Malanpur, Dist-Bhind (MP) for manufacturing of 578 TPA
- (iii) Project site is located between Latitude 26°21'3.18"N - and Longitude 78°17'38.63"E
- (iv) The proposed project is covered under 5 (f) category (B) of the schedule of EIA Notification issued by the Ministry of Environment & Forests vide S.O.1533 (E), dtd. 14.09.2006 and its amendments hence is required to obtain prior EC. In the context

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of pandemic COVID -19, GoI's MoEF&CC issued dtd. 15.10.2021 for considering the API & Bulk drug Projects as B-2 category.

- (v) There is no interstate boundary (12.06.2017) within 05 km and no National park, Sanctuary and Eco-sensitive areas (DFO letter dtd. 16.11.2017) within 05 km of the project area hence General condition are not attracted.

- (vi) Salient features of the project is as follows:-

Project Name	Manufacturing of Bulk drug and Intermediates
Location	Malanpur Industrial Area, Dist. Bhind
Production capacity	578 M Ton per Annum, (48.17 MT per month)
Estimated Project Cost	Proposed : 21.50 Crore
EMP Cost (Capital )	Proposed : -141.40 Lacs
EMP Cost Recurring	Proposed 94.90 Lacs
Acquired Land	19789.15 sqmtrs
Total Water Consumption	Total= 40 KLD
Net fresh Water Consumption	28 KLD as fresh 12 KLD of treated water will be recycled.
Source of Water Supply	AKVN
Waste Water Generation	Total= 16 KLD
Treatment Facility available and proposed	Effluent treatment facility ETP is of 40 KLD, RO of 20- KLD and proposed MEE of 10 KL/day. The treated water will be used for cooling towers, floor washing and green belt.
Source of power supply	Madhya KshetraVidyutVitaran Company
Power Requirement	Total :300-KVA
Fuel Options Coal/Agro waste ( TPD ) FO ( Lit/Hr)	Thermo Pack : FO : 54kg/hour. Boiler -1 :Coal/bio fuel/Pet coke : 36 Kg/Hr Boiler -2 :Coal/bio fuel/Pet coke : 54 Kg/Hr Thermopack : FO : 50Kg/hour DG set : HSD : 45kg/hour
Major equipments	Reactors, Centrifuge, Vacuum Try Dryer, Filters, Boiler, Cooling Tower, MEE, ETP, Brine Plant, Chilling Plant and RO etc.
Green belt (sqmt)	7530 Sq Meter
Employment generation	proposed : 150

- (vii) An already established factory shed of M/s Kodak India Limited spread in an area of 19,789.15 M2 on plot numbers 79 & 100 in Malanpur Industrial area has been acquired by M/s Helios Life sciences Limited. The entire Infrastructure including plant and machinery of Kodak India Limited has been acquired for establishing Contract Research and Bulk Drug Manufacturing Services (CRAMS) Unit.

- (viii) PP has proposed Production Capacity 578 TPA with following products :-

S.No.	Name Of Proposed Product	Quantity in TPA	Major Uses/ End Use
1	Carboplatin	14	Oncology (Anti-Cancer)
2	Cisplatin		
3	DocetaxelTrihydrate		
4	Paclitaxel		
5	ImatinibMesylate IP		
6	Erlotinib Hydrochloride IP		
7	Letrozole USP/BP		
8	Pemetrexeddosodium IP		
9	Gefitinib IP		
10	Oxaliplatin		

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11	Bortezomib
12	Bendamustine Hydrochloride
13	FosaprepitantDimeglumine
14	Capecitabine
15	Gemcitabine Hydrochloride
16	Hydroxyurea
17	Fludarabine Phosphate
18	Methotrexate
19	Nilotinib Hydrochloride
20	SorafenibTosylate
21	Temozolomide
22	Etoposide
23	EribulinMesylate
24	Dacarbazine
25	Bicalutamide
26	Thalidomide
27	Fulvestrant
28	VinblasineSulphate
29	Vincristine Sulphate
30	VinorelbineTartate
31	Carfilzomib
32	Cytarabine
33	Zoledronic Acid
34	Boceprevir
35	Apremilast
36	Bexpiprazole
37	Anastrozole
38	Cabazitaxel
39	Flutamide
40	Irinotecan Hydrochloride
41	Axitinib
42	Crizotinib
43	Osimertinib
44	Brigatinib
45	Pazopanib Hydrochloride
46	5-Fluorouracil
47	Afatinibdimalate
48	Ibrutinib
49	Olaparib
50	Ceritinib
51	Dasatinib
52	Lapatinib
53	Chlorambucil
54	MelphalanHCl
55	Carmustine
56	Enzalutamide
57	Palbociclib
58	Regorafenib
59	Acalabrutinib
60	Apalutamide
61	Neratinib
62	PonatinibHCl
63	Trabactidine
64	Topotecan
65	Abiraterone Acetate

