

SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)	
STANDARD OPERATING PROCEDURE	
Document No.: SOP/U-2/EHS/GEN/023/01	Issue date : 15/09/22
	Effective date : 26/09/22
Supersedes : SOP/U-2/EHS/GEN/023/00	Next Review : Aug-2024
	Page 1 of 10
TITLE: ASPECTS/ HAZARDS IDENTIFICATION AND EVALUATION	

1.0 Purpose:

The purpose of this SOP is to provide guidance on identification, evaluation and control of an Aspects / Hazard, which has significant impact / OHS risk on Environment, Health and safety & to determine safe working / operating procedure covering the life cycle of the products manufactured by Shilpa, procedures and Identification of OHS opportunities to enhance OHS performance at Shilpa Pharma Lifesciences Limited, Raichur.

2.0 Scope:

This procedure is applicable for aspects / hazards identification and their significance / unacceptable, risk/opportunity level assessment / evaluation / calculation of the activities related to process and services, which involves complete operations both business and manufacturing operations performed at Shilpa Pharma Lifesciences Limited and Environmental aspects throughout the life cycle of the process where Shilpa can control and monitor at Shilpa Pharma Lifesciences Limited, Raichur.

3.0 Definitions / Abbreviations:

SOP : Standard Operating Procedure	HIRA : Hazard Identification & Risk Assessment
AIIE : Aspect Identification & Impact Evaluation	EHSMP : Environment, Health & Safety Management Programme
ISO : International Organization for standardization	S.No. : Serial number
MR : Management Representative	OHS : Occupational Health & Safety

4.0 Responsibility:

- 4.1 All user Department personnel.
- 4.2 EHS department personnel.
- 4.3 Projects and Engineering department personnel.

	Prepared by	Reviewed by	Approved by
Name	D. Srenivasulu	J. Raghu	K. Sharath Reddy
Designation	Sr. Executive-EHS	Sr. Manager-EHS	Director
Sign & Date	<i>[Signature]</i> 05/09/22	<i>[Signature]</i> 06/09/22	<i>[Signature]</i> 17/09/22

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5.0 Accountability:


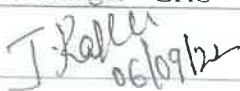

- 5.1 Concerned HODs Capture all aspects or hazards in to Risk index as per inventory of activities.
- 5.2 EHS shall coordinate with all departments to carryout aspects / hazard identification provides training for department in-charges to carryout aspects / hazard identification effectively.

6.0 Procedure:

6.1 **Pro-active Aspects / Hazards Identification & Evaluation:**


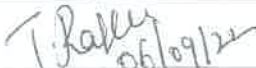

Identify the total pro-active aspects / hazards including Routine (Periodic) / Non Routine (Occasional / Emergency) in three-step method whenever starting a new activity or service or any significant change (either temporary or permanent) to the existing process / related activity and record as per the Annexure -1 "Aspect Identification & Impact Evaluation" and Annexure-2 "Hazard Identification & Risk Assessment (HIRA).

- A team consisting of person from EHS department & personnel from concerned department including worker representative (operator/helper/technician) shall be identified before aspect / hazard identification.
- The team shall be decided by Unit Head in consultation with concerned HOD.
- Whenever a new activity, service is initiated, the respective department shall coordinate with EHS for identification of aspects / hazards.
- The team comprising of worker representative, staff representative of the concerned department and representative from EHS department will be responsible for identification of aspects / hazards department wise.
- **Processes:** Identify aspect / hazards area wise for all general operations/activities, which have impact on Safety, Health & Environment (Water, Air & Soil).
- **Products:** Prepare a flow chart for the total manufacturing operational activity for every product covering the life cycle of the product and identify all the aspects / hazards, which have impact on EHS. If HAZOP studies are carried out for any products, Aspect / Hazard identification is generally not required.

