

"To develop low cost biosimilar Ustekinumab"

Serum Institute of India Private Limited

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Institutional Bio-Safety Committee (IBSC) is constituted and meets regularly.	- Institutional Bio-Safety Committee is In place and working
EHS Team	EHS team is deployed at site.	EHS Team is In place and working
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	SOPs are available at site. Waste generation record is maintained in line with compliance of the local law requirement. (Form No 10 Manifest for hazardous & other waste & Form 03 monthly report)	The validity and availability of the document shall be monitored periodically and proactive action taken to mitigate if there is any foreseeable risks
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	SOPs are available at site. (SOP No 030 0006 Rev 02)	The adherence to SOPs will be ensured by dedicated personal and committee
General Safety and Storage	General safety storage requirements are fulfilled in line with type of risk and requirements to contain the same.	The adherence to SOPs will be ensured by dedicated personal and committee

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	1. Briquette Boiler Emissions 2. FO Boiler Emissions DG sets Emissions Accidental escape of recombinant microbes	Emissions of dust, SOx and NOx Recombinant microbes in air	1. Bag filters/Cyclone separator is provided for Boiler to control the dust emission. 2. Switched over to environmental friendly fuel – i.e. Furnace Oil is replaced with CNG for few boilers to reduce the pollution load (i.e. SOx and NOx.) 3. Stacks height provided is as per guidelines. 4. Regular Monitoring of all stacks through MoEF and CC (Ministry of Environment Forest & Climate Change) approved laboratory and records maintained. Closed operation in GMP/ GLP facility with proper AHU and terminal high-efficiency particulate air (HEPA) filter

			which is monitored and maintained on regular basis
Water Pollution and Waste water treatment	<ol style="list-style-type: none"> 1. Process washings, Utilities wastewater 2. Domestic Wastewater 3. Waste water from Animal House. 4. Other 	Water pollution	<ol style="list-style-type: none"> 1. Containment is provided to waste water tanks and pit to avoid the spreading of waste water. 2. Provision of Effluent treatment plant - consisting - Equalization tanks followed by Primary, secondary and tertiary treatment system. 3. Minimum 60 % of treated effluent is being recycled in plant and rest of effluent disposed of into local drainage. 4. SOP's (SOP No 030 0011 Rev 06) are in place for monitoring the operations of ETP plant.
Chemical waste	<ol style="list-style-type: none"> 1. Off specification chemicals 2. Date expired chemicals 3. Rejected raw materials, solvents 4. and lab chemicals 	Contamination of water or soil and health risk	<ol style="list-style-type: none"> 1. Segregation, collection of waste as per the Hazardous waste Rule 2016. Disposal of chemical waste through Common Hazardous Waste Treatment storage Disposal facility. (CHWTSDF) – Approved by statutory authority).
Biological Waste	<p>All types microbiological wastes, OHC wastes</p> <p>Escape of recombinant microbes</p>	<p>Health risk</p> <p>Escape of recombinant microbes to environment</p>	<ol style="list-style-type: none"> 1. Segregation, collection, secured storage of Biological waste as per the Bio-medical waste management Rule 2016. 2. Bio-Medical waste Incinerator plant provided as per the CPCB guidelines for the treatment of waste. 3. Incinerator ash is disposed of to CHWTSDF. 4. SOP (SOP No 030 0004 Rev 03) is in place for operation of Incinerator plant. <p>All biological waste is decontaminated by autoclaving before discharge to Effluent Treatment Plant (ETP). We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes.</p>
Heavy metals	minimal risk	project implementation does not create adverse heavy metals	project implementation does not create adverse heavy metals

Radiation Waste	minimal risk	project implementation does not create adverse Radiation Waste	project implementation does not create adverse Radiation Waste
Electronic Waste	minimal risk	project implementation does not create adverse Electronic Waste	project implementation does not create adverse Electronic Waste
Hazardous and C&D Waste	1. ETP Sludge 2. Waste oil 3. Incinerator ash	Contamination of water or soil	Hazardous waste is disposed through Common Hazardous Waste Treatment Storage Disposal Facility (CHWTSDF).
Destruction/alteration of surrounding ecosystem	Specific Project implementation aspects will not cause any adverse ecological effects Escape of recombinant microbes	Escape of recombinant microbes to environment	All Lab practices will be as per standards We operate in a closed system GLP/GMP facility. Our product is small volume parenteral. We discharge waste generated after proper treatment through our well established effluent treatment plant and do not allow it to go to surrounding environment. So our operation does not destroy or alter the surrounding ecosystem