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66	Nilotinib Dihydrochloride		
67	Nintedanib		
68	Ruxolitinib		
69	Tofacitinib		
70	Sunitinib Maleate		
71	Lenvatinib		
72	Cediranib		
73	Palibociclib		
74	Cabozatinib		
75	Lomustine		
76	Moxifloxane Hydrochloride		
77	Nitrofurantoin		
78	Tegicycline	16	Antibiotic
79	Colistimethate Sodium		
80	Enoxaparin Sodium		
81	Heparin Sodium		
82	Dalteparin Sodium		
83	Nadroparin Calcium		
84	Bemiparin		
85	Tinzaparin		
86	Parnaparin	3	Anticoagulant (Biological)
87	Reviparin		
88	Ardeparin		
89	Certoparin		
90	danaparoid		
91	Gensparin		
92	Ticagrelor		
93	Apixaban		
94	Dabigatran Etexilate Mesylate	2	Anticoagulant (Synthetic)
95	Rivaroxaban		
96	Fondaparinux		
97	Atracurium Besylate		
98	Vecuronium bromide	0.5	Neuromuscular blocking agent
99	Rocuronium bromide		
100	Misoprostol		
101	Cadexomer Iodine	6	Antiulcers
102	Glycopyrrolate		
103	Canagliflozin		
104	Dapagliflozin		
105	Sitagliptin	0.5	Anti Diabetic
106	Empagliflozin		
107	Vigabatrin		
108	Dextromethorphan Hydrobromide	160.2	Other APIs
109	Trazodone HCl		

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110	Tacrolimus
111	Rifaximin
112	Diphenoxylate HCL
113	Luliconazole
114	Caspofungin Acetate
115	Pinaverium Bromide
116	KetotifenFumarate
117	Hydroxychloroquine sulfate
118	Norethindrone Acetate
119	Bretylum Tosylate
120	Aripiprazole
121	Citicoline Sodium
122	Isotretinoin
123	Ursodeoxycholic Acid
124	Chlorothalidone
125	Propofol
126	CerebroproteinHydrolysate
127	Trimetazidine
128	Niacin
129	Niacinamide
130	Chromium Picolinate
131	Coenzyme Q10
132	Fexofenadine Hydrochloride
133	Isoniazid
134	Methyl Cobalamin
135	Cyanocobalamin
136	Hydroxocobalamin
137	Chlorhexadine
138	Calcium stearate
139	Magnesium stearate
140	Crosscarmilose sodium
141	Methyl paraben
142	Isosorbide
143	MethoxyPhenacyl Bromide
144	4-Aminopyridine
145	ChlorhexadineGluconate
146	Cetrimide
147	4- aminobenzaldehyde
148	Thyroxine sodium
149	MethoxyPhenacyl Bromide