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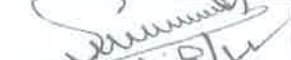
- **Services:** Prepare a chart for the life cycle of every Material (both on-site and off-site) and identify all the aspects / activity hazards, which have impact on Environment, health and safety.
- Aspect / hazards are identified for processes, services in the following categories:
- Safety of employees and surrounding public.
- Activities of all personnel having access to the workplace (including contractors and visitors).
- Other identified hazards originating outside the workplace.
- Health of employees
- Hazards within the workplace created by the activities of operations.
- Work Practices
- Infrastructure, equipment and materials at workplace, provided by Shilpa or others
- Changes being done in the site
- Temporary changes and their impacts on operations, process and activities
- Any applicable legal obligations relating to risk assessment and implementation of necessary controls
- Design of work areas, process installations, and machinery / equipment, SOPs and work organization including their adaptation to human capabilities
- Emission to air
- Discharge of water
- Waste Management practice
- Contamination of Soil
- Uses of raw material & natural resources
- Re-cycle and re-use of waste and scrap material
- Other local and community issues
- Noise levels
- Human behavior, capabilities and other Human Factors
- Equipment Preventive Maintenance

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- All Operations
 - 6.1.1 Aspect / Hazard identification also includes identification of health and safety hazards and environmental impact assessment.
 - 6.1.2 Aspects / Hazards identified are classified as personal safety, health hazard, fire hazard, water pollution, air pollution, noise pollution, depletion of natural resource, personal discomfort and soil contamination, etc.
 - 6.1.3 The identified and assessed Aspects / Hazards & Impacts / Unacceptable risk related documents shall be maintained by EHS department electronically and circulated to MR and concerned HODs of the departments.
 - 6.1.4 EHS Department in consultation with unit head and respective HOD's shall conduct significant Impact study for all the listed Aspects / Hazards.
 - 6.1.5 Whenever the new aspects / hazards are added or deleted, the same shall be updated by EHS in-charge including the updated number and date.
 - 6.1.6 After the yearly review when found no changes to the existing processes / products / services the respective document shall be updated with reviewed date.
 - 6.1.7 EHS Aspect: Elements of Shilpa's activities, services that can interact with Environment, Health & Safety.
 - 6.1.8 EHS Impact: Any change to the Environment, Health & Safety whether adverse or beneficial, wholly or partially resulting from Shilpa's activities, services.
 - 6.1.9 Quantity: Magnitude of damage to Natural resource / Human.
 - 6.1.10 Frequency: It is the probability of Occurrence of an identified aspect.
 - 6.1.11 Detection: It is the ability/rider to identify an aspect.
 - 6.1.12 Severity: It is the degree of seriousness of an identified aspect.
 - 6.1.13 Hazard: Source, situation, or act with a potential for harm in terms of human injury or ill health or a combination of these.
 - 6.1.14 Life cycle of the product: Consecutive and interlinked stages of a product (or service) system from raw material acquisition or generation from natural resources to final disposal.

6.2 Aspects / Hazards Evaluation Process:

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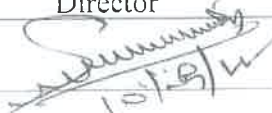
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Identified team & EHS department shall evaluate each aspect /Hazard identified in the following manner.

- 6.2.1 Check whether situation / activity identified is Normal / abnormal / Emergency / routine / Non-Routine with concerned area In-charge.
- 6.2.2 Asses Impact /Risk associated (adverse / beneficial) on Environment, Health & Safety (Water, Air & Soil).
- 6.2.3 Check if aspect identified is violating any Legal Requirement / Standards or require legal compliance.
- 6.2.4 Scoring / rating criteria for each impact /Risk level is provided in the following pages.
- 6.2.5 Identify hazards and to assess and control the OH&S risks/opportunities arising from.
 - a) The contractors' activities and operations that impact the organization;
 - b) The organization's activities and operations that impact the contractor workers;
 - c) The contractors' activities and operations that impact other interested parties in the workplace.
- 6.2.6 Any additional controls required to control the OHS risks or improve the OHS performance are identified as OHS opportunities. And for all such identified OHS opportunities action plans are prepared and reviewed periodically with Management in Review Meetings.


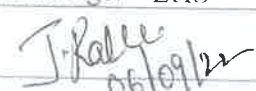

6.3 Significant Aspects / Hazard Evaluation:

- 6.3.1 Any Aspect / Hazard with rating greater than the 41 shall be considered as "Significant" & can have Significant Impact / Un-acceptable risk. An immediate Control plan in the form of an EHSMP or an Operational Control Procedures or SOP's shall be needed to keep the significance minimised. The procedure for arriving to significant number is given in subsequent pages.
- 6.3.2 All Legal & Emergency aspects are considered as significant aspects.

