

“Development of an economical manufacturing process for rHu biosimilar insulin lispro”.

M/s CSIR-National Chemical Laboratory, Pune and Indian Institute of Technology, Delhi

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Existing at CSIR-NCL, Pune and IIT-Delhi.	Routine protocol at CSIR-NCL and IIT-Delhi will be followed in the project activity.
EHS Team	Not applicable	Not applicable
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	Not applicable	Not applicable
SOPs related to Environment Compliance e.g. Chemical spillage handling, waste segregation etc.	Existing at CSIR-NCL, Pune and IIT-Delhi.	Routine disposal protocol at CSIR-NCL and IIT-Delhi will be followed in the project activity.
General Safety and Storage	Existing at CSIR-NCL, Pune and IIT-Delhi.	Routine Safety and Storage protocols at CSIR-NCL and IIT-Delhi will be followed in the project activity

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Not applicable	Not applicable	Not applicable
Water Pollution and Waste water treatment	Not applicable	Not applicable	Not applicable
Chemical waste	Not applicable	Not applicable	Not applicable
Biological Waste	Yes, SDS-PAGE gels	Not applicable	Routine disposal protocol at CSIR-NCL and IIT-Delhi will be followed in the project activity

Heavy metals	Not applicable	Not applicable	Not applicable
Radiation Waste	Not applicable	Not applicable	Not applicable
Electronic Waste	Not applicable	Not applicable	Not applicable
Hazardous and C&D Waste	Not applicable	Not applicable	Not applicable
Destruction/alteration of surrounding ecosystem	Not applicable	Not applicable	Not applicable

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Yes	Safety concerns	Routine safety protocols at CSIR-NCL and IIT Delhi will be followed to minimize the risk with heat hazard, chemical hazard, pathogenic and biological hazard.
Chemical hazards, including fire and explosions	Yes	Safety concerns	
Pathogenic and biological hazards	Yes	Safety concerns	
Radiological hazards	Not applicable	Safety concerns	
Electronic Waste	Not applicable	Safety concerns	
Hazardous and C&D Waste	Not applicable	Safety concerns	
Noise	Yes	Safety concerns	
Process safety	Yes	Safety concerns	

4. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Yes	Safety concerns	Routine safety protocols at CSIR-NCL and IIT Delhi will be followed to minimize the risk with heat hazard, chemical hazard, pathogenic and biological hazard.
Emergency preparedness and participation of local authorities and potentially affected communities	Yes	Safety concerns	
In case your organization already has EHS guideline , please summarise the same. Also, share details of the EHS Officer/ Contact Person of the organization. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.			