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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सत्यमेव जयते

No.: 4517 /SEIAA/ 20
Date : 27/10/20

To,
Anil Satwani, Director
M/s Symbiotec Pharmalab Pvt. Ltd,
Plot No. 385/2, Pigdamber, Rau,
Indore- MP 453331

Sub:-Case No. 7727/2020 : Prior Environment Clearance for proposed Capacity Expansion of Manufacturing of Bulk Drug & Intermediate from 30 MTPA to 96 MTPA TPA at Plot No. 385/1, 385/2, 390/1/2, 389/1, Village- Pigdamber, Tehsil - Mhow & Dist. Indore (MP) Project Area: 22258 sq.m. Production Capacity: Existing-30 MTPA Propsed Capacity-96 MTPA by Anil Satwani, Director M/s Symbiotec Pharmalab Pvt. Ltd, Plot No. 385/2, Pigdamber, Rau,Indore- MP 453331 e-mail:symbioyec@ symbiotec.in Mob No. – 9630090963 Ph- 0731-6676456 Env. Con.-Creative Enviro Services, Bhopal (M.P.).

Ref: Your application dtd. 15.09.20 received in SEIAA office on 18.09.2020

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 14th September 2006 and its amendments, on the basis of the mandatory documents enclosed with the application viz., Form I, 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 Capacity Expansion in Manufacturing of Bulk Drug and Intermediaties. The Company is now planning for increasing the production capacity of from from 30 MTPA to 96 MTPA.

(ii) The Co-ordinates of the project site are latitude from 22037'4.09"N and longitude 75048'12.26"E with ground level 590m MSL

(iii) 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 of pandemic COVID -19, GoI's MoEF&CC issued a OM vide dated 13.04.2020, for considering the API & Bulk drug Projects as B-2 category.

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

(v) PP has submitted capacity of existing and proposed products are as follows:-

Existing and Proposed Products And Its Capacity				
Sr. No.	List of Products	Existing Capacity	Proposed capacity	Grand Total
(A)	Non Sterile Products (Existing & proposed)			
1	Betamethsone Propionate	8	8	16
2	Betamethsone sodium phosphate			
3	Betamethasone valerate			
4	Clobetasol propionate			
5	Beclometasone dipropionate			
6	DTMD mesylate			
7	Halobetasol propionate			
8	Budesonide			
9	Prednisolone acetate			
10	Prednisolone sodium phosphate			
11	Triamcinolone acetonide			
12	Dexamethasone sodium phosphate			
13	Mometasone Epoxide			
14	Mometasone Furoate			
15	Hydrocortisone acetate			
16	Methylprednisolone acetate			
17	Deflazacort			
18	Abiraterone Acetate			
19	Betamethasone Acetate			
20	Clobetasone Butyrate			
21	Clorprednol			
22	Desonide			
23	Desoximetasone			
24	Dexamethasone			
25	Dexamethasone Acetate			
26	Diflorasone Diacetate	8	8	16
27	Drospirenone			
28	Halometasone Monohydrate			
29	Hydrocortisone Hemisuccinate			
30	Hydrocortisone Hydrogen Succinate			
31	Hydroxyprogestrone Caproate			
32	Methylprednisolone			
33	Trimicinolone Sodium Phosphate			
34	Betamethasone			
35	Flucinolone Acetonide			
36	Flucinolone Pivolate			
37	Flumethazone			
38	Fluoxymesterone			
39	Fluticasone Furoate			
40	Methylprednisolone Aceponate			
41	Potassium Canrenone			
42	Hydrocortisone			
43	Fluticasone propionate			
44	Prednisolone Hemisuccinate			

45	Prednisolone			
46	4 TR			
47	3 TR / Tetrane Acetate			
48	Fluromethlone			
49	Methyl prednisolone Sodium Succinate			
50	Methylprednisolone Hydrogen Succinate			
51	Hydrocortisone Sodium Succinate			

