



CONTROL MEASURES PROVIDED AT EVERY STAGE STARTING FROM DEVELOPMENT STAGE TO PRODUCT END OF LIFE

SYMBIOTEC PHARMALAB (P) LTD

	AREA OF CONCERN	CONTROLS AND MITIGATION MECHANISM
<p>PROCESS DESIGNING & DEVELOPMENT STAGE</p>	<p>Use of dangerous process like Hydrogenation, run away reactions etc put high process hazards.</p> <p>In manufacturing plants, any accident due to dangerous process will lead to injuries, threat to life and adverse environmental impacts</p>	<p>a) Adoption of Enzymic Route</p> <p>During the design stage Symbiotec Pharma Lab is taking utmost care while developing manufacturing processes. We are continuously working on development of biochemical processes and replacing step wise high hazard chemical synthetic process with that of biochemical process. We have developed biochemical process for our one of the most hazardous process progesterone where hydrogenation was involved which is one of the most hazardous process. In newly developed process the reaction part was replaced by using enzymes. Thus we replaced the dangerous process.</p> <p>b) Adoption of Continuous Flow Chemistry</p> <p>We have hired external resources and started trials on continuous flow chemistry which is an environmental friendly technology and involves a series of continuous specialized equipment like plug flow reactors, annular centrifugal extractor, thin film reactors etc. This is an end to end process meaning addition of input at one end and collection of output from other end. There shall be fully automated operations with DCS</p> <p>BENIFITES</p> <ul style="list-style-type: none"> • Very first benefits of continuous flow chemistry includes, elimination of possibilities of major fire due to high inventory of flammable chemicals , in new process less inventory of chemicals in plant is required say use of 16 KL conventional reactor shall be replaced with that of mere 100 lts plug flow reactors. • This process will lead to considerable reduction in waste generation. • Use of very less energy as compared to conventional process where equipment consume lot of electrical and thermal energy. • Because of closed systems there shall be reduction in VOC emissions and less exposure to workmen.

	<p>During design stage if the substitution of poisonous and dangerous chemicals is not considered definitely it will create adverse environmental impacts, health issues and workplace related injuries during different activities in manufacturing plants.</p>	<p>From the designing stage we shall work on hierarchy of controls like elimination, substitution, engineering controls, administrative controls and personnel protective equipment. Consideration for replacing poisonous and hazardous chemicals shall be the part of our research and development process.</p>
--	--	---

	AREA OF CONCERN	CONTROLS AND MITIGATION MECHANISM
<p>PROCUREMENT STAGE</p>	<p>In line with PSCI Guidelines and United Nation’s Global Compact Principles too, sustainable procurement plays a crucial role. The areas of concern at the end of supplier area :</p> <p>a) Compliance of EHS and Labour & Ethics norms along with requirement of management systems is the area of concern.</p> <p>b) Compliance of legal requirements</p>	<p>To ensure sustainable procurement we have following mechanism in place :</p> <ul style="list-style-type: none"> ● Sustainable Procurement Policy. ● SOP on Sustainable Procurement. ● Sharing of ”Supplier’s code of conduct” with suppliers. ● Supplier’s Audit in order to check compliance. ● SOP on Contractor’s safety Management. ● Declaration on the part of contractors. <p><i>Reference SOP- SYM/EHSOP/EHS/010, SYM/CEHSP/PRO/006</i></p>

	<ul style="list-style-type: none"> c) Any major incident, accident, environmental accident at supplier's site. d) Accidents during transportation. e) Compliance at the end of transporter 	
--	---	--

	AREA OF CONCERN	CONTROLS AND MITIGATION MECHANISM
WAREHOUSING STAGE	1) Emissions and exposure of solid and liquid chemicals during storage and dispensing activities.	1) Breather valves and insulation on tanks. 2) Fume hoods attached with scrubbers are in place. The scrubbing media is aqueous and drained directly to effluent treatment plant. In ETP, water is treated and recycled and re used. 3) For solid material dust collectors are in place, whatever dust is collected from dust collectors is sent to cement industry as an alternative fuel. <i>(Reference SOP- SYM/EHSOP/ENV/008)</i>
	2) Loss of containment as the result of over flow of tanks and leakage of chemical drums and	1) Procedure on Handling of Chemical Spillage-SYM/EHSOP/SAF/016. 2) Overflow protection like sensors and interlocking.