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150	4-Aminopyridine		
151	Remdesivir		
152	Baclomethasone	9	Steroid Product and its Intermediate
153	BaclomethasoneDipropionate		
154	Betamethasone		
155	Betamethasone Dipropionate		
156	Betamethasone sodium phosphate		
157	Betamethasone Valerate		
158	Dexamethasone		
159	Dexamethasone Sodium Phosphate		
160	Clobetasol		
161	Flumethasone		
162	fluorometholone		
163	fluorometholone Acetate		
164	Hydroxoprogesterone		
165	HydroxoprogesteroneCaproate		
166	Mometasonefuroate		
167	Nandrolone		
168	Nandrolonedecanoate		
169	Deflazacort		
170	Triamcinolone acetonide		
171	Hydrocortisone Acetate		
172	Hydrocortisone hemisuccinate		
173	Methyl Prednisolone	0.8	Hormones
174	Prednisolone acetate		
175	Prednisolone Sodium Phosphate		
176	Halobetasol Propionate		
177	Testosterone		
178	Testosterone cypionate	0.8	Hormones
179	Testosterone propionate		
180	Testosterone Decanoate		
181	Methyl testosterone		
182	Alpha Picolinic Acid		
183	Zinc Picolinate	346	Other Bulk Intermediates
184	Isonicotinic Acid		
185	Isonipecotic Acid		
186	3-(Trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine hydrochloride (Sitagliptin intermediate-2) (762240-92-6)		
187	2,4,5-trifluoro phenylacetic acid (Sitagliptin intermediate-1) (209995-38-0)		
188	Boc-(R)-3-Amino-4-(2,4,5-Trifluoro-Phenyl)-		

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	Butyric Acid	
189	2,4-Difluorobenzylamine (72235-52-0)	
190	2,4-Difluorobenzylalcohol (56456-47-4)	
191	(S,S)-2,8-Diazabicyclo[4,3,0]nonane 151213-42-2/151213-40-0)	
192	(S)-2-Aminobutyramide Hydrochloride [SABAM HCl] (7682-20-4)	
193	GCLE (104146-10-3)	
194	4-Fluorophenol (371-41-5)	
195	3-Fluorophenol (372-20-3)	
196	2,4-Dichlorobenzonitrile (6574-98-7)	
197	2,4,6-trifluorobenzyl amine (214759-21-4)	
198	5,7-difluorochroman-4-one (844648-22-2)	
199	5,7-difluorochroman-4-ol (917248-51-2)	
200	4-hydroxy-N,N-2-trimethyl-1-(4-methylbenzene-1-sulfonyl)-1H-benzimidazole-6-carboxamide (942195-86-0)	
201	4R-5,7-difluoro-3,4-dihydro-2H-1-benzopyran-4-ol (1270294-05-7)	
202	2,6-Dichloro-4-trifluoromethyl aniline (24279-39-8)	
203	4-Fluorobenzonitrile (1194-02-1)	
204	4-Fluorobenzylamine (140-75-0)	
205	1,3,4-trifluorobenzene (367-23-7)	
206	2,6-Difluoro Aniline (5509-65-9)	
207	2,6-Difluorobenzonitrile (1897-52-5)	
208	4-chloro-N-Methyl Picolinamide (2200000-87-3)	
209	2,6-Difluorobenzamide (18063-03-1)	
Total (TPA)		578

- (ix) The project occupies a plot Area of 19789.15 sq.m. of land. PP has submitted copy of the registry of the land documents. As per the land documents the landownership is the name of M/s Helios Life Sciences Ltd. The land use breakup of the project area is as follows:-

Land Use Pattern		
S.no	Area	Total Area (Sq.Mtr)
1	Total Plot Area	19789.15
2	Total Built up Area	6333.81
3	Green Area/Plantation Area	7530

- (x) The major facilities will be Boiler, MEE ( 10 KLD), Reactors, Cooling Towers, Effluent Treatment Plant (ETP-40 KLD), and R.O Plant ( 20 KLD). Facilities like administrative office, parking and greenbelt/plantation has already been developed.
- (xi) Total raw water requirement for the proposed project will be 40 (28 KLD fresh water and 12 KLD recycled water). The water will be sourced from IIDC Gwalior (MP). The total wastewater generation will be 16.00 KLD .