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- 6.3.3 EHS in charge shall maintain the significant Aspects & Impacts list as per the Annexure-3 “ List of significant Aspects & Annexure-4 “List of Un acceptable Risks) and circulate to MR & respective department heads.
- 6.3.4 To reduce the significant impacts and Un-acceptable risk levels, various measures shall be implemented, such as operational control procedures / EHSMP and setting objectives and Targets.
- 6.3.5 Setup EHS objectives as per Annexure-5 “EHS Objectives & Targets” , write EHSMP as per Annexure -6 “ Environment,Health&Safety Management programme” and/or operational control procedures and other actions as required.
- 6.3.6 EHSMP are documented in the EHSMP format, and implement the actions shall be implemented as per the EHSMP by respective department head and status of the implementation is reviewed in the Management Review Meeting.
- 6.3.7 Area In-charge in-coordination with EHS In-charge are responsible for the implementation of the relevant operational control procedures / risk reduction procedures / ensuring all necessary Personal Protective Equipment / Impact controls usage in practice, as applicable.
- 6.3.8 EHSMPs to be reviewed as per Annexure-7 “Environment Health &Safety Management Programme Review plan “ for every six months or whenever the programme completes whichever is less to take next course of action to complete the programme.
- 6.3.9 The Aspect / impact or Hazard / Risk and significant impact / Un-acceptable risk level Estimation rating is reviewed by EHS In-charge at least once in a year or whenever there is a technological change or after any emergency/incident.
- 6.4 **Scoring for Aspects and Hazards Evaluation, conditions for Significant Number:**
 - 6.4.1 Aspects / Hazards in which Legal requirements are not complied.
 - 6.4.2 Aspects / Hazards having highest scores in any two of its columns.
 - 6.4.3 Hazards having Severity score 5
 - 6.4.4 Remaining Aspects / Hazards having scored more than 41 in descending order.

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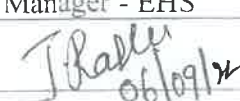

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6.4.5 Any Aspect / Risk level with a score of above 41 shall be considered to be significant & can have a high risk, hence an immediate control plan (EHSMP/SOP) to be taken up.

6.4.6 Aspects & Risk register will review as & when required.

Examples of Non-Routine Activities	
Facilities or Equipment Cleaning	Refurbishment
Temporary Process Modifications	Extreme weather conditions
Non-scheduled maintenance	Utility disruptions
Plant or Equipment Start-up or Shut-down	Temporary arrangements
Off site visit	Emergency situations


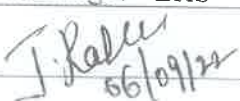

Examples for Abnormal and Emergency Situations	
Abnormal Operations	Emergencies
Start-up / Shutdown	Fire
Mistakes	Power Supply interruptions
Breakdown	Spillage
-	Explosion
-	Flood
-	Vapor release

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Types of Activities - Hazards	
Machinery / Equipment / Tool Hazards	Gravity Hazards
<ul style="list-style-type: none"> • Moving Parts - entanglement, impact, crushing • Sharp edges • Guarding, Safety Devices, Interlocks • Pressurized Plant • Confined Space • Compressed Air • Burns, Scalds & Heat Stress • Vehicle Movements • Noise & Vibration 	<ul style="list-style-type: none"> • Fall from Height • Fall into a Hole • Tripping • Slipping • Dropping of Object from Height • Overturning of Machine/Object

Fire/Explosion Hazards <ul style="list-style-type: none"> • Flammable/Explosive Material • Gases & Vapours • Chemical Reactions • Emergency Access/Egress • Fire Extinguishers 	Electrical Hazards <ul style="list-style-type: none"> • Defective Wires & Plugs • Exposed Wires • High Voltages • Overloaded Sockets • Live Testing/Working • Electric Shock
Chemical Hazards <ul style="list-style-type: none"> • Eye Contact • Skin Contact • Respiratory Effects • Spillage • Oxygen Deficiency 	Manual Handling / Ergonomic Hazards <ul style="list-style-type: none"> • Lifting, Carrying • Pushing, Pulling • Supporting • Repetitive Movements

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<ul style="list-style-type: none"> • Incompatible Storage • Biological Hazards 	

