

Environmental Health Risk Management Plan (EHRMP)

Aurobindo Pharma Limited

Proposal entitled: Vaccine to prevent and control COVID-19

(i) Brief description of the proposed activity: Development of Vaccine to prevent and control COVID-19 disease.				
(ii) List of environment related regulatory clearances required for the activity: CFO, Third Party authorizations				
Institutional Arrangement				
Area of Risk	Yes	No	Details	Proposed Plan
1. Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	✓		Full time employee was dedicated for this project from EHS Department, Aurobindo Pharma Limited, Unit-18.	Activities related to environment, health and safety issues will be timely and properly addressed by well-trained EHS staff.
2. Does the EHS staff handle the following?				
Occupational Health and Safety	✓		1. Medical and health Checkups are conducted periodically.	The Firm is conducting the annual health checkups ,maintaining all records and training the staff by EHS team periodically.
Waste Management	✓		2. Solid and liquid waste management practices are available.	
List of consents and regulatory clearances	✓		3. CFE was granted from PCB authorities , Form 29 from the DCGI	
Record keeping of accidents and procedures	✓		4. FIR for accidents and incidents are being maintained for recording the incidents.	
EHS trainings for staff	✓		5. Trainings are provided periodically on general safety and chemical safety, fire fighting, mock drills.	
Environment Management Framework compliance for Innovate in India Project	✓		We have in place a robust environmental management framework to address environmental related issues.	
3. Is there a reporting structure in place regarding EHS issues?	✓		Reporting to Plant Head followed by Corporate EHS President	Immediate action will be taken in case of any issues with respect to EHS
4. Are regular EHS trainings provided to staff?	✓		Frequency: Every 6 months	Every 6 months and periodically
5. Institutional Bio-Safety Committee (IBSC)	✓		IBSC meetings (9 th and 10 th) were conducted for this project and their MOMs were uploaded in RCGM-IBKP web portal.	11 th IBSC meeting is planning to discuss the permissions related to this project in the near

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6.	Ethics Committee (EC)		✓	No in-house animal facility	future. At present we are not having in-house animal facility and animal studies are out sourcing. In future if required we will form the EC and will be intimated.
General Occupational Health and Safety					
	Area of Risk	Yes	No	Details	Proposed Plan
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	✓		SOP: Handling of Spillage in Viral Vaccine Pilot Plant PRD/SOP/130.00	Implementation of instructions as mentioned in SOPs to avoid the spillages of acid, alkali, flammable, chemical, biological and recombinant materials.
8.	Are the following in place?	✓		All emergency equipment's are placed at designated places to avoid the accidents and injuries. Registers of accidents and injuries maintained at Occupational Health Center (OHC)	Functional and general maintenance of all safety equipment are regularly followed. Mock drills and safety training were planned periodically to all the staff members.
	Chemical spill kits	✓			
	Eye wash	✓			
	Shower stations	✓			
	First Aid Kit	✓			
	Fire Extinguishers	✓			
	Register of accidents and injuries	✓			
9.	Are proper signage and storage system in place?	✓		Emergency signage's are placed at escape routes and emergency exits.	Emergency contacts will be updated in change of any key members.
	Display of Material Safety Data Sheet (MSDS) where relevant	✓		Emergency contacts numbers available at security office. MSDS area available	While handling the flammable material suitable PPE's are used.
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	✓			
	Signage across the facility (labs, storage, hazardous areas, etc.)	✓		Flammable materials are stored in cool, dry places and away from the source of ignition with adequate ventilation.	
	Are flammable materials appropriately stored to prevent fire hazards?	✓			
10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	✓		List: MCPS area maintained and smoke detectors are available in all areas inside the facility.	New MCPS, smoke detectors will be arranged depending on area /section
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	✓		List: Stack monitoring is in place.	Done by PCB authorized third party
12.	Are regular mock drills conducted for emergency preparedness and safety?	✓		Frequency (type wise): 6 Months	Mock drills are conducted every 6 months and are