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- Storm water drainage system shall be developed and shall be maintained preciously to prevent the flow of silt and other contaminant outside of the site
  - The entire trade effluent will be divided into two streams i.e. Stream-I (high concentrated streams) and Stream-II (low concentrated stream). Both the streams will be treated in well-designed ETP, RO and MEE.
  - Low COD /TDS wastewater (including process effluent, washing, blow downs from cooling towers, boiler, scrubber, Softener regeneration) will be sent to ETP followed by RO. Treated water will be reused.
  - High COD / TDS wastewater (consisting process effluent & RO reject) will be sent to MEE/ATFD. Condensate will be reused and bottom salt will be sent to a common TSDF site.
  - Utilization of treated wastewater in toilet flushing, greenbelt development and dust suppression
  - A drain along the boundary wall shall be made, which will be connected proposed settling tank to protect the flow of contaminant towards nearby area
  - M/s Helios will install Multi Effective Evaporator, with treatment capacity of 05 KL/Hr. The treated water will be used for cooling towers, floor washing and gardening/green belt.
  - Storm water drainage system will be developed for unit and shall be maintained preciously to prevent the flow of silt and other contaminant outside of the site.
  - Blow downs from cooling towers, boiler, ACF/MGF Cleaning, Softener regeneration, Vacuum pump will go to ETP
  - Water harvesting structure need to provide further strength with proper maintenance
  - ZERO effluent discharge has been implemented, and after expansion, the same shall be maintained.
- (xii) Air pollutants, such as carbon monoxide (CO), sulfur dioxide (SO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), volatile organic compounds (VOCs), heavy metals, and respirable particulate matter (PM-2.5 and PM-10), differ in their chemical composition, reaction properties, emission, time of disintegration and ability to diffuse in long or short distances. Volatile organic compounds (VOCs) are emitted as gases from certain solids or liquids. VOCs include a variety of chemicals, some of which may have short and long-term adverse health effects. For control of air pollution PP has proposed following measures:-
- All tankers shall be PUC Certified from time to time.
  - DG Sets will be operated during power failure.
  - Greenbelt will be developed at the facility to mitigate the impact of pollution.
  - Use of raw materials will have VOC emissions, which will be controlled by taking the following measures:
  - Provision for immediate isolation of such equipment, in case of a leakage will be made. All the mechanical seals of pumps and reactors will be monitored and maintained periodically as per preventive maintenance schedule.
  - Monitor VOCs through portable VOC's meter.



- Closed handling and charging systems shall be provided for chemicals.
  - Pumps shall be provided with mechanical seals to prevent leakages.
  - Flammable gas detectors shall be installed in the appropriate locations.
  - Venting equipment having toxic / flammable material shall have vapor recovery/scrubbing system. Measuring Instruments with sound alarm and having strategically placed sensing elements shall be provided for alerting the personnel in case of any escape of gases. Interlock with blower shall be provided.
- (xiii) Solid waste generated during the manufacturing process and wastewater treatment process is mainly sludge and will be disposed of at authorized TSDF facility, as per Hazardous and Other Waste (Management & Transboundary Movement) Rules, 2008 (Amendment 2016). M/s RLSPL will take authorization Under Hazardous Waste (Management, Handling & Transboundary Movement), Rules.
- (xiv) Power will be sourced from the existing line of 'Madhya Pradesh Madhya Kshetra Vidyut Vitaran Company'. The total requirement will be 300 KVA In case of power failure, D.G. of 1X250 KVA will be used as a backup power source.
- (xv) The existing green belt already developed in 6530 Sq m. area within and periphery of the plant with a total of 850 nos. Now PP has proposed a 1000 sq.m area for green belt development by planting 250 nos of trees around the periphery outside of the unit.
- (xvi) The green belt of 5-10 m width shall be developed over 1000 sq. meter apart from the existing green belt ( 6530 Sq mtrs) within and periphery of the plant ( with a total of 850 no), in downward wind direction and along roadsides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (xvii) The total fixed cost of the project is estimated as INR 2150 Lacs.
- (xviii) The total capital cost for environmental measures is kept as Rs. 141.400 Lacs (capital cost) is allocated for environmental management systems and the annual recurring cost for the same is Rs 94.90 Lacs
- (xix) PP has proposed physical targets as per the needs of the local population under Corporate Environment Responsibility (CER) with respect to Project Cost.i.e 10.0 lakh as follows:

Need Based CER activities along with Budgetary Allocation and it's Implementation Schedule			
S. N.	Need Identified For CER Plan	Activities	Budgetary Provision In Lacs (Capital)
1	Infrastructure development at School	Provision of infrastructure facility to the middle school and Aganwadi of Gohad Tehsil at distBhind (MP) in terms of boundary wall, furniture and other requirement in consultation with district administration	Rs. 10 Lac
	Total		Rs 10 Lacs