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Burns	Injuries	1. Insulation is provided to hot surfaces to avoid the contact. 2. Personal Protective Equipment/s are provided to those employees who are working in such environment. 3. Precautionary Signage's are displayed.
Chemical hazards, including fire and explosions	Fire Toxic chemicals process	Injuries, property loss Soil and Ground water contamination	1. Trained persons are available in each shift to tackle the emergency. 2. Fire hydrant system is provided to extinguish the fire. 3. Fire detection and Alarm system is provided for early detection of fire.

			<p>4. Public Address system is provided for communication in during emergency.</p> <p>5. Fire extinguishers are provided to extinguish the fire.</p> <p>6. Fire tender is available to extinguish the fire.</p> <p>7. The company has well designed Effluent Treatment Plant (ETP) to treat the chemical waste as per environmental safety norms of India.</p>
Pathogenic and biological hazards	Exposure to Pathogens	Health Risk	<p>1. Bio safety cabinets provided to avoid the exposure.</p> <p>2. Controlled working environment with HEPA filter to avoid the contamination and usage of disinfectants.</p> <p>3. Immunization of concerned personnel to avoid the health risk.</p> <p>4. Access control system is provided to avoid unauthorised entry.</p> <p>All biological waste is decontaminated by autoclaving before discharge to ETP. We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes.</p>
	Escape of recombinant microbes	Escape of recombinant microbes environment	
Radiological hazards	minimal risk	project implementation does not create any radiological hazards	project implementation does not create any radiological hazards
Electronic Waste	minimal risk	project implementation does not create any Electronic Waste	project implementation does not create any Electronic Waste
Hazardous and C&D Waste	<p>1. ETP Sludge</p> <p>2. Waste oil</p> <p>3. Incinerator ash</p>	Contamination of water or soil	<p>1. Hazardous waste is disposed through Common Hazardous Waste Treatment Storage Disposal Facility (CHWTSDF).</p>
Noise	High noise	Hearing loss	<p>1. Acoustic enclosures, silencers are provided to high noise equipment to control the noise within permissible limit.</p> <p>2. PPE's like Ear plugs/muffs provided to worker to avoid the high noise exposure.</p> <p>3. Audiometric testing of employees during annual</p>

			<p>medical check-up to observe the noise impact on health.</p> <p>4. Regular Noise Monitoring through MoEF and CC approved laboratory to check the noise level.</p> <p>5. Equipment Maintenance schedule is in place to avoid the excess noise.</p>
Process safety	Engineering and Equipment maintenance shall be undertaken as per SOPs	Health Risk	<p>Process risk assessment and engineering controls are provided to avoid the impact on health of employees.</p> <p>Personal protective equipments are in use and operation is in closed system</p>

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)	<p>Fuels, lab chemicals and reagents, raw materials</p> <p>Accidental spillage harvest / material contains recombinant microbes (GMOs)</p>	<p>Spills</p> <p>Escape of recombinant microbes to environment</p>	<p>Transportation of hazardous waste is done only by RTA approved vehicles.</p> <p>All biological waste are decontaminated by autoclaving before discharge to ETP.</p>
Emergency preparedness and participation of local authorities and potentially affected communities	<p>Low hazard facility</p> <p>Accidental spillage harvest / material contains recombinant microbes (GMOs)</p> <p>Fire/explosion</p>	<p>Low hazard facility</p> <p>Infection to immune compromised people comes in contact of recombinant microbes</p> <p>Casualties</p>	<p>1. Onsite emergency plan in place to tackle the emergency situation.</p> <p>2. Regular mock drills are conducted to check the employee's response and preparedness during the emergency.</p> <p>We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes We operate in a closed system GLP/GMP facility. All biological and hazardous wastes are decontaminated by autoclaving before discharge to ETP.</p> <p>We have well established fire fighting system, alarms, emergency system. Our employees are gone through</p>

			compulsory fire frightening training
<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>			