6.5 **Communication:**


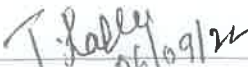
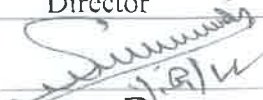
The significant aspects/hazards shall be communicated to the concerned employees/contractors working within the Shilpa premises and to external interested parties as decided by the top management as per the communication procedure. MR shall identify which of the significant aspects needs to be communicated to specific external interested parties. The Unit Head through the management review procedure will decide on the need to communicate the identified significant aspects/hazards to the effected external interested party. The decision is recorded in the master List of significant aspects/hazards. If the decision is to communicate, MR will communicate in writing to the external interested party and maintain a record. The decision on the identified significant aspects/hazards communication may be reviewed at any subsequent management review meeting on needed basis.

7.0 **Related Documents:**

7.1 Aspect Identification & Impact Evaluation	: Annexure-I
7.2 Hazard Identification & Risk Assessment	: Annexure-II
7.3 List of Significant Aspects	: Annexure-III
7.4 List of Un-Acceptable Risks	: Annexure-IV
7.5 EHS Objectives and Targets	: Annexure-V
7.6 Environment, Safety & Health Management program (EHSMP)	: Annexure-VI
7.7 Environment Health & Safety Management program review plan	: Annexure-VII

8.0 **Distribution record:**

S. No	Department/Block	No. of Copies	Remarks
1	Environment, Health & Safety	01	----
2	Quality Assurance	01	----


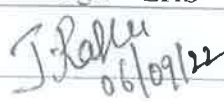
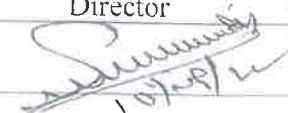
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4	AO	01	----
5	AM	01	----
6	C	01	----
7	D	01	----
8	E	01	----
9	I	01	----
10	AI	01	----
11	H	01	----
12	AJ	01	----
13	G	01	----
14	Engineering	01	----
15	Warehouse	01	----
16	R&D	01	----

9.0 Revision Record:

S. No.	Revision Status	Details of Revision	Effective date	Remarks
01	00	<ul style="list-style-type: none"> First Issue. SOP/U-2/EHS/GEN/023/00	22.10.21	---
02	01	<ul style="list-style-type: none"> SOP Revised as per the Change Control: (Ref. CRAF No. CRAF/EHS/081/22/U-2) Company name changed from Shilpa Medicare Limited to Shilpa Pharma Lifesciences Limited. Shilpa Medicare limited Logo removed. Distribution list updated as per current practices 	26/09/22	---

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SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)

ANNEXURE - I

ASPECTS IDENTIFICATION & IMPACT EVALUTION

Document No: SOP/U-2/EHS/GEN/023/01

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Main Activity / Process / Product Code		Routine (R) / Non-Routine (NR)	Department Name
Location / Area :	Update No.		Updated on

Sub-Activity	R / NR	Aspect	Impact	Aspect No.	Situation (N / A / E)	Impact Without Controls					Impact with Current Controls					Impact after Additional Controls					% of Impact Reduction
						Occurrence (O)	Detection (D)	Severity (S)	Total Score (O x D x S)	Legal Regulation Yes/No	Control(s)	Occurrence (O)	Detection (D)	Severity (S)	Total Score (O x D x S)	Legal Regulation Complied Yes/No	Additional Controls/EMS Opportunities Identified	Occurrence (O)	Detection (D)	Severity (S)	
Temporary																					

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SHILPA PHARMA LIFE SCIENCES LIMITED (UNIT-2)

ANNEXURE - II

HAZARD IDENTIFICATION & RISK ASSESSMENT

Document No: SOP/U-2/EHS/GEN/023/01

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Main Activity / Process / Product Code	Routine (R) / Non-Routine (NR)
Location / Area :	Update No.
	Department Name
	Updated on

Sub-Activity	R / NR	Hazard	Risk	Hazard No.	Situation (N / A / E)	Risk Without Controls				Risk with Current Controls				Additional Controls/ OHS Opportunities identified	Risk after Additional Controls				% of Risk Reduction
						Frequency (F)	Likelihood (L)	Severity (S)	Total Score (F x L x S)	Legal Regulation Yes/No	Control(s)	Frequency (F)	Likelihood (L)		Severity (S)	Total Score (F x L x S)	Legal Regulation Complied Yes/No	Frequency (F)	
Template																			

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	Reviewed by J. Raghun
	Sr. Manager - EHS
	Approved by K. Sharath Reddy
	Director
	<i>[Signature]</i>

SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)
ANNEXURE - VI

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EHS MANAGEMENT PROGRAMME

Document No: SOP/U-2/EHS/GEN/023/01

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Department:		Prepared by:	1.	
Objectives No			2.	
Significant Aspect/Hazard No.			3.	
EHSMP No.			4.	