	<p>falling of containers during transferring activities.</p>	<p>Spilled material during overflow is collected in drums/ container or soaked in absorbent (based on the quantity) which is Hazardous waste. All the hazardous waste is sent to cement industries as alternative fuel (Coproprocessing). Alternatively, if cement industries do not accept the waste, the same is sent to government authorized TSDF (Treatment, storage and disposal facility) where this material is incinerated in a controlled and planned way.</p>
	<p>3) Generation of hazardous waste during dispensing of RMs , transferring to production & Expired raw materials</p>	<p>All this waste is called as hazardous waste which is stored at a dedicated place called as ‘Hazardous Waste Storage Area’. This area remains under lock and key and only authorized persons are allowed to enter in this area. This area is maintained in line with the requirement of pollution control board. All the hazardous waste is sent to cement industries as alternative fuel (Coproprocessing). Alternatively if due to any reason, cement industries do not accept the waste, the same is sent to government authorized TSDF (Treatment, storage and disposal facility) where this material is incinerated in a controlled and planned way. <i>(Reference SOP- SYM/EHSOP/ENV/008)</i></p>

	<p>AREA OF CONCERN</p>	<p>CONTROLS AND MITIGATION MECHANISM</p>
<p>PRODUCTION STAGE</p>	<p>In production area, starting from batch charging to final stage i.e. transferring of finished goods to warehouse there are many significant environmental aspects for that environmental aspect- Impact study has been carried out. However to</p>	<p>Our plant are well equipped and have sufficient controls to reduce significance of the environmental aspects and their impacts. a. All the spillage is collected and absorbed using absorbent, tied and sent to Hazardous waste storage area. Finally this waste is sent to cement industries as alternative fuel (Coproprocessing). Alternatively if due to any reason, cement industries do not accept the waste, the same is sent to government authorized TSDF (Treatment, storage and disposal facility). All the solid spillage is collected in poly bags, labelled & tied and sent to Hazardous waste storage area. Finally this waste is sent to cement industries as alternative fuel</p>

	<p>summarize it following are the significant environmental concerns:</p> <ul style="list-style-type: none"> a. Spillage /Leakage/Overflow of liquid raw materials and solvent b. Spillage of solid Raw Materials c. VOC generation d. Fumes generation e. Hazardous waste generation like used centrifuge bags, polybags, containers. f. Energy consumption. g. Generation of electronic waste h. Spent Solvent generation i. Distillation residues generation j. Dissolved solid chemicals in effluent. 	<p>(Coproducting). Alternatively if due to any reason, cement industries do not accept the waste, the same is sent to government authorized TSDF (Treatment, storage and disposal facility).</p> <p><i>(Reference SOP- SYM/EHSOP/ENV/008)</i></p> <ul style="list-style-type: none"> b. To control the VOC generation, reactors are provided with double stage condensers. Tanks are provided with insulation for volatile materials whereas breather valves. Containers of volatile chemicals are stored in a cooled dedicated places. c. To prevent escape of chemical fumes in atmosphere, reactors are attached with different scrubbers. The scrubbing media is aqueous and drained directly to effluent treatment plant. In ETP, water is treated and recycled and re used. d. Hazardous waste generated during various activities is handled in environment friendly manner. All the combustible material like filter bags, is sent to cement industries as alternative fuel where as containers and poly bags are disposed to government approved authorized recyclers. (Reference SOP- SYM/EHSOP/ENV/008) e. Company has taken various measures for energy savings like installation of VFDs (variable frequency drives), Auto cut at set temperature in cold rooms and controlled temp rooms, Batch production records clearly indicate the time of each operation which is monitored and ensured by effective supervision. f. All the electronic waste is collected, segregated and stored at a dedicated place which is under lock and key and controlled by Environment Department. This Electronic waste is sent to government authorized recyclers and the annual report is submitted to Pollution control board. We have an SOP - SYM/EHSOP/ENV/013 on handling of electrical and electronic waste. g. During production activities some mother liquors are generated which contain large amount of solvents. These mother liquors are distilled in distillation kettles to get pure solvents which might have some impurities. Because we are manufacturing life saving drugs we do not re use this recovered solvent, we use only fresh solvent. We sell this spent solvent to various recyclers to use in various processes like in paints.
--	---	--

		<p>h. After distillation process of mother liquor, the left over waste is called distillation residue which is hazardous in nature having high calorific values. This distillation residue is collected in drums and sent to cement industry for alternative fuel. If for any reason like shut down or maintenance of cement plant, this material can be sent to government approved facility (RAMKY) as an alternative fuel.</p> <p>i. Effluent generated from various processes contains high amount of dissolved solids which do not get isolated in ETP. The effluent after ETP treatment is subjected to Reverse Osmosis System (RO) to get pure recyclable water. The reject of RO is subjected to MEME system and dryer to get solid salts which is hazardous waste having high calorific value and sent to cement industry as alternative fuel. If for any reason like shut down or maintenance of cement plant, this material can be sent to government approved facility (RAMKY) as an alternative fuel.</p>
--	--	--

