Development and manufacturing of end to end room temperature stable molecular diagnostic reagents

Huwel Lifesciences Private Limited

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Handling of Laboratory strain of E coli	Introduction in environment	Facility is designed considering safety of the personnel staying around the facility. Huwel has ISO8/9 based facility which filters the inlet and out let air.
	Exhaust from generator	Environmental Air Pollution	The industry runs on diesel generator set of capacity 170 KVA each. It will be used only during power break downs depending upon the requirement. The Generator is attached to stacks of 20 meters height. The fuel consumption is 20 litres per hour of usage. The emissions from the DG stacks are monitored for the parameters SPM and SO_2. The Values of Stack emissions would be monitored periodically and any deviations in the values would be intimated to AMC provider for immediate action.
Water Pollution and Waste water treatment	Bacterial Culture used for enzyme	Drain pollution with recombinant E.coli	Bacterial Culture used for enzyme production would be lysed during process. After harvesting it would be

			autoclaved for completely killing the remnant live bacteria if any, then collected waste, would be neutralised in collection tank.
Chemical waste	NA		
Biological Waste	Bacterial Culture, Clinical sample , Control remnants		Bacterial Culture used for enzyme production would be lysed during process. After harvesting it would be autoclaved for completely killing the remnant live bacteria if any, then collected waste, would be neutralised in collection tank. Discarded in hypo containing containers as per guidelines. All the
Heavy metals	NA		
Radiation Waste	NA		
Destruction/ alteration of surrounding ecosystem	NA		

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards			
Chemical hazards, including fire and explosions	NA		
Pathogenic and biological hazards	Laboratory strain of E.coli	Introduction in environment	E.coli is handled under laminar airflow under ISO 8.

		As process does not involve handling of any sharp object , and proper attire is defined there is practically zero risk of any infection	Only technical staff will be handling after proper training under a biosafety Level 2 cabinet. Proper cleaning procedures are in place to handle all types of spillages. Only technical staff will be handling after proper training under a biosafety Level 2 cabinet. Proper cleaning procedures are in place to handle all types of spillages.
Radiological hazards	NA		
Noise	NA		
Process safety	Handling of E.coli		Facility is designed considering safety of the personnel staying around the facility. Huwel has ISO8/9 based facility which filters the inlet and out let air. All the processes involving bacteria are carried out under Level 2 biosafety hood.

Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Clinical samples		Project does not involve transportation of any hazardous material.
Emergency preparedness and participation of local authorities and potentially affected communities	Several equipments are used during project execution. Voltage fluctuation or short circuit	Fire caused due to electrical mishap	Voltage stabilisers, UPS are in place. Fire safety training and ceasefire

Fire	none	none	installation as per requirements. Water sprinklers are installed in each room

Notwithstanding the above, other risks that will be relevant to the project activities, identified in due course, shall be addressed as per standard mitigation measures. Monitoring parameters and manner of record keeping shall be in accordance to the recommendations of the project monitoring committee or subject expert engaged by BIRAC