

## M.J. Biopharm Private Limited

### To establish a world class Process Development Lab and an Injectable fill finish facility for Biosimilar development and commercial Manufacturing”

#### Environmental and Health Risk Management Plan

##### 1. Institutional Arrangements

<b>Requirements</b>	<b>Current Status</b>	<b>Mitigation Steps</b>
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.	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 : SOP/EHS/009	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

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Air Pollution	Minimal risk	Negligible	Quarterly monitoring of air pollution is carried out and parameters are maintained well below as per Air (Prevention

			and Control of Pollution) Act, 1981.
Water Pollution and Waste water treatment	Minimal risk	<ol style="list-style-type: none"> <li>1. The potential impact is negligible as the Effluent water treatment is carried out in ETP inside the facility and maintained as per MPCB norms.</li> <li>2. The parameters are maintained well below as mentioned in the control of Pollution act.</li> <li>3. The treated Effluent water is utilized for Gardening purpose.</li> </ol>	<ol style="list-style-type: none"> <li>1. To maintain the parameters within limit daily analysis of Effluent samples is carried out in house</li> <li>2. Monthly Analysis of effluent samples by external Laboratory certified by NABL &amp; MoEF.</li> <li>3. The Parameters are maintained well below as per Water (Prevention and Control of Pollution) Act, 1974</li> </ol>
Chemical waste	Minimal risk	The potential impact is low as chemical waste is discarded as per SOP to Maharashtra Enviro Power Limited (certified and approved by Maharashtra Pollution control board)	The chemical & Hazardous waste is disposed as per SOP: <b>SOP No:</b> SOP/EHS/013 - Handling, storage, transportation and disposal of hazardous waste.
Biological Waste	Minimal risk	The potential impact is low as Biological waste is discarded as per SOP to Life secure Enterprises (certified by Maharashtra Pollution control board.	Controlled through Handling storage and disposal of Biomedical waste Standard Operating Procedure : SOP No: SOP/EHS/24
Heavy metals	Minimal risk	No activity related to utilization or generation of heavy metals is part of project plan.	No activity related to utilization or generation of heavy metals is part of project plan.
Radiation Waste	Minimal risk	Radiation waste is not generated in the company. No activity related to generation or use of radio isotopes in research or manufacturing is under research plan.	Radiation waste is not generated in the company. No activity related to generation or use of radio isotopes in research or manufacturing is under research plan.
Electronic Waste	Minimal risk	The potential impact is negligible as it will be	An SOP for Electronic waste shall be prepared for handling E-waste.

		discarded through authorized dealer.	
Hazardous and C&D Waste	Minimal risk	The potential impact is low as Hazardous waste is discarded as per SOP to Maharashtra Enviro Power Limited as certified by Maharashtra Pollution control board.	<ol style="list-style-type: none"> <li>1. The project management team will ensure that the construction debris are cleared as per the Norms of MIDC.</li> <li>2. The chemical &amp; Hazardous waste is disposed as per SOP: <b>SOP No:</b> SOP/EHS/013, Handling, storage, transportation and disposal of hazardous waste.</li> </ol>
Destruction/alteration of surrounding ecosystem	Minimal risk	Very low	The area is demarked for the construction of new facility and there is minimal impact or destruction of Eco system.

### 3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Minimal risk	Risk of burn injuries	The Steam lines and hot surfaces shall be insulated as per the Factories Act, section 13 (ii)
Chemical hazards, including fire and explosions	Minimal risk	The potential impact will be low as it is controlled through SOP.	<p>The chemical hazards including fire and explosions will be minimal as hazardous chemical handling is controlled through SOP :</p> <p><b>SOP No:</b> SOP/WH/006: receipt, storage and issuance of solvents.</p> <p>For Controlling fire and explosions and on site emergency plan is in place and employees are trained</p>
Pathogenic and biological hazards	Minimal Risk	The potential impact is low as pathogens and biologicals are handled in controlled conditions.	Pathogens and biological hazards are handled through SOP SOP No: SOP/P1/087 : Handling and decontamination of Liquid & Solid biohazards waste

Radiological hazards	No Risk	Minimal Risk	Radiological waste will not be generated from the new facility.
Electronic Waste	Low Risk	Low	An SOP shall be prepared and updated for discarding of E-waste
Hazardous and C&D Waste	Minimal Risk	The potential impact is low as Hazardous waste is discarded as per SOP to Maharashtra Enviro Power Limited (certified & approved by Maharashtra Pollution control board)	<ol style="list-style-type: none"> <li>1. The project management team will ensure that the construction debris are cleared as per the Norms of MIDC(Maharashtra Industrial development Corporation)</li> <li>2. The chemical &amp; Hazardous waste is disposed as per SOP: Handling, storage, transportation and disposal of hazardous waste. SOP No : SOP/EHS/013</li> </ol>
Noise	Minimal Risk	Minimal Risk	Quarterly monitoring of Noise pollution will be carried out and parameters will be maintained as per Noise Pollution (Regulation and Control) Rules, 2000
Process safety	Low Risk	Low impact	<ol style="list-style-type: none"> <li>1. To minimize the risk HIRA (Hazard identification &amp; risk Assessment) HAZOP (Hazard and operability) study are carried out and preventive measures are implemented as per the Factories Act.</li> <li>2. Risk shall be minimized by regular safety trainings of Employees, usage of Personal Protective equipment's.</li> </ol>

#### 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)	Minimal risk	The potential impact is low as Hazardous material is discarded as per SOP to Maharashtra Enviro Power Limited (certified & approved by Maharashtra	The chemical & Hazardous waste is disposed as per SOP: Handling, storage, transportation and disposal of hazardous waste. The transportation is carried out in special vehicles certified by MPCB to Maharashtra Enviro Power Limited <b>SOP No : SOP/EHS/013</b>

		Pollution control board)	
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal Risk	Low impact	<ol style="list-style-type: none"> <li>1. On site emergency preparedness is in place with all the safety measures like Fire Hydrant, smoke detectors, fire alarm, sprinklers etc. is in place.</li> <li>2. Fire safety committee and training procedure for employees is in place.</li> </ol>

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. EHS Team is in place and working (**EHS Team: Mr. Arun Pawale : +91- 9860962605**)

**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.**