

Plasma fractionation process for production of albumin, Immunoglobulin and other products for therapeutic uses

National Institute of Immunology

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk	<p>1. Volatile organic compounds (VOCs) and particulates may be emitted from development processes.</p> <p>2. Product development activities are also expected to cause odour nuisance both to the people working within and outside product development area.</p>	<p>1. Under this project, the process will be developed for albumin and immunoglobulin at R&D scale.</p> <p>2. Decontamination of waste and equipment with chemical methods and autoclaving.</p> <p>3. Decontamination area by fumigation of proper disinfectant.</p>
Water Pollution and Waste water treatment	Release of raw material, media and chemicals in water.	<p>1. Programme activities and operation of facilities are expected to generate wastewater from laboratory processes, sterilization and facility wash water, etc.</p> <p>2. Contamination of area, ground water and drains in the plant or surrounding area.</p>	<p>1. Proper control and release of media by authorized person only.</p> <p>2. Restricted accesses and recording of entry.</p> <p>3. Proper decontamination of water and media release.</p> <p>4. Use of sterile drain and proper treatment of effluent before discharge.</p>
Chemical waste	Minimal risk	Project implementation will	Procedure are in place to address spillage etc.

		not cause any adverse chemical waste.	
Biological Waste	Disposal of empty bags of plasma may cause minimal risk	Empty bags of plasma may cause Health hazard	Proper decontamination before disposal at designated place.
Heavy metals	Minimal Risk	Project implementation will not cause any adverse heavy metals.	If any risk arises, appropriate measures will be taken.
Radiation Waste	Minimal Risk	Project implementation will not cause any adverse radiation waste	If any risk arises, appropriate measures will be taken.
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation will not cause any adverse destruction /alteration in surrounding ecosystem.	If any risk arises, appropriate measures will be taken.

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Autoclave and DHS may cause minimal risk	Burn due to release of steam or hot air oven	Suitable equipments with safety features and proper training to employees.
Chemical hazards, including fire and explosions	Minimal Risk	Burn, destruction of equipment or facility	Fire control system with fire extinguishers and water hydrant system, alarm system, emergency exit and training.

Pathogenic and biological hazards	Moderate Risk	Exposure to pathogens may occur	NII will follow biohazard policy following good laboratory practice as mentioned in page 15.
Radiological hazards	Minimal Risk	Project implementation will not cause any adverse radiological waste	If any risk arises appropriate measures will be taken.
Noise	Minimal Risk	Project implementation will not cause any adverse noise pollution	Laboratory equipments shall be used for this project. We do not anticipate any risk, if there is any, the personnel protection equipment (PPE) will be used by the workers
Process safety	Release of virus if present in plasma may cause minimal risk.	Virus inactivation and removal and engineering and equipment maintenance shall be undertaken as per SOPs	Highly pure as the product is inject able. Process risk assessment and engineering control

3. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Transport and supply of source plasma without its required testing.	Plasma pooling may contaminate the batch.	1. Properly closed containers, labelling, warning and minimal frequency of transportation under qualified and competent personnel. 2. Maintaining of record of plasma.
Emergency preparedness and participation of local	Transport and supply of source plasma	Plasma pooling may	1. Information to the blood bank from

authorities and potentially affected communities	without its required testing.	contaminate the batch	where the plasma was collected. 2. Local authorities about the emergency measures.
<p>In case your organization already has EHS guideline, please summarise the same.</p> <p>If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.</p>			

At NII we follow most of the biohazard policy following good laboratory practice. The main parts of the policy are-

1. Guidelines on equipment and operation for different level of bio-safety.
2. Good laboratory technique and procedure.
3. Chemical, fire and electrical safety in laboratory
4. Safety organization and training.
5. Safety checklist

The Summary of the policy is as under – The laboratories are designed according to their design features, constructions and containment facilities and the parameters for bio-safety level requirement.

Under Good laboratory techniques and procedure, clearly defined techniques for the safe handling of specimen in the lab including specimen containers, transport to the laboratory, opening of package, use of pipetting aids, techniques for avoiding the dispersal of biological materials, techniques for the use of biological safety cabinets, techniques for the care and use of refrigerators, freezers and cold rooms, contingency plan and emergency procedure are mentioned.

The policy clearly defines the equipment related hazards and how to eliminate or reduce the hazard, incompatible chemicals, toxic effects of chemicals, chemicals spillage, compressed and liquefied gases, fire in the laboratory, electrical hazards and waste hazards.

The safety checklist describes the laboratory premises as its cleaning, any defects in floors, walls and roofs, working space, furniture, pest control program etc. The safety checklist includes storage facilities, sanitation and staff facilities, HVAC and lighting, security and fire prevention, personnel protection, health and safety of staff, laboratory equipments and disposal of lab waste.

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.