SERVICING BY	AREA OF CONCERN	CONTROLS AND MITIGATION MECHANISM
<p>MAINTENANCE/ UTILITY DEPARTMENTS (ENGINEERING OPERATIONS)</p>	<p>Engineering department is a service department and helps in smooth running of production plants. It consists of different subfunctions like utility, electrical, maintenance & civil departments. There are certain areas of environmental concerns:</p> <p>a) Emissions from stakes b) Use of natural resource (Furnace oil) in boilers.</p>	<p>Symbiotec being a responsible corporate citizen considers protection of environment at it's prime responsibility. We have taken following steps to address environmental issues arose from activities of engineering department:</p> <p>a) & b) To address emission issues we have installed bio fuel boilers (briquettes) at our both the sites. At SEZ site we have also installed a boiler of PNG. Bag filters are provided to boilers prevent SPM generation. The ash is sent to the manufacturer of bricks.</p> <p>c) We understand that water is precious, we are doing steam recovery, we are using ETP treated water in to our cooling towers.</p> <p>d) Waste oil collected from different stages is stored at a dedicated place under lock and key. The same is sold to government authorized recycler, as per the direction of pollution control board.</p> <p>e) We have installed VFDs wherever required, sensors in cold rooms and controlled temperature rooms. Replaced conventional lights with automatic LED lights which are</p>

	<ul style="list-style-type: none"> c) Water consumption in boilers d) Waste oil generations e) High Electrical Consumption f) Noise generation in utility areas. g) Electrical and electronic waste generation 	<p>connected with sensors. In addition to this we have certain controls like supervision, campaigns to avoid misuse of electricity.</p> <ul style="list-style-type: none"> f) High Noise areas are restricted and acoustic enclosures are provided where operators work. Further use of ear muffs is made compulsory in these areas. g) All the electronic waste is collected, segregated and stored at a dedicated place which is under lock and key and controlled by Environment Department. This Electronic waste is sent to government authorized recyclers and the annual report is submitted to Pollution control board. We have an SOP - SYM/EHSOP/ENV/013 on handling of electrical and electronic waste.
--	---	--

	AREA OF CONCERN	CONTROLS AND MITIGATION MECHANISM
<p>QUALITY CONTROL</p>	<p>Quality units also contributes in some significant environmental concerns like:</p> <ul style="list-style-type: none"> a) Waste FG and RM samples generation b) Waste chemical generation e. g. after expiry of the chemical, left over after analysis 	<p>Following are the controls provided in QCL to address the environmental issues:</p> <ul style="list-style-type: none"> a) & b) All the waste samples are hazardous in nature, these are collected & sent to Hazardous waste storage area. Finally these waste samples along with other hazardous waste are sent to cement industries as alternative fuel (Coproprocessing). Alternatively if due to any reason, cement industries do not accept the waste, the same is sent to government authorized TSDF (Treatment, storage and disposal facility). c) In microbiology lab culture and media is used which is autoclaved and sent for disposal at government approved Biomedical Waste treatment facility. We have authorization from Pollution control board. d) Electronic waste collected from maintenance of equipment and discarded equipment collected, segregated and stored at a dedicated place which is under lock and key and

	<p>c) Bio medical waste generation from microbiology laboratory</p> <p>d) Electronic and electrical waste generation e.g. During maintenance and discarded GC/HPLC/Equipment</p>	<p>controlled by Environment Department. This Electronic waste is sent to government authorized recyclers and the annual report is submitted to Pollution control board. We have an SOP - SYM/EHSOP/ENV/013 on handling of electrical and electronic waste.</p>
--	--	---

	AREA OF CONCERN	CONTROLS AND MITIGATION MECHANISM
DISPATCH	<p>Here two critical aspects are identified which need due attention for disposal in an environment friendly manner:</p> <p>1) Market returns Product. 2) Date Expired Product</p>	<p>If any batch of finished goods is not meeting the specification or is market returned material it is finally reprocessed to make it reusable</p> <p>If for any reason it can not be reprocessed , it shall be disposed in an environmentally friendly manner by sending it to cement industry where it is co processed with other waste and used as alternative fuel for cement kilns All this waste is called as hazardous waste which is stored at a dedicated place called as ‘Hazardous Waste Storage Area’. This area remains under lock and key and only authorized persons are allowed to enter in this area. This area is maintained in line with the requirement of pollution control board.</p> <p>All the hazardous waste is sent to cement industries as alternative fuel (Co processing). Alternatively if due to any reason, cement industries do not accept the waste, the same is sent to government authorized TSDF (Treatment, storage and disposal facility) where this material is incinerated in a controlled and planned way.</p> <p><i>(Reference SOP- SYM/EHSOP/ENV/008)</i></p>

PROCESS FLOW DIAGRAM -1