Based on the information submitted at Para i to xix above and others, the State Level Environment Impact Assessment Authority (SEIAA) considered the case in its 674<sup>th</sup>

meeting held on 07.04.2021 and decided to accept the recommendations of 496<sup>th</sup> SEAC meeting held on dtd. 03.04.21

Hence, Prior Environmental Clearance is accorded under the Manufacturing Unit Bulk Drugs, & API Production at 79 and 100, Industrial Growth Center, Malanpur, Bhind, MP- 477117 Project Area- 19789.15 sq.m Production capacity -578 TPA (48.17 MT per month) by Director, M/s Helios Lifesciences Limited, Shri Sunil Gandhi 17, Shri Ram Colony, Jhansi Road, Gwalior, MP- 474002 subject to the compliance of the Standard Conditions and the following additional Specific Conditions as recommended by SEIAA & SEAC in its meetings.

**A. Specific Conditions as recommended by SEIAA**

1. The entire demand of fresh water should be met through IIDC Gwalior and there should be no extraction of groundwater. Freshwater should not be used for Irrigation and gardening purposes.

**2. Waste water:**

(a) PP should ensure "Zero effluent discharge" from the unit by 100% recycling. The water softening reject, boiler blowdown reject and cooling blowdown will be treated in ETP. Further treated wastewater will go through the RO and finally reused / recycled in the process and unused waste water evaporates in MEE.

(b) RO and MEE should be provided for treatment of high COD waste streams and only in case of emergency/breakdown high COD wastes should be disposed off through CTSD, Pithampur, Dhar.

**3. For Air Pollution:**

(a) PP should ensure regular Stack monitoring Ambient air quality monitoring and should be carried out as per the guidelines/norms of MPPCB/CPCB.

(b) In plant control measures for checking fugitive emission from all the vulnerable sources shall be provided. Fugitive emission shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator/bag filters and water sprinkling system.

(c) Company shall carry out the HAZOP study and report shall be submitted to ministry MoEF & CC Regional Office, Bhopal.

(d) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal/CNG for use in coal/CNG fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions from the boiler, DG set shall be dispersed through a stack of adequate height as per CPCB/SPCB guidelines.

(e) For control of fugitive emission and VOCs following steps should be followed:-

- Chilled brine circulation system shall be provided and it should be ensured that the solvent recovery efficiency is not less than 95%.
- Reactor and solvent handling pump shall be provided with mechanical seal to prevent leakage.





- Solvent shall be taken from underground storage tank to reactor through closed pipeline. Storage tank shall be vented through trap receivers and condensers operated on chilled water.

#### 4. Hazardous Waste Management:

- As proposed above, PP should ensure disposal of hazardous waste regularly and there should be no dumping of these materials in the premises/outside.
- PP should ensure handling, disposal and management of hazardous waste as per the related prescribed rules.
- PP should obtain Renewal of authorization regularly from MPPCB for collection storage and disposal of hazardous waste (Management, handling & transboundary Movement) Rules 2008 and its amendments. Membership of the TSDF should be obtained for hazardous waste disposal.
- Hazardous chemicals should be stored in sealed tanks, drums etc. Flame arrestors shall be provided on tanks. To avoid the spillage from the processing unit, Industry shall provide a fully mechanized filling and packaging operation unit.

#### 5. Green Belt Development:

- PP should ensure plantation as proposed 1000 sq. m of area with 250 number of trees Plantation in the project area of indigenous local varieties like Neem, Peepal, Kadam and Kachnaar.
  - Every effort should be made to protect the existing trees on the plot.
  - Green areas including thick green-belt shall be developed in 33% of the plot area as proposed to mitigate the effect of fugitive emissions all around the plant in consultation with the forest department as per the guidelines of CPCB.
- PP should ensure the implementation of CER activities to the extent of Rs. 10 lakh for providing infrastructure facility to the middle school and Anganwadi of Gohad Tehsil at dist Bhind (MP) in terms of boundary wall, furniture and other requirement in consultation with district administration as committed during presentation
  - Total quantity of runoff water generated and green belt area should be collected in underground tank & used for processes in plant to minimize fresh water requirements.
  - PP should ensure to explore the possibility to use biomass or CNG as fuel instead of coal.
  - PP should ensure to submit half yearly compliance report and CER activity report with photographs of plantation in MP-SEIAA. If PP is failed to upload or submit two consecutive half yearly compliance reports of EC conditions to concerned authority (SEIAA and Regional Office, MoEF&CC, GoI, Bhopal) than prior environmental clearance issued to PP will automatically be treated as cancelled/ revoked as per OM No. 930/SEIAA/2019 dated 30.05.2019 issued by MPSEIAA.