Date of Start:
 Date of Review:
 Date of Completion:


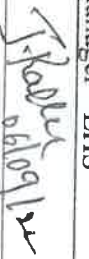

Methodology:

Step No.	Title of the Step	Target date	Responsibility
1	Identify the sources of		
2	Identify the conditions leading		
3	Evolve methodology for suppression		
4	Study feasibility		
5	Prepare necessary Designs and drawings		
6	Resource Planning – Manpower/finance etc.		
7	Material Procurement		
8	Execution		
9	Evaluation		

Approved / Not Approved

Management Representative (Signature & Date)

Unit Head (Signature & Date)

Name	Prepared by D. Srenivasulu	Reviewed by J. Raghu	Approved by K. Sharath Reddy Director
Designation	Sr. Executive - EHS	Sr. Manager - EHS	
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SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)

ANNEXURE - V



EHS OBJECTIVES & TARGETS

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S.No	Function / Area	EHS Objectives	Target	Unit of Measurement	Formula	Current Status	Frequency of Measurement	Source of Information	Responsibility	EHSMP Taken (If Applicable)

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ANNEXURE - IV



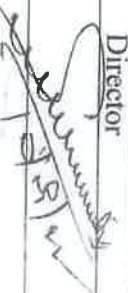
LIST OF UN-ACCEPTABLE RISKS

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Department Name		Un-acceptable Risk will be having Score more than	41
Update No.		Updated on	

Hazard No.	Description of Significant Hazard	Description of Un-acceptable Risk	Total Score	Rank	Action Taken		
					OC (Under Operational control)	Monitoring	EHSMP - Reference

	Prepared by		Reviewed by		Approved by
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SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)

ANNEXURE - III

LIST OF SIGNIFICANT ASPECTS

Document No: SOP/U-2/EHS/GEN/023/01




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LIST OF SIGNIFICANT ASPECTS

Department Name	Significant Aspect will be the having Score		41
Update No.	Updated on		

Aspect No.	Description of Significant Aspect	Description of Significant Impact	Total Score	Rank	Action Taken	
					OC (Under Operational control)	Monitoring

Template

Name	Prepared by D. Srenivasulu	Reviewed by J. Raghun	Approved by K. Sharath Reddy Director
Designation	Sr. Executive - EHS	Sr. Manager - EHS	
Sign & Date	 05/09/22	 06/09/22	 06/09/22

SHILPA PHARMA LIFE SCIENCE LIMITED (UNIT-2)

ANNEXURE - VII

EHS PROGRAMME REVIEW PLAN

Document No: SOP/U-2/EHS/GEN/023/01

Effective Date: 26/09/22
Page 1 of 1

CONTROLLED COPY

Progress		Signature	Period review remarks - HOD / Site Manager
Date	Action Taken / Status / Remarks		



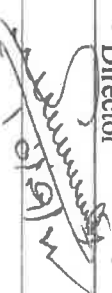
Progress Report / Review Remarks:

EHSMP Completed

Summary Benefits, etc

S.No	Activity	Score		Remarks / Reference
		Previous	Current	
1.	The related aspects are re-evaluated updated.			
2.	All the new aspects related to this EHSMP are identified and evaluated.			
3.	All he SOP's / OCP's related to the activities of this EHSMP are prepared or revised.			
4.	Cost benefit analysis conducted, if applicable.			

Unit Head:
Sign & Date:

	Prepared by D. Srenivasulu Sr. Executive - EHS	Reviewed by J. Raghunath Sr. Manager - EHS	Approved by K. Sharath Reddy Director
Name			
Designation			
Sign & Date	 05/09/22	 06/09/22	 06/09/22

