

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee	Institutional Biosafety	Institutional Biosafety
(IBSC)	Committee (IBSC) is	Committee is in place and
	constituted and meets	working
	regularly.	
EHS Team	EHS team is deployed at	EHS Team is in place and
	site.	working
Documentation and Record Keeping	SOPs are available at site.	The validity and availability of
in reference to the risks mentioned	Waste generation record is	the document shall be
below and quantifiable records of	maintained in line with	monitored periodically and
generated waste and compliance	compliance of the local law	proactive action taken to
measures.	requirement.	mitigate if there is any
		foreseeable risks
SOPs related to Environment	SOPs are available at site.	The adherence to SOPs will be
Compliance. E.g: Handling of	SOP No : EHD/015 &	ensured by the Managers and
Biohazardous, hazardous and	EHD/020	EHS Dept.
unwanted pharmaceutical wastes		
generated in plant.		
General Safety and Storage	General safety storage	The adherence to SOPs will be
	requirements are fulfilled in	ensured by dedicated
	line with type of risk and	personnel and committee
	requirements to contain the	
	same.	

2. Environmental Impact and Risk Mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal risk	Negligible	Monthly monitoring of Ambient air quality 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	1. The potential impact is negligible as the Effluent water treatment is carried out in ETP inside the facility and maintaining the parameters as per PCB norms.	 To maintain the parameters within limit and daily analysis of Effluent samples is carried out in the inhouse lab. Monthly Analysis of effluent samples by external Laboratory certified by NABL & MOEF.



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		2. The parameters	3. The Parameters are
		are maintained well	maintained well below as
		below as mentioned	per Water (Prevention and
		in the CFO.	Control of Pollution) Act,
		3. The treated	1974
		Effluent water i.e RO	
		permeate is used for	
		Utilities and	
		Gardening purpose.	
Chemical waste	Minimal risk	The potential impact	The chemical & Hazardous
		is low as chemical	waste is disposed as per
		waste is discarded as	SOP: EHD/020. SOP title-
		per SOP to the third	Destruction and safe
		party approved by	disposal of Unwanted
		Telangana State	Pharmaceutical and other
		Pollution control	material.
		board.	
Biological Waste	Minimal risk	The potential impact	Controlled through Handling
		is low as Biological	storage and disposal of
		waste is discarded as	Biomedical waste Standard
		per SOP to GJ	Operating Procedure: SOP
		Multiclave (India)	No: EHD/015 Title: Handling
		Pvt.Ltd. (certified by	of Biohazardous/Hazardous
		Telangana State	waste generated in plant.
		Pollution control	
		board.	
Heavy metals	Minimal risk	No activity related to	No activity related to
		utilization or	utilization or generation of
		generation of heavy	heavy metals is part of
		metals is part of	project plan.
		project plan.	
Radiation Waste	Minimal risk	Radiation waste is	Radiation waste is not
		not generated in the	generated in the company.
		company. No activity	No activity related to
		related to generation	generation or use of radio
		or use of radio	isotopes in research or
		isotopes in research	manufacturing is under
		or manufacturing is	research plan.
		under research plan.	
Electronic Waste	Minimal risk	The potential impact	SOP is in place. SOP no.
		is negligible, as it will	EHD/047, Title: E-Waste
		be discarded through	Management.
		authorized dealer.	
Hazardous and C&D	Minimal risk	The potential impact	1. The project management
Waste		is low as Hazardous	team will ensure that the
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		waste is discarded as	construction debris are
		waste is discarded as per SOP to Telangana	construction debris are cleared as per the Norms of



		authorized third party.	as per SOP: SOP No: SOP/EHD/015, Title: Handling of Biohazardous /Hazardous waste generated in plant.
Destruction/alteration of surrounding ecosystem	Minimal risk	Very low	As the existing building is used for the project, there will be minimal impact or even no impact on surrounding 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 are insulated along with display of hazard indicating signages.
Chemical hazards, including fire and explosions	Minimal risk	The potential impact will be low as the activities related to Solvent handling are controlled through SOP along with execution of all non- routine activities through "Work Permit System". Procedure in place to handle on- site emergencies.	SOP no. EHD/ 046, Title: Work Permit System. SOP No. EHD/052 Title: General Safety and Emergency Response Planning. Along with these, trained Emergency Response Team (ERT) is available at site.
Pathogenic and biological hazards	Minimal Risk	The potential impact is low as pathogens and biologicals are handled in controlled conditions	Solid waste and liquid waste decontamination procedures are in place.
Radiological hazard	No Risk	Minimal Risk	Radiological waste will not be generated from the facility.
Electronic Waste	Low Risk	Low	An SOP is in place for handling E-waste. SOP No. EHD/047, Title: E- waste Management.
Hazardous and C&D Waste	Minimal Risk	The potential impact is low as Hazardous waste is discarded as	The project management team will ensure that the



		per SOP to third party approved by TSPCB)	construction debris are cleared as per the Norms of TSIIC(Telangana State Industrial Infrastructure Corporation) 2. The Hazardous waste is disposed as per SOP No. EHD/ 015 with title, "Handling of Biohazardous and Hazardous waste generated in plant.
Noise	Minimal Risk	Minimal Risk	Monthly monitoring of Noise pollution will be carried out by the authorized third party and parameters are maintained as per Noise Pollution (Regulation and Control) Rules, 2000
Process safety	Low Risk	Low impact	To minimize the risk HIRA (Hazard identification & risk Assessment) HAZOP (Hazard and operability) study are carried out and preventive measures are implemented as per the Factories Act. 2. Risk shall be minimized by regular safety trainings of Employees, usage of Personal Protective equipment.



Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of Biohazardous / hazardous material)	Minimal risk	The potential impact is low as Biohazardous /Hazardous material are discarded as per SOP to the third party authorized by Telangana State Pollution Control Board (TSPCB).	The Biohazardous /Hazardous waste is disposed as per SOP No. EHD / 015 with title, "Handling of Biohazardous / hazardous waste generated in plant.
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal Risk	Low impact	1. SOP is in place. SOP No. EHD/ 052, title "General Safety and Emergency Response Planning". Fire hydrant system for the site is in place with SOP No. EHD/057, title " Operation and maintenance of Fire Hydrant System". Trained ERT and mock drills are in place.

4. Community Health and Safety and Risk Mitigation

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.