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					documented	
13.	Are staff provided with OHS training?	✓		Describe: General Safety	All the staff are provided with trainings including newly joined staff.	
Biomedical Waste (BMW)						
	Area of Risk	Yes	No	Details	Proposed Plan	
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	✓		If Yes, provide a list of biomedical waste produced in the facility: Decontaminated cell stacks, Media Plates If No, provide a list of all waste produced in the facility.	Biomedical waste will be sent to PCB authorized third party.	
15.	Is there trained staff to handle biomedical waste in the grantee?	✓		Staff trained on the decontamination process (Autoclave) and trained on the SOP biomedical waste management	Autoclaved at 121 degrees Centigrade for half an hour.	
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	✓		Authorization issued by state PCB	BMW authorization done	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	✓		Yellow	✓	Segregated in yellow bags and disposed.
				Red		
				White		
				Blue		
18.	Is the bar code system for the segregated waste in place?	✓		Bags segregated with bar code.	Bags are procedure by the approved vendor	

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19.	Is the biomedical waste being sent to an authorized common BMW facility?	✓		Name and address of CBMWF: M/s Dharma & Co Distance from facility: 120 kms Frequency and Mode of transport: M/S Dharma & Co Who transports? M/S Dharma & Co	BMW will be sent to PCB Authorized facility every two days.
20	Does the grantee have an in-house BMW treatment facility?		✓	Reason: No Facility	Sending to PCB authorized third party for disposals within 48 hours.
	Is the treatment facility own (individual)?		✓	Authorization:	
	Is the treatment facility a shared facility in an industrial park?		✓	Distance of nearest CBWM from facility: Types of treatment:	
21	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?	✓		Types of treatment: Decontaminating by Autoclaving the material	After autoclave, lab waste will be sent to PCB authorized party for disposal for every 48 hours.
22	Is the liquid waste checked for active cells before sending to treatment plant?	✓		Standard procedures available for checking active cells	Before sending to effluent treatment tank the liquid wastes is subjected to chemical treatment and later sent to kill tank.
23	Are necessary waste pre-treatment equipment in place?	✓		List of equipment (autoclaves, shredders, incinerators, etc.): Autoclaves	Pre-Treatment will be done by decontamination by our staff regularly.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	✓		Details of waste pre-treatment: Kill tank	

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24.	Are chlorinated plastic gloves and bags phased out in the grantee?		✓	For disposal of microbiology lab waste	After packing send to authorized PCB authorized 3rd party.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	✓		Frequency: 6 months Trainer: HOD	Internal Training was conducted.

26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	✓		1. Medical examinations are conducting with yearly frequency. 2. The persons involved in BMW were vaccinated with Hepatitis B & Tetanus	Reports are being maintained.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	✓		Records are Maintained and verified by the Corporate EHS	Daily records will be maintained.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	✓		Biomedical waste reports will be submitted to SPCB	Annual submissions will be done.

Hazardous Waste (HW)

	Area of Risk	Yes	No	Details	Proposed Plan
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	✓		If Yes, provide a list of hazardous waste produced in the facility: List of hazardous waste generated at the grantee submitted to the PCB If No, provide a list of all waste produced in the facility.	will be sending the hazardous wastes to PCB authorized agency.

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30.	Is there trained staff in the facility to identify and handle hazardous waste?	✓		Trained staff from all departments.	Trainings conducted and their records will be maintained.
31.	Does the grantee have authorization from SPCB for hazardous waste?	✓		Authorization granted from PCB.	Timely renewals and compliance of PCB rules and regulations will be done.
32.	Is there a secure location for storage of HW with proper signage?	✓		Describe how each item is stored – 1. platforms: are designed with 2ft height from the ground level , distances from critical installations/movement areas, dykes are using as spill collectors, Stored in designated hazardous waste storage area.	Well-ventilated area and separated room will be used for storing the Hazardous waste during the Project.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		✓		
33.	Is the hazardous being send to an authorized disposal facility or user?	✓		Name and address of facility: HWMP, Dundigal, Hyderabad.	Timely renewal of contract with the PCB Authorized third party will be done for this purpose.
	Is the disposal facility in house?		✓		
	Is the disposal facility external/outsourced?	✓			
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?	✓		Online manifests are following according to PCB guidelines.	Registers will be maintained throughout the Project.
E-Waste and Batteries					
	Area of Risk	Yes	No	Details	Proposed Plan
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		✓	Till now no e-waste generated.	In future, planning for generated e-waste will be sent to PCB authorized 3 rd party for recycling.
36.	Has the grantee obtained SPCB authorization on e-waste?		✓	No e- waste generated now	If generated will be sent to authorized vendor.