Existing and Proposed Products And Its Capacity				
Sr. No.	**List of of Products**	**Existing Capacity**	**Proposed capacity**	**Grand Total**
	List of Additional products for EC			
52	Fluocortolone Pivalate (FOP)			
53	Fluocortolone Hexanoate			
54	Clascoterone / Cortexolone 17a-PROPIONATE - In- House			
55	Betamethasone Acetate			
56	Fluocortolone Hexanoate			
57	Clascoterone / Cortexolone 17a - PROPIONATE - In - House			
58	Flurandrenolide(FLN)			
59	Clocortolone Pivalate(CCP)		8	16
60	Prednisolone sodium meta sulfo benzoate (PMB)			
61	Prednisolone caproate(PRC)			
62	Fluocortolone (FON)			
63	Flucortolone Hexanoate			
64	Diflucortolone (DON)			
65	Diflucortolone valerate (DOV)			
66	Methylprednisolone Aceponate (MAP)			
67	Ergocalsiferol (Vitamin D-2)			
68	Cholcalciferol (Vitamin D-3)			
	Total			
(B)	**Sterile Products (Existing)**			
69	Methyl Prednisolone Sodium Succinct for injection USP for manufacturer's use.	22	58	80
70	Hydrocortisone Sodium Succinate for injection USP for manufacturer's use			
	Total	**30**	**66**	**96**

(vi) PP has submitted compliance report certified by Regional office, MoEF& CC vide no. 1286 dated 04.04.2019 with following recommendations:

"Implementation of Conditions:- It is inferred from the above that the implementations of environmental conditions are found as 11 agreed to comply, 16 being compiled, 02 partly compiled and some compliance needs improvements which are in progress, PA has been advised for implementation is to be taken care with the project development , attention is to be given to the vital conditions like environmental management, green belt development,

capacity & treatment of ETP and also the submission and uploading of six monthly compliance as per stipulation".

(vii) The case was discussed in SEAC meetings 461st dated 29.09.2020, and recommended for grant of prior EC.

(viii) The project occupies Total Plot Area of 22258 sqm. The expansion is proposed in the company's existing premises of 22258 sq.m. Regarding land documents PP has submitted sale deed and lease deed dtd. 14.10.05. As per the land documents the the said land is allotted to M/s Symbiotec Pharmalab Pvt. Ltd through Director Shri Anil Satwani.The land use breakup of the project area is as follows:

Existing And Proposed Land Use Breakup			
	Existing	**Proposed**	**Total**
	SQM	**Expansion in Existing plant. Hence no additional area is required**	SQM
Production Block	1390		1550
Administration Block	479		479
Solvent Area	1080		1080
Scrap Yard & Boiler	750		1000
Security	30		30
Utility	375		455
R & D Lab	538		538
ETP	364		1164
Road	1710		1950
Parking Area	304		304
Total Built Up Area	7020		8550
Green Belt / lawn Area	12344		12344
Future Expansion Area	2894		1364
Total Plot Area	**22258**		**22258**

(ix) The major facilities involved area Boiler, Cooling Towers, Effluent Treatment Plant (ETP), STP and R.O Plant Facilities like administrative office, parking and greenbelt/plantation also developed as per plan/requirement.

(x) The water requirement for the existing project is 73.50 KL per day which will be increased to a 189.00 KLD and sourced from surface water supply. The net fresh water requirement shall be 100 KLD as 81.515 KLD of treated water will be recycled. The water supply for the project is being sourced from Narmada water supply (Local body) through pipeline network for which PP has applied (dtd. 10.09.2020) to Indore Municipal Corporation.

(xi) Total cumulative waste water generation from existing unit is 55.3 KLD which will be increased to 123.90 KLD. The WW will be treated in ETP of 100 KLD, RO of 100 KLD, and MEE of 30 KL/day respectively. The net fresh water requirement shall be 105.485 KLD and 81.515 KLD will be recycled. The rejected water will be reused for floor washing and gardening/green belt.

(xii) Power requirement of 4000 KVA will be sourced from existing line of 'Madhya Pradesh Madhya Kshetra Vidyut Vitaran Company'. In case of power failure, D.G. set (Existing 750 KVA, 320 KVA, 1000 KVA and proposed 2000 KVA) will be used as a backup power source.

