

Process scale-up and pre-clinical toxicity studies for biosimilar rHu Ranibizumab

CSIR-National Chemical Laboratory, Pune

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Existing at CSIR-NCL, Pune	Routine protocol at CSIR-NCL will be followed in the project activity.
EHS Team	Team in place for EHS review to look after all EHS related compliances and activities.	EHS team provides training on all safety aspects to employees and mock drills are conducted in regular intervals.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	Biowaste generation & disposal records maintained.	Maintaining records for biomedical waste segregation and waste disposal.
SOPs related to Environment Compliance e.g. Chemical spillage handling, waste segregation etc.	SOPs related to Environment Compliance e.g. Chemical spillage handling, waste segregation etc are existing at CSIR-NCL, Pune.	Routine disposal protocol at CSIR-NCL will be followed in the project activity.
General Safety and Storage	SOPs related to General Safety and Storage Existing at CSIR-NCL, Pune.	Routine Safety and Storage protocols at CSIR-NCL will be followed in the project activity

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk	Project implementation will not create any adverse air pollution.	Project implementation will not create any adverse air pollution.

Water Pollution and Waste water treatment	Minimal Risk	Project implementation will not create any adverse water pollution.	Project implementation will not create any adverse water pollution
Chemical waste	Minimal Risk	Project implementation will not create any adverse Chemical waste	Project implementation will not create any adverse Chemical waste
Biological Waste	Minimal Risk	SDS-PAGE gels needs proper disposal.	Routine disposal protocol at CSIR-NCL will be followed in the project activity
Heavy metals	Minimal Risk	Project implementation will not create any adverse Heavy metals	Project implementation will not create any adverse Heavy metals
Radiation Waste	Minimal Risk	Project implementation will not create any adverse Radiation Waste	Project implementation will not create any adverse Radiation Waste
Electronic Waste	Minimal Risk	Project implementation will not create any adverse Electronic Waste	Project implementation will not create any adverse Electronic Waste
Hazardous and C&D Waste	Minimal Risk	Project implementation will not create any adverse Hazardous and C&D Waste	Project implementation will not create any adverse Hazardous and C&D Waste
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation will not create any adverse Destruction/alteration of surrounding ecosystem	Project implementation will not create any adverse Destruction/alteration of surrounding ecosystem

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Moderate risk	Safety concerns of the user	Routine safety protocols at CSIR-NCL will be followed to minimize the risk with heat hazard,

			chemical hazard, pathogenic and biological hazard.
Chemical hazards, including fire and explosions	Moderate risk	Safety concerns of the user	
Pathogenic and biological hazards	Moderate risk	Safety concerns	
Radiological hazards	minimal risk	Project implementation does not create any adverse radiological hazards.	
Electronic Waste	Minimal Risk	Project implementation does not create any adverse Electronic Waste s	
Hazardous and C&D Waste	Minimal Risk	Project implementation does not create any adverse Hazardous and C&D Waste	
Noise	Moderate Risk	Safety concerns of the user	
Process safety	Moderate Risk	Process activities including any use, storage, handling or the on-site movement of hazardous chemicals	

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)	Accident or damage to vehicle and accidental spillage	Safety concerns of the persons involved	Routine safety protocols at CSIR-NCL will be followed to minimize the risk with heat hazard, chemical hazard, pathogenic and biological hazard. Onsite emergency plan is in place
Emergency preparedness and participation of local authorities and potentially affected communities	Fire accident	Damage to property and persons. Shut down of operations.	

<p>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.</p>			

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.