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37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		✓	Name and address of disposal facility/ recycler: Inhouse or outsourced Facility:	If generated will be sent to PCB authorized vendor
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓	Describe: The grantee is not manufacturing any electronic equipments / the electronic and electric waste will be sent to PCB authorized recycler	Will be sent to PCB authorized recycler
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		✓	No e-waste generated now	If generated will be sent to authorized vendor
40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		✓	No e-waste generated now	If generated will be sent to authorized vendor
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		✓	No e-waste generated now	If generated will be sent to authorized vendor
42.	Does the grantee submit annual reports on e-waste to SPCB?	✓			If Generated will be sent to authorized recycler
43.	Is there accident reporting and records in place?	✓		Injuries ,accidents	Maintaining records at OHC
44.	Are PPEs available to staff?	✓		PPE are available	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		✓	We are not manufacturing any batteries	We are not manufacturing any batteries.
46.	Does the grantee generate battery waste?	✓		Minimal quantity is being generated	Battery waste will be sent to authorized Recycler

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47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?	✓		Name and address of battery waste receiving entity: TSPCB authorized recycler	Battery waste will be sent to authorized Recycler
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		✓	No manufacturing of batteries	We are not manufacturing any batteries
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	✓		Trem cards	Safely Transported by PCB authorized agency
50.	Emergency preparedness and participation of local authorities and potentially affected communities	✓		Incident management	On site emergency Plan maintained

Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		✓	No isotopes / radiation equipment	In future also will not use
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		✓	Describe: No isotopes / radiation equipment	In future also will not use
	Are radioactive warning signs in place?		✓	No isotopes / radiation equipment	In future also will not use
52.	Is the lab/room air regularly checked for microbial contamination?	✓		Environmental monitoring and AHU'S	Cleaning regularly
53.	Are there any odor control measures in place?	✓		Cleaning	Cleaning and maintain records
54.	Are fume hoods and exhausts regularly checked and maintained?	✓		The preventive maintenance is in place for the fume cup boards	Fume cup boards are periodical checking with PM SOPs
55.	Does the grantee use DG set > 15 KVA?	✓		Grant form PCB and power department	Control air emissions from stack monitoring by third party and will maintain these controlling measures throughout the Project.
	Does the grantee have consent for DG > 15 KVA?	✓			
	Are emissions from boilers and DG sets regularly	✓			

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	monitored to be within the prescribed norms?				
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	✓		Describe: solid waste carboys, plastic containers	Solid waste are segregated and sent to PCB Authorized Vendor.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	✓		Types of wastewater: Treatment of wastewater : Kill tank Chemical management in wastewater treatment plants:	Periodic checks will be done and the treated water will be sent to CETP.
	Are there sludge management and cut off drains in place for wastewater?		✓	No sludge from process	If generated will be segregated and disposed as per PCB
58.	Are necessary provisions for noise cancellation in place?	✓		Describe : Boiler area by using PPE	Utilization ear buds /ear muffs during the project to mitigate this risk in future.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		✓	Describe: No cultivation land near by Distance from premises:	Located and surrounded by industrial area
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	✓		Roads on all the sides are easy access for fire vehicles.	Fire vehicles will be accessed in our existing premises

COVID Precautions & Guidelines Implementation

61.	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	✓		Treatment will be done by autoclaving 121 degree per hour and the spillages are handling with treating of 10% sodium hypochlorite.	After autoclaving waste will be disposed.
62.	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	✓		Handling of spillages in Viral Vaccine Pilot plant PRD/SOP/130.00	Implementation of instructions as mentioned in SOPs to avoid the spillages of acid, alkali, flammable, chemical, biological and

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					recombinant materials will be ensured.
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Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.