(xiii) PP has proposed various mitigation measures for water management and wastewater management are mentioned below:

a. Storm water drainage system has been developed for existing unit and shall be maintained preciously to prevent the flow of silt and other contaminant outside of the site and towards river side
b. Blow downs from cooling towers, boiler, scrubber, Softener regeneration, Vacuum pump will go to ETP. High COD wastewater will be sent to COD Stripper. Remaining waste water will be treated in ETP.
c. Utilization of treated domestic wastewater in toilet flushing, greenbelt development and dust suppression shall be continue
d. A drain along the boundary wall shall be made, which will be connected proposed settling tank/water reservoir to protect the flow of contaminant towards nearby area
e. Regular monitoring and analysis of pond and nalla is proposed
f. 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

(xiv) To mitigate the impact of pollutants from boiler stack, diesel generator sets, sources of fugitive emission and vehicular traffic during the operational phase of the site, following measures are proposed for implementation:
a. Height of all the stacks will be as per statutory requirement. All the stacks will have Stack Monitoring Facility (SMF) consisting of sampling port-hole, platform and access ladder.
b. Bag Filters and venturi scrubber are proposed as per the requirement andn nature of pollutant.
c. Online monitoring system for the pollutants from the stacks with an arrangement to reflect gaseous emission parameters on company's server shall be provided.
d. Transport vehicles will be properly maintained to reduce air emissions. Vehicles will be periodically checked for pollutant emissions against stipulated norms.
e. Provision of enclosure for all the loading & unloading operations, if possible.
f. Regular monitoring of the stack emission of existing and proposed scrubber shall be carried out.
g. Regular monitoring of VOC, concentration in work zone
h. Additional greenbelt will be developed around the plant to arrest the fugitive emission
i. Bag filter shall be provided at proposed boiler to control the emission below 150 mg per cubic meter.
j. Alkaline Scrubber will be attached to the reactor vent to control process SO2 emission.
k. In order to control the fugitive dust emissions due to transportation activity, all the operational roads within the plant area shall be asphalted.

(xv) Noise attenuating devices like earplugs and earmuffs shall be provided to workers exposed to high noise levels. Noise barriers, silencer and enclosures shall be incorporated in the equipments, which emit high noise level. All basic equipments and various machineries should be kept well maintained. Green belts are good noise barriers and same will be developed around the plant. The sufficient green belt may be proposed to control noise levels.

(xvi) Solid waste generated during the manufacturing process and sludge from waste water treatment process will be disposed at authorized TSDF facility, as per Hazardous and Other Waste (Management & Trans-boundary Movement) Rules, 2008 (Amendment 2016). M/s SPPL will take expanded authorization Under Hazardous Waste (Management, Handling & Trans-boundary Movement), Rules.

(xvii) Particulate matters & other gaseous emission are envisaged as pollutant from boiler and other sources apart from other sources of fugitive emission .Depending on quality of emission from different sources, suitable air pollution control system will be provided.

(xviii) Existing green belt developed in an area of 12344 sq.m with 3417 nos. of plants. After expansion the green belt will be developed by planting 500 nos of trees i.e. 3917.

(xix) PP has also proposed Green belt development at school and other areas such as Navda School - 250 plants Panda School -250 plants.

(xx) PP has submitted on site and of site emergency plan including Disaster Management, Risk Assessment and Fire Fighting.

(xxi) The proposed project has planned extensive pollution control and environmental conservation measures. Also having provisions of CSR expenditure for the welfare activities. Under the CER PP has proposed following activities with 23.70 Lakh budgetary provision:-

CER Activities Along with Budgetary Allocation And It's Implementation Schedule						
S. N.	Need Identified For CER Plan	Activities	Budgetary Provision In Lacs (Capital) & Implementation Period (F.Y. 2020-21 to 2024-25)			
			1st Year	2nd Year	3rd Year	Total
1	Infrastructure development at School, Aganwadies	Infrastructure facilities at schools in terms of provision of computers, teachers, facility of safe drinking water, separate toilets for girls and boys, provision of furniture, additional rooms etc. In consultation with district administration at Panda, Rau, Tihi, Shahada, Bhamti, Umri,	Rs. 5.0	Rs 5 .0	R s 5.0	Rs 15
2	Covid Related Activities	Nearby hospitals, health centers and aganwadies	Rs. 5	-	-	Rs 5
3	Execution of Need base Activities	Execution of need base activities in coordination with district administration Dhar and Indore	-	Rs.3.70	-	Rs 3.70
	Total		**Rs 10**	**Rs 8.70**	**Rs 5**	**Rs 23.70**

