

Phase III Clinical Trial - Comparative Study to Test the non-inferiority of Biosimilar Liraglutide manufactured by Levim Biotech with Victoza manufactured by Novo Nordisk in Patients with Type 2 Diabetes Mellitus

Levim Biotech LLP

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Minimum 2 meeting held in a year as per norms	Periodic biosafety audits are conducted by IBSC as per current biosafety guidelines
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 Maintaining records for hazardous waste segregation and waste disposal
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	SOP for handling & usage of laboratory chemicals, Chemical MSDS & spill kits available for handling spillage, Segregated storage for acids & solvents	SOP for handling & usage of laboratory chemicals, Chemical MSDS & spill kits available for handling spillage, Segregated storage for acids & solvents
General Safety and Storage	Emergency exist boards, signages, available of PPEs at place of work, fire extinguishers with status tag, spill containment trays for liquid storage, charge dissipation through grounding etc.	Procedures and equipment's are in-place

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Accidental escape of genetically modified microbes may pose moderate risk.	Genetically modified microbes in air which will cause air contamination.	Closed operation in GMP/ GLP facility with proper AHU and terminal HEPA filter which is monitored and maintained on regular basis as per SOP-LVBUE-005

Water Pollution and Waste water treatment	Untreated effluent discharge may pose moderate risk.	Untreated effluent discharge may lead to the Ground water contamination	All drains are routed to the ETP & performance of ETP checked by regular testing by the TICEL Biopark Authority
Chemical waste	Toxic process chemicals may pose moderate risk.	Soil and Ground water contamination	The Effluent Treatment Plant (ETP) is suited to treat chemical waste by TICEL Biopark as per environmental safety norms of India.
Biological Waste	Escape of genetically modified organism & environmental isolates	Escape of microbes in environment	All biological waste are separately decontaminated in autoclave as per SOP-LVBQC-038 and disposed off as biohazard waste through authorized agency – GJ multiclave (India) Pvt. Ltd, Chennai
Heavy metals	Project implementation will not cause any adverse heavy metal waste.	Project implementation will not cause any adverse heavy metal waste.	No heavy metal containing material is used
Radiation Waste	Project implementation will not cause any adverse radiation waste.	Project implementation will not cause any adverse radiation waste.	No radioactive material is used
Electronic Waste	Disposal of electronic waste with general waste	Toxic material release to environment	Disposal through authorized recycling vendors
Hazardous and C&D Waste	Spent solvent release to sewage drain	Hazardous waste release to environment	Spent solvent are either routed to process drains connected to TICEL Biopark's ETP or sold for recycling to third parties
Destruction/alteration of surrounding ecosystem	Release of genetically modified organism	Escape of genetically modified organism to environment	Closed operation in GMP/GLP facility with proper AHU and terminal HEPA filter which is monitored as per SOP-LVBUE-005 and maintained on regular basis

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
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Heat Hazards	Operation of boiler may pose moderate risk.	Heat injury to operator is a possibility	We have trained boiler operator and operate boilers as per SOP-LVBUE-003
Chemical hazards, including fire and explosions	Solvent storage & handling can cause fire	Solvent storage & handling can cause fire Fire damage	Electric charge dissipation by grounding all equipment, effective exhaust & air handling equipment to avoid vapour accumulation, fire detection & fighting system (SOP-LVBUE-014), emergency alarm & exit system (SOP-LVBUE-017)
Pathogenic and biological hazards	Release of genetically modified organism	Escape of genetically modified organism to environment	Closed operation in GMP/GLP facility with proper AHU and terminal HEPA filter which is monitored as per SOP-LVBUE-005 and maintained on regular basis
Radiological hazards	Project implementation may not cause any adverse radiological hazards.	Project implementation may not cause any adverse radiological hazards.	No radioactive material is used
Electronic Waste	Minimal Risk	Project implementation may not cause any adverse electronic waste	Project implementation may not cause any adverse electronic waste.
Hazardous and C&D Waste	Solvent & other chemical vapour accumulation	Irritation to eyes, nose, throat	Effective exhaust & air handling systems
Noise	Minimal Risk	Project implementation may not cause any adverse noise.	Project implementation may not cause any adverse noise
Process safety	Process activities including any use, storage, manufacturing, handling or the on-site movement of hazardous chemicals Personnel handling high concentration product	Injuries to the user due to Intoxication	Personal protective equipment are in use and operation is in closed system

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)	Accidental spillage. Improper segregation and packing of waste	Release of toxic materials to environment	Disposal of hazardous waste only through authorized agencies
Emergency preparedness and participation of local authorities and potentially affected communities	Accidental spillage, exposure to hazardous materials, fire hazard	Infection, casualties	Closed operations in GMP/ GLP facility, requirement to wear PPEs such as coverall, nose mask & gloves in process areas, fire detection & fire fighting equipment
<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>			
<p>Levim Biotech LLP has all the relevant SOPs in place and have been mentioned in their respective columns</p> <p>EHS officer:</p> <p>Mr. Murali Ramu Head – Utilities & Engineering Levim Biotech LLP, 5th Floor, TICEL Bio park, Phase II, CSIR Road, Taramani, Chennai E-mail: murali@levimbiotech.com Contact : +91 80568 41467; +91 44 2254 1341</p>			