

**Four-in-one subunit dengue vaccine development program**

**Sunpharma Advance Research Company Ltd.**

**Environmental and Health Risk Management Plan**

**1. Environmental Impact and risk mitigation**

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Air Pollution	Risk of BSL II organisms released as aerosol due to operation steps.	Minimal Risk	The experiments are performed in BSL II compliant facilities Sun Pharma Advanced Research Company has the required authorizations from State Pollution Control Board as per Environment protection act.
Water Pollution and Waste water treatment	Disposal of untreated waste	Contamination of water bodies	Sun Pharma Advanced Research Company follows the necessary protocols while disposing wastes
Chemical waste	Chemical waste generation will be negligible.	Contamination of environment	Sun Pharma Advanced Research Company follows the necessary protocols while disposing wastes
Biological Waste	All operations/activities involved in this project are BSL level – 2 or less.	Accidental release	Sun Pharma Advanced Research Company follows the necessary protocols while disposing wastes
Heavy metals	Heavy metals are not used in project	Not Applicable	Not Applicable
Radiation Waste	Radiation is not used or generated in the project.	Not Applicable	Not Applicable
Destruction/alteration of surrounding ecosystem	Project has very small footprint/ scale of operations.	Minimal	Sun Pharma Advanced Research Company will not perform any experiments that harm

			the ecosystem in any possible way
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## 2. Occupational Health and Safety and risk mitigation

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Heat Hazards	Only source of heat hazard emanates from autoclaving and drying operations of project glasswares and reagents	Low	Trained manpower equipped with protective equipment to handle these activities. Periodic maintenance, calibration and safety assessment of autoclave and ovens.
Chemical hazards, including fire and explosions	Hazardous chemical and explosives not used in present project	Minimal to nil	First aid, eye and body showers in place.
Pathogenic and biological hazards	BSL II organisms in minute quantities will be used	Minimal risk of exposure	All operations in Biosafety cabinets, all activities, equipment and protocols designed to eliminate aerosol generation.
Radiological hazards	Radiation is not used or generated in the project.	Not applicable	Not applicable
Noise	Noise from running equipment and air handling units.	Minimal Risk	Equipment and AHU that is constantly ON in laboratory generates less than 90 dBA. Other equipment (e.g Biosafety cabinets, cryostats, refrigerators, refrigerated centrifuges, and freezers) are either kept in separate rooms or operator exposure is limited to less than 2 hours.
Process safety	Low volume analytical activities will be undertaken in current project. BSL II waste will be generated.	Minimal Risk	Decontamination, an autoclave of appropriate size for decontamination of laboratory wastes is available on the same floor as the laboratory. The waste that cannot be autoclaved is sent to central waste

			management facility present on-site for appropriately compliant disposal.
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### 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)	Spillage during transportation. Low volumes of pre-decontaminated and or inactivated materials involved.	Minimal Risk	We have existing agreement for disposal of solid bio – waste.
Emergency preparedness and participation of local authorities and potentially affected communities	Please see below		
<p>In case your organization already has <b>EHS guideline</b>, please summarise the same.            If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.            SPARC: We would like to apprise you that Sun Pharma Advanced Research Company R&amp;D at Tandalja is embraced with full-fledged EHS department at site to cater safety and Environment risk.            The site has world class Safety and Environment protection systems to support health &amp; safety management framework. EHS has its own website containing guidelines to deal with Bio- safety hazards and flammability risk in the laboratories.            Site is observing two management systems to comply with Environment protection Statutory requirements. To cater community health and safety aspects every exhaust is equipped with dry scrubbers to take care of environmental hazards. Routine trainings are imparted to employees to acquaint them about safety perils in the lab operations.            All lab activities have been examined pertaining environmental and safety aspects and mitigation plan is place to deal with any untoward incident.</p>			

**Notwithstanding the above other risk (relevant to the project activities) that will be identified in due course shall be addressed as per standard mitigation major monitoring parameters & manner of records keeping shall be accordance to the recommendation of the project monitoring committee on subject experts engaged by BIRAC.**