#### B. Specific Conditions as recommended by SEAC

##### (A) Statutory compliance:

- The project proponent shall obtain Consent to Establish/Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the Madhya Pradesh Pollution Control Board(MPPCB).
- The project proponent shall obtain authorization under the Hazardous and other



Waste Management Rules, 2016 as amended from time to time & permission of competent authority if any tree falling is to be carried out.

- iii. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.

**(B) Air quality monitoring and preservation**

- i. The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connect it to MPPCB and CPCB online servers and calibrate these system from time to time according to equipment supplier specification through labs recognized under Environment (Protection) Act, 1986 or NABL accredited laboratories.
- ii. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognized under Environment (Protection) Act, 1986.
- iii. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (if applicable). The gaseous emissions from the boiler, DG set and scrubber shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
- iv. Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.
- v. The DG sets (1 X 250 KVA-Proposed ) shall be equipped with suitable pollution control devices and the adequate stack height so that the emissions are in conformity with the extant regulations and the guidelines in this regard.
- vi. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended from time to time shall be followed.
- vii. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with.

**(C) Water quality monitoring and preservation**

- i. The project proponent shall provide online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.
- ii. As already committed by the project proponent Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
- iii. The High COD/TDS process effluent (3.0 KLD) and RO Reject will be treated through MEE/ ATFD. The MEE condensates will be recycled/ reused and MEE bottom will be sent to TSDF site
- iv. The Low COD/TDS effluent, 5 KLD will be treated in an on-site ETP of 40 KLD.
- v. The treated effluent will be reused/ recycled.
- vi. Adhere to 'Zero Liquid Discharge and No industrial effluent from the unit shall be discharged outside the plant premises. PP should also install Internet Protocol PTZ camera with night vision facility along with minimum 05X zoom



- and data connectivity must be provided to the MPPCB's server for remote operations.
- vii. The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the Madhya Pradesh Control Board while granting Consent under the Air/Water Act, whichever is more stringent.
  - viii. Total net fresh water requirement shall not exceed 28 KLD and Tanker water supply shall be used
  - ix. Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
  - x. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.
  - xi. Dedicated power supply shall be ensured for uninterrupted operations of treatment systems.

**(D) Noise monitoring and prevention**

- i. Acoustic enclosure shall be provided to DG (1x250 KVA) set for controlling the noise pollution.
- ii. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation.
- iii. The ambient noise levels should conform to the standards prescribed under E(P)A Rules, 1986 viz. 75 dB(A) during day time and 70 dB(A) during nighttime.

**(E) Energy Conservation measures**

- i. The energy sources for lighting purposes shall preferably be LED based.
- ii. The total power requirements for project will be 300 KVA . The power will be supplied by Madhya Pradesh Electricity Board. Coal/ Bio Fuel/ Pet Coke will be used in existing boiler of 1 X 0.6 TPH and Proposed Boiler of 1 X 2 TPH

**(F) Waste management**

- i. Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps
- ii. As proposed minimum 95% solvent recovery shall be achieved and recovered solvent shall be reused in the process.
- iii. Hazardous wastes such as spent solvents, organic incinerable wastes/residues, used filter bags, packaging materials, rejected/expired raw materials and off specification/ rejected finished products from the manufacturing plants shall be directly sent to CTSDf, Pithampur.
- iv. The Fly ash generated from boilers shall be stored in silos and disposed of through cement manufacturers by bulkers / closed containers and should comply with Fly Ash Utilization Notification, 1999 and as amended subsequently.
- v. If any Flammable, ignitable, reactive and non-compatible wastes should be stored separately and never should be stored in the same storage shed.
- vi. Automatic smoke, heat detection system should be provided in the sheds. Adequate