Based on the information submitted at Para i to xxii above and others, the State Level Environment Impact Assessment Authority (SEIAA) considered the case in its 643rd meeting held on 06.10.2020 and decided to accept the recommendations of 461st SEAC meeting held on dtd. 29.09.20

Hence, Prior Environmental Clearance is accorded under the provisions of EIA notification dtd. 14th September 2006 & its amendments for the Proposed Capacity Expansion of Manufacturing of Bulk Drug & Intermediate from 30 MTPA to 96 MTPA TPA at Plot No. 385/1, 385/2, 390/1/2, 389/1, Village- Pigdamber, Tehsil - Mhow & Dist. Indore (MP) Project Area: 22258 sq.m. Production Capacity: Existing-30 MTPA Propsed Capacity-96 MTPA by Anil Satwani, Director M/s Symbiotec Pharmalab Pvt. Ltd, Plot No. 385/2, Pigdamber, Rau,Indore- MP 453331, subject to the compliance of the Standard Conditions and the

following additional Specific Conditions as recommended by SEIAA & SEAC in its meetings.

A. <u>Specific Conditions as recommended by SEIAA</u>

1. PP should ensure the implementation of the observations of MOEF & CC RO, Bhopal report dtd 04.04.2019.
2. The entire demand of fresh water should be met through surface water Supply / Indore Municipal Corporation and there should be no extraction of ground water. PP should obtain NOC from Municipal Corporation ,Indore for which applied on 10.09.2020
3. **Waste water:**
   (a) PP should ensure "Zero effluent discharge" from the unit by 100% recycling. The water softening reject, boiler blow down reject and cooling blow down will be treated in ETP. Further treated waste water will go through the RO and finally re used / 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 CTSDF, Pithampur,Dhar.
4. **For Air Pollution:**
   a) 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.
   b) Dust suppression system including water sprinkler system/ foaming arrangement shall be provided at loading and unloading areas to control dust emission.
   c) Fugitive emission in the work zone environment, product, raw material storage areas etc. shall be regularly monitored.
   d) Transportation of raw material and finished goods should be carried out in covered trucks.
   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 will not be less than 98%.
      - Reactor and solvent handling pump shall be provided with mechanical seal to prevent leakage.
      - Closed handling system should be provided for chemicals.
      - System of leak detection and repair of pump/pipeline should be based on preventive maintenance.
      - Solvent shall be taken from underground storage tank to reactor through closed pipeline. Storage tank shall be vented through trap receiver and condenser operated on chilled water.
5. **Hazardous Waste Management:**
   (a) As proposed above, PP should ensure disposal of hazardous waste regularly and there should be no dumping of these materials in the premises/outside.
   (b) PP should ensure handling, disposal and management of hazardous waste as per the related prescribed rules.
   (c) 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.
   (d) Hazardous chemicals should be stored in sealed tanks, drums etc. Flame arrestors shall be provided on tanks. To avoid the spillage from processing

unit, Industry shall provide fully mechanized filling and packaging operation unit.

6. PP should obtain NOC /approval from competent authority for health & safety measure, Onsite & Offsite disaster management, and Risk management plan before commencing the operation of the unit.
7. PP should ensure installation of photovoltaic cells (solar energy) for lighting in common areas, LED light fixtures and energy efficient equipments.
8. **Green Belt:**
   (a) PP should ensure plantation as proposed in 12344 sq.m sq. m by planting 500 nos of trees at the proposed locations and Plantation in the project area of indigenous local varieties like Neem, Peepal, Kadam, Kachnaar etc.
   (b) Every effort should be made to protect the existing trees on the plot.
   (c) Green area including thick green-belt shall be developed in the plot area to mitigate the effect of fugitive emissions all around the project area in consultation with the forest department as per the guidelines of CPCB.
9. PP should ensure the implementation of CER activities to the extent of Rs. 23.70 lakhs will be used Infrastructure facilities at schools in terms of provision of computers, teachers, facility of safe drinking water, separate toilets for girls and boys, provision of furniture, additional rooms etc. In consultation with district administration at Panda, Rau, Tihi, Shahada, Bhamti, Umri, Covid Related Activities, Execution of need base activities in coordination with district administration Dhar and Indore.
10. Total quantity of runoff water generated and green belt area should be collected in underground tank & used for process in plant to minimize fresh water requirement.
11. 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. <u>Specific Conditions as recommended by SEAC</u>

(A) Statutory compliance

i. 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).

ii. 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 ant 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 connected 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 (as 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 (Existing - 1 X 2000 KVA and Proposed 1 X 2000 KVA) 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 161h 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 (34 KLD) and RO Reject (24.45 KLD) 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, [consisting, process effluent (23KLD), Utility blow down 31 KLD will be treated in an on-site ETP followed by RO system.

v. The treated effluent 81.515 KLD will be reused/ recycled and the RO reject will be sent MEE/ATFD as stated above.

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 fresh water requirement shall not exceed 105.485 KLD and AKVN 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 ((Existing - 1 X 2000 KVA and Proposed 1 X 2000 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 night time.

(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 400 KVA . The power will be supplied by Madhya Pradesh Electricity Board. 8000 kg per day Husk will be used as fuel in existing (1+3 TPH) and proposed boiler 4 TPH). (Source Indigeneous)

(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, 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, Dhar.

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 fire fighting 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. The spill kits should be provided with compatible sorbent material in adequate quantity.

xi. Recent MSDS of all the chemicals used in the plant be displayed at appropriate places.

xii. Proper fire fighting arrangements in consultation with the fire department should be provided against fire incident.

xiii. 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.

xiv. Log-books shall be maintained for disposal of all types hazardous wastes and shall be submitted with the compliance report.

xv. Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.

xvi. The company shall undertake waste minimization measures as below:

xvii. Metering and control of quantities of active ingredients to minimize waste.

xviii. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.

xix. Use of automated filling to minimize spillage.

xx. Use of Close Feed system into batch reactors.

xxi. Venting equipment through vapour recovery system.

xxii. Use of high pressure hoses for equipment clearing to reduce wastewater generation.

(G) Green Belt

a. The green belt of 5-10 m width has been developed over 12344 sq. meter of land within plant (with 3417 no of tress which shall be increased to 3917 no of tress along the plant periphery, 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.

b. 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. As proposed 500 no of plants in one years shall be planted. 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) Corporate Environment Responsibility

i. The project proponent shall comply with the provisions contained in this Ministry's OM vide F.No. 22-65/2017-IA.III dated 1st May 2018, as applicable, regarding Corporate Environment Responsibility.

ii. 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.

iii. 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.

iv. Fund should be exclusively earmarked for the implementation of EMP through a separate bank account.

v. The proposed EMP cost is Rs. 1005.20 Lakhs as capital and 43+28= 71.00 Lakhs /year as recurring cost.

vi. Under CER activity, Rs. 23.70 Lakhs as capital costs has proposed for different activities. PP shall complied with the commitment of providing infrastructure facility at school .

vii. 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.

viii. 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, commitment made during Public Hearing 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, GoI 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, GoI, Bhopal and MP PCB shall monitor compliance of the stipulated conditions. A complete set of documents including Environment Impact 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** and a copy of the same shall be forwarded to the Regional Office, MoEF, GoI, Bhopal and MP PCB.

12. Any change in the correspondence address be duly intimated to all the regulatory authority within 30 days of such change.

13. 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

14. 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 Environmental (Protection) Act, 1986, to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.

15. 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.

16. The Ministry or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.

17. 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.

18. 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.

19. 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.

20. 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_2, NOx (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.

21. The environmental statement for each financial year ending 31st 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.

(Tanvi Sundriyal)
Member Secretary

Endt No. 4518 / SEIAA/ 2020 Dated 27/10/20

Copy to:-

(1). Principal Secretary, Urban Development & Environment Deptt. 3rd 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.

(4). The Collector, District Indore, M.P.

(5). Managing Director, M.P. Audyogik Kendra Vikas Nigam (Indore) Limited, Free Press House First Floor, 3/54 Press Complex, Agra–Mumbai Highway Indore (M.P).

(6). Director, I.A. Division, Monitoring Cell, MoEF, GoI, Ministry of Environment & Forest Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110 003

(7). Director (S), Regional office of the MOEF, (Western Region), Kendriya Paryavaran Bhawan, Link Road No. 3, Ravi Shankar Nagar, Bhopal-462016.

(8). Guard file.

(Dr. Sanjeev Sachdev)
Officer-in-Charge