- firefighting systems should be provided for the storage area.
- vii. In order to have appropriate measures to prevent percolation of spills, leaks etc. to the soil and ground water, the storage area should be provided with concrete floor of inert material or steel sheet depending on the characteristics of waste handled and the floor must be structurally sound and chemically compatible with wastes.
  - viii. Measures should be taken to prevent entry of runoff into the storage area. The Storage area shall be designed in such a way that the floor level is at least 150 mm above the maximum flood level.
  - ix. The storage area floor should be provided with secondary containment such as proper slopes as well as collection pit so as to collect wash water and the leakages/spills etc.
  - x. Storage areas should be provided with adequate number of spill kits at suitable locations.
  - xi. The spill kits should be provided with compatible sorbent material in adequate quantity.
  - xii. Recent MSDS of all the chemicals used in the plant be displayed at appropriate places.
  - xiii. Proper fire fighting arrangements in consultation with the fire departments should be provided against fire incident.
  - xiv. All the storage tanks of raw materials/products shall be fitted with appropriate controls to avoid any spillage / leakage. Bund/dyke walls of suitable height shall be provided to the storage tanks. Closed handling system of chemicals shall be provided.
  - xv. Log-books shall be maintained for disposal of all types hazardous wastes and shall be submitted with the compliance report.
  - xvi. The company shall undertake waste minimization measures as below:
    - a. Metering and control of quantities of active ingredients to minimize waste.
    - b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
    - c. Use of automated filling to minimize spillage.
    - d. Use of Close Feed system into batch reactors.
    - e. Venting equipment through vapour recovery system.
    - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.

**(G) Green Belt**

- i. The green belt of 5-10 m width shall be developed over 1000 sq. meter apart from the existing green belt ( 6530 Sq mtrs) within and periphery of plant ( with total of 850 no), in downward wind direction and along road sides etc. Selection of plant species shall be as per the CPCB guide lines in consultation with the State Forest Department.
- ii. Peripheral plantation all around the project boundary shall be carried out using tall saplings of minimum 2 meters height of species which are fast growing with thick





canopy cover preferably of perennial green nature. PP will also make necessary arrangements for the causality replacement and maintenance of the plants.

**(H) Safety, Public hearing and Human health issues**

- i. Emergency preparedness plan based on the Hazard identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented.
- ii. The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.
- iii. The PP shall provide Personal Protection Equipment (PPE) as per the norms of Factory Act.
- iv. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- v. Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.
- vi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- vii. There shall be adequate space inside the plant premises earmarked for parking of vehicles for raw materials and finished products, and no parking to be allowed outside on public places.

**(I) EMP**

- i. The company shall have a well laid down environmental policy duly approve by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental/ forest/ wildlife norms/ conditions. The company shall have defined system of reporting infringements /deviation/ violation of the environmental / forest / wildlife norms / conditions and or shareholders /stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF&CC as a part of six-monthly report.
- ii. A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly to the head of the organization.
- iii. Fund should be exclusively earmarked for the implementation of EMP through a separate bank account.
- iv. The proposed EMP cost is Rs. 141.40 Lakhs as capital and 94.90 Lakhs /year as recurring cost.
- v. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other purpose. Year wise progress of implementation of action plan shall be

reported to the Ministry/Regional Office along with the Six Monthly Compliance Report.

- vi. Self-environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried-out.

**(J) Miscellaneous**

- i. PP shall be responsible for discrepancy (if any) in the submissions made by the PP to SEAC & SEIAA.
- ii. The project authorities must strictly adhere to the stipulations made by the MP Pollution Control Board and the State Government.
- iii. The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, and also that during their presentation to the Expert Appraisal Committee.
- iv. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forests and Climate Change (MoEF&CC).
- v. The above conditions shall be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India/ High Courts and any other Court of Law relating to the subject matter.

**Standard Conditions:**

1. The company shall carry out the HAZOP study and the report shall be submitted to Regional Office of MoEF, Gol at Bhopal.
2. The company shall comply with the CREP guidelines prepared by MPPCB for Bulk Drug Plants.
3. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixings of accidental spillages with domestic waste and storm drains.
4. Industry should get the Emergency Disaster Management Plan approved by DTHS and should also comply with the provisions made in Public Liability Insurance Act, 1991.
5. All parameters listed in Environmental Monitoring Plan approved by SEAC must be monitored at approved locations and frequencies.
6. The funds earmarked for environmental protection measures shall be kept in separate account and shall not be diverted for other purpose. Year wise expenditure shall be reported to the Regional office of the Ministry of Environment and Forest, Bhopal and MP PCB.
7. All other statutory clearances such as the approvals for storage of diesel from Chief Controller of Explosives, Fire Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wildlife (Protection) Act, 1972 etc. shall be obtained (as and when applicable), by the project proponent from the respective competent authorities.
8. The Regional Office, MoEF, Gol, Bhopal and MP PCB shall monitor compliance of the stipulated conditions. A complete set of documents including Environment Impact

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- Assessment Report, Environmental Management Plan, should be given to Regional Office, MoEF, GoI, Bhopal and MP PCB.
9. A copy of the environmental clearance shall be submitted by the Project Proponent to the Heads of the Local Bodies, Panchayat and Municipal Bodies as applicable in addition to the concerned Government Departments / organization responsible for controlling the proposed projects who in turn has to display the same for 30 days from the date of receipt.
  10. The project proponent has to strictly follow directions/guideline issued by the MoEF, GoI, CPCB and other Govt. agencies from time to time.
  11. The Project Proponent shall advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the clearance letter informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with the State Pollution Control Board and also at web site of the State Level Environment Impact Assessment Authority (SEIAA) website at [www.mpseiaa.nic.in](http://www.mpseiaa.nic.in) and a copy of the same shall be forwarded to the Regional Office, MoEF, GoI, Bhopal and MP PCB.
  12. The Project Proponent has to upload soft copy of half yearly compliance report of the stipulated prior environmental clearance terms and conditions on 1st June and 1st December of each calendar year on MoEF & CC web portal - <http://www.environmentclearance.nic.in/> or <http://www.efclearance.nic.in/> and submit hard copy of compliance report of the stipulated prior environmental clearance terms and conditions to the Regulatory Authority also
  13. The SEIAA of M.P. reserves the right to add additional safeguard measures subsequently, if found necessary, and to take action including revoking of the environment clearance under the provisions of the Environment (Protection) Act, 1986, to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.
  14. These stipulations would be enforced among others under the provisions of Water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and control of Pollution) Act 1981, the Environment (Protection) Act, 1986, the Public Liability (Insurance) Act, 1991 and EIA Notification, 2006.
  15. The Ministry or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.
  16. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.
  17. Any appeal against this prior environmental clearance shall lie with the Green Tribunal, if necessary, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
  18. The prior Environmental Clearance granted for the project is valid for a period of seven years as per EIA notification dtd. 14.09.2006 & its amendments.
  19. The proponent shall upload the status of compliance of the stipulated EC conditions, including results of monitored data on their website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of MoEF, the respective Zonal Office of CPCB and the SPCB. The criteria pollutant levels namely; SPM, RSPM, SO<sub>2</sub>, NO<sub>x</sub> (ambient levels as well as stack emissions) or critical



sectoral parameters, indicated for the project shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.

20. The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated to be submitted by the project proponent to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of EC conditions and shall also be sent to the Regional Office of MoEF.

Endt No. 1070 / SEIAA/ 2021  
Copy to:-

Dated 01.6.21

(Shriman Shukla)  
Member Secretary

- (1). Principal Secretary, Urban Development & Environment Deptt. 3<sup>rd</sup> Floor, Mantralaya Vallabh Bhawan, Bhopal.
- (2). Secretary, SEAC, Research and Development Wing Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5, Arera Colony Bhopal-462016.
- (3). Member Secretary, Madhya Pradesh Pollution Control Board, Paryavaran Parisar, E-5, Arera Colony, Bhopal-462016.
- (2). The Collector, Distt- Bhind - M.P.
- (4). M.D. M P Audyogik Kendra Vikas Nigam (Gwalior) Ltd 52, Ravi Nagar Gwalior – 474002
- (5). Director, I.A. Division, Monitoring Cell, MoEF, Gol, Ministry of Environment & Forest Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110 003
- (6). Director (S), Regional office of the MOEF, (Western Region), Kendriya Paryavaran Bhawan, Link Road No. 3, Ravi Shankar Nagar, Bhopal-462016.
- (7). Guard file.

(Alok Nayak)  
Officer-in